KEN PAXTON
ATTORNEY GENERAL OF TEXAS

February 18, 2022

The Honorable Matt Krause
Chair, House Committee on General
Investigating
Texas House of Representatives
Post Office Box 2910
Austin, Texas 78768-2910

Opinion No. KP-0401

Re: Whether certain medical procedures performed on children constitute child abuse (RQ-0426-KP)

Dear Representative Krause:

You ask whether the performance of certain medical and chemical procedures on children—several of which have the effect of sterilization—constitute child abuse.[1] You specifically ask about procedures falling under the broader category of "gender reassignment surgeries." Request Letter at 1. You state that such procedures typically are performed to "transition individuals with gender dysphoria to their desired gender," and you identify the following specific "sex-change procedures":

> (1) sterilization through castration, vasectomy, hysterectomy, oophorectomy, metoidioplasty, orchiectomy, penectomy, phalloplasty, and vaginoplasty; (2) mastectomies; and (3) removing from children otherwise healthy or non-diseased body part or tissue.

Id. at 1 (footnotes omitted). Additionally, you ask whether "providing, administering, prescribing, or dispensing drugs to children that induce transient or permanent infertility" constitutes child abuse. *See id.* at 1–2. You include the following categories of drugs: (1) puberty-suppression or puberty-blocking drugs; (2) supraphysiologic doses of testosterone to females; and (3) supraphysiologic doses of estrogen to males. *See id.*

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[1] *See* Letter from Honorable Matt Krause, Chair, House Comm. on Gen. Investigating, to Honorable Ken Paxton, Tex. Att'y Gen. at 1 (Aug. 23, 2021), https://www2.texasattorneygeneral.gov/opinions/opinions/51paxton/rq/2021/pdf/RQ0426KP.pdf ("Request Letter"); *see also* Letter from Honorable Jaime Masters, Comm'r, Tex. Dept. of Family & Protective Servs., to Honorable Greg Abbott, Governor, State of Tex. at 1 (Aug. 11, 2021), https://gov.texas.gov/uploads/files/press/Response_to_August_6_2021_OOG_Letter_08.11.2021.pdf (on file with the Op. Comm.) (hereinafter "Commissioner's Letter").

You qualify your question with the following statement: "Some children have a medically verifiable genetic disorder of sex development or do not have the normal sex chromosome structure for male or female as determined by a physician through genetic testing that require procedures similar to those described in this request." *Id.* at 2. In other words, in rare circumstances, some of the procedures you list are borne out of medical necessity. For example, a minor male with testicular cancer may need an orchiectomy. This opinion does not address or apply to medically necessary procedures.

I. Executive Summary

Based on the analysis herein, each of the "sex change" procedures and treatments enumerated above, when performed on children, can legally constitute child abuse under several provisions of chapter 261 of the Texas Family Code.

- These procedures and treatments can cause "mental or emotional injury to a child that results in an observable and material impairment in the child's growth, development, or psychological functioning." TEX. FAM. CODE § 261.001(1)(A).

- These procedures and treatments can "caus[e] or permit[] the child to be in a situation in which the child sustains a mental or emotional injury that results in an observable and material impairment in the child's growth, development, or psychological functioning." *Id.* § 261.001(1)(B).

- These procedures and treatments can cause a "physical injury that results in substantial harm to the child." *Id.* § 261.001(1)(C).

- These procedures and treatments often involve a "failure to make a reasonable effort to prevent an action by another person that results in physical injury that results in substantial harm to the child[,]" particularly by parents, counselors, and physicians. *Id.* § 261.001(1)(D).

In addition to analysis under the Family Code, we discuss below the fundamental right to procreation, issues of physical and emotional harm associated with these procedures and treatments, consent laws in Texas and throughout the country, and existing child abuse standards. Each of the procedures and treatments you ask about can constitute child abuse when performed on minor children.

II. Nature and context of the question presented

Forming the basis for your request, you contend that the "sex change" procedures and treatments you ask about are typically performed to transition individuals with gender dysphoria to their desired gender. *See* Request Letter at 1. The novel trend of providing these elective sex changes to minors often has the effect of permanently sterilizing those minor children. While you refer to these procedures as "sex changes," it is important to note that it remains medically impossible to truly change the sex of an individual because this is determined biologically at

conception. No doctor can replace a fully functioning male sex organ with a fully functioning female sex organ (or vice versa). In reality, these "sex change" procedures seek to destroy a fully functioning sex organ in order to cosmetically create the illusion of a sex change.

Beyond the obvious harm of permanently sterilizing a child, these procedures and treatments can cause side effects and harms beyond permanent infertility, including serious mental health effects, venous thrombosis/thromboembolism, increased risk of cardiovascular disease, weight gain, decreased libido, hypertriglyceridemia, elevated blood pressure, decreased glucose tolerance, gallbladder disease, benign pituitary prolactinoma, lowered and elevated triglycerides, increased homocysteine levels, hepatotoxicity, polycythemia, sleep apnea, insulin resistance, chronic pelvic pain, and increased cancer and stroke risk.[2]

While the spike in these procedures is a relatively recent development,[3] sterilization of minors and other vulnerable populations without clear consent is not a new phenomenon and has an unsettling history. Historically weaponized against minorities, sterilization procedures have harmed many vulnerable populations, such as African Americans, female minors, the disabled, and others.[4] These violations have been found to infringe upon the fundamental human right to procreate. Any discussion of sterilization procedures in the context of minor children must, accordingly, consider the fundamental right that is at stake: the right to procreate. Given the uniquely vulnerable nature of children, and the clear dangers of sterilization demonstrated throughout history, it is important to emphasize the crux of the question you present today—*whether facilitating (parents/counselors) or conducting (doctors) medical procedures and treatments that could permanently deprive minor children of their constitutional right to procreate, or impair their ability to procreate, before those children have the legal capacity to consent to those procedures and treatments, constitutes child abuse.*

The medical evidence does not demonstrate that children and adolescents benefit from engaging in these irreversible sterilization procedures. The prevalence of gender dysphoria in children and adolescents has never been estimated, and there is no scientific consensus that these sterilizing procedures and treatments even serve to benefit minor children dealing with gender dysphoria. As stated by the Centers for Medicare and Medicaid Services, "There is not enough high-quality evidence to determine whether gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria and whether patients most likely to benefit from these types of surgical intervention can be identified prospectively."[5] Also, "several studies show a higher rate of regret at being sterilized among younger women than among those

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[2]*See* Timothy Cavanaugh, M.D., *Cross-Sex Hormone Therapy*, FENWAY HEALTH (2015), https://www.lgbtqiahealtheducation.org/wp-content/uploads/Cross-Sex-Hormone-Therapy1.pdf.

[3]SOCIETY FOR EVIDENCE BASED GENDER MEDICINE, https://segm.org/ (demonstrating a spike in referrals to Gender Identify Development Services around the mid-2010s).

[4]Alexandra Stern, Ph.D., *Forced sterilization policies in the US targeted minorities and those with disabilities – and lasted into the 21st Century*, (Sept. 23, 2020), https://ihpi.umich.edu/news/forced-sterilization-policies-us-targeted-minorities-and-those-disabilities-and-lasted-21st.

[5]Centers for Medicare and Medicaid Services, Decision Memo for Gender Dysphoria and Gender Reassignment Surgery (CAG-00446N) (Aug. 30, 2016), http://www.lb7.uscourts.gov/documents/17-264URL1DecisionMemo.pdf.

who were sterilized at a later age." 43 FED. REG. at 52,151, 52,152. This further indicates that minor children are not sufficiently mature to make informed decisions in this context.

There is no evidence that long-term mental health outcomes are improved or that rates of suicide are reduced by hormonal or surgical intervention. "Childhood-onset gender dysphoria has been shown to have a high rate of natural resolution, with 61-98% of children reidentifying with their biological sex during puberty. No studies to date have evaluated the natural course and rate of gender dysphoria resolution among the novel cohort presenting with adolescent-onset gender dysphoria."[6] One of the few relevant studies monitored transitioned individuals for 30 years. It found high rates of post-transition suicide and significantly elevated all-cause mortality, including increased death rates from cardiovascular disease and cancer, although causality could not be established.[7] The lack of evidence in this field is why the Centers for Medicare & Medicaid Services rejected a nationwide coverage mandate for adult gender transition surgeries during the Obama Administration. Similarly, the World Professional Association for Transgender Health states that with respect to irreversible procedures, genital surgery should not be carried out until patients reach the legal age of majority to give consent for medical procedures in a given country.[8]

Generally, the age of majority is eighteen in Texas. TEX. CIV. PRAC. & REM. CODE § 129.001. With respect to consent to sterilization procedures, Medicaid sets the age threshold even higher, at twenty-one years old. Children and adolescents are promised relief and asked to "consent" to life-altering, irreversible treatment—and to do so in the midst of reported psychological distress, when they cannot weigh long-term risks the way adults do, and when they are considered by the State in most regards to be without legal capacity to consent, contract, vote, or otherwise. Legal and ethics scholars have suggested that it is particularly unethical to radically intervene in the normal physical development of a child to "affirm" a "gender identity" that is at odds with bodily sex.[9]

State and federal governments have "wide discretion to pass legislation in areas where there is medical and scientific uncertainty." *Gonzales v. Carhart*, 550 U.S. 124, 163 (2007). Thus, states routinely regulate the medical profession and routinely update their regulations as new trends arise and new evidence becomes available. In the opioid context, for instance, states responded to an epidemic caused largely by pharmaceutical companies and medical professionals. Dismissing as "opioidphobic" any concern that "raising pain treatment to a 'patients' rights' issue could lead to overreliance on opioids," these experts created new pain standards and assured doctors that

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[6]SOCIETY FOR EVIDENCE BASED GENDER MEDICINE, https://segm.org/.

[7]*See* Cecilia Dhejne, et al., *Long-term Follow-up of Transsexual Persons Undergoing Sex Reassignment Surgery: Cohort Study in Sweden*, 6 PLOS ONE, Issue 2, 5 (Feb. 22, 2011) (19 times the expected norm overall (Table 2), and 40 times the norm for biological females (Table s1)), https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0016885.

[8]WORLD PROFESSIONAL ASS'N FOR TRANSGENDER HEALTH, *Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People* at 59 (7th ed. 2012), available at https://www.wpath.org/media/cms/Documents/SOC%20v7/SOC%20V7_English2012.pdf?_t=1613669341.

[9]Ryan T. Anderson & Robert P. George, Physical Interventions on the Bodies of Children to "Affirm" their "Gender Identity" Violate Sound Medical Ethics and Should Be Prohibited, PUBLIC DISCOURSE: THE JOURNAL OF THE WITHERSPOON INSTITUTE (Dec. 8, 2019), https://www.thepublicdiscourse.com/2019/12/58839/.

prescribing more opioids was largely risk free.[10] *Id.* As we know now, the results were—indeed, *are*—nothing short of tragic.[11] There is always the potential for novel medical determinations to promote purported remedies that may not improve patient outcomes and can even result in tragic harms. The same potential for harm exists for minors who have engaged in the type of procedures or treatments above.

The State's power is arguably at its zenith when it comes to protecting children. In the Supreme Court's words, that is due to "the peculiar vulnerability of children." *Bellotti v. Baird*, 443 U.S. 622, 634 (1979); *see also Ginsberg v. New York*, 390 U.S. 629, 640 (1968) ("The State also has an independent interest in the well-being of its youth."). The Supreme Court has explained that children's "inability to make critical decisions in an informed, mature manner" makes legislation to protect them particularly appropriate. *Bellotti*, 443 U.S. at 634. The procedures that you ask about impose significant and irreversible effects on children, and we therefore address them with extreme caution, mindful of the State's duty to protect its children. *See generally T.L. v. Cook Children's Med. Ctr.*, 607 S.W.3d 9, 42 (Tex. App.—Fort Worth 2020), *cert. denied*, 141 S. Ct. 1069 (2021) ("Children, by definition, are not assumed to have the capacity to take care of themselves. They are assumed to be subject to the control of their parents, and if parental control falters, the State must play its part as *parens patriae*. In this respect, the [child]'s liberty interest may, in appropriate circumstances, be subordinated to the State's *parens patriae* interest in preserving and promoting the welfare of the child.") (citation omitted).

III. To the extent that these procedures and treatments could result in sterilization, they would deprive the child of the fundamental right to procreate, which supports a finding of child abuse under the Family Code.

A. The procedures you describe can and do cause sterilization.

The surgical and chemical procedures you ask about can and do cause sterilization.[12] Similarly, the treatments you ask about often involve puberty-blocking medications. Such medications suppress the body's production of estrogen or testosterone to prevent puberty and are being used in this context to pause the sexual development of a person that occurs during puberty. The use of these chemical procedures for this purpose is not approved by the federal Food and Drug Administration and is considered an "off-label" use of the medications. These chemical procedures prevent a person's body from developing the capability to procreate. There is insufficient medical evidence available to demonstrate that discontinuing the medication resumes a normal puberty process. *See generally Hennessy-Waller v. Snyder*, 529 F. Supp. 3d 1031, 1042 (D. Ariz. 2021), citing *Bell v. Tavistock and Portman NHS Foundation Trust*, 2020 EWHC 3274

[10] *See* David W. Baker, *The Joint Commission's Pain Standards: Origins and Evolution* 4 (May 5, 2017) (footnotes omitted), https://perma.cc/RZ42-YNRC ("[N]o large national studies were conducted to examine whether the standards improved pain assessment or control.").

[11] *See generally* U.S. HEALTH & HUMAN SERVS., WHAT IS THE U.S. OPIOID EPIDEMIC?, https://www.hhs.gov/opioids/about-the-epidemic/index html.

[12] *See* Philip J. Cheng, *Fertility Concerns of the Transgender Patient*, TRANSL ANDROL UROL. 2019;9(3):209-218 (explaining that hysterectomy, oophorectomy, and orchiectomy "results in permanent sterility"), https://www ncbi nlm nih.gov/pmc/articles/PMC6626312/.

¶ 134 (Dec. 1, 2020) (referring to *Bell's* conclusion that a clinic's practice of prescribing puberty-suppressing medication to individuals under age 18 with gender dysphoria and determining such treatment was experimental). Thus, because the procedures you inquire about can and do result in sterilization, they implicate a minor child's constitutional right to procreate.

B. The United States Constitution protects a fundamental right to procreation.

The United States Supreme Court recognizes that the right to procreate is a fundamental right under the Fourteenth Amendment. *See Skinner v. Oklahoma*, 316 U.S. 535, 541 (1942). Almost a century ago, the Court explained the unique concerns sterilization poses respecting this fundamental right:

> The power to sterilize, if exercised, may have subtle, far reaching and devastating effects. In evil or reckless hands it can cause races or types which are inimical to the dominant group to wither and disappear. There is no redemption for the individual whom the law touches. Any experiment which the State conducts is to his irreparable injury. He is forever deprived of a basic liberty.

Id. To the extent the procedures you describe cause permanent damage to reproductive organs and functions of a child before that child has the legal capacity to consent, they unlawfully violate the child's constitutional right to procreate. *See generally* 43 FED. REG. at 52,146–52,152 (discussing ripeness for coercion and regret rates among minor children).

C. Because children are legally incompetent to consent to sterilization, procedures and treatments that result in a child's sterilization are unauthorized and infringe on the child's fundamental right to procreate.

Under Texas law, a minor is a person under eighteen years of age that has never been married and never declared an adult by a court. *See* TEX. CIV. PRAC. & REM. CODE § 129.001; TEX. FAM. CODE §§ 1.104, 101.003 (including a minor on active duty in the military, one who does not live with a parent or guardian and who manages their own financial affairs, among others). State law recognizes seven instances in which a minor can consent to certain types of medical treatment on their own. *See id.* § 32.003. None of the express provisions relating to a minor's ability to consent to medical treatment addresses consent to the procedures used for "gender-affirming" treatment. *See generally id.*

The lack of authority of a minor to consent to an irreversible sterilization procedure is consistent with other law. The federal Medicaid program does not allow for parental consent, has established a minimum age of 21 for consent to sterilization procedures, and imposes detailed requirements for obtaining that consent. 42 C.F.R. §§ 441.253(a); 441.258 ("Consent form requirements"). Federal Medicaid funds may not be used for any sterilization without complying with the consent requirements, meaning a doctor may not be reimbursed for sterilization procedures performed on minors. *Id.* § 441.256(a).

The higher age limit for sterilization procedures was implemented due to a number of special concerns, including historical instances of forced sterilization. *See* 43 FED. REG. 52146, 52148. "[M]inors and other incompetents have been sterilized with federal funds and . . . an indefinite number of poor people have been improperly coerced into accepting a sterilization operation under the threat that various federally supported welfare benefits would be withdrawn unless they submitted to irreversible sterilization." *Relf v. Weinberger*, 372 F. Supp. 1196, 1199 (D.D.C. 1974), *vacated*, 565 F.2d 722 (D.C. Cir. 1977). In addition, the 21-year minimum age-of-consent rule accounted for concerns that minors were more susceptible to coercion than those over 21 and that younger women had higher rates of regret for sterilization than those who were sterilized at a later age. 43 FED. REG. at 52,151 (pointing to comments suggesting that "persons under 21 are more susceptible to coercion than those over 21 and are more likely to lack the maturity to make an informed decision" and acknowledging "these considerations favor protecting such individuals by limiting their access to the procedure"); *see id.* at 52,151–52,152 (pointing to "several studies [that] show a higher rate of regret at being sterilized among younger women than among those who were sterilized at a later age").

Regarding parental consent, Texas law generally recognizes a parent's right to consent to a child's medical care. TEX. FAM. CODE § 151.001(a)(6) ("A parent of a child has the following rights and duties: . . . (6) the right to consent to the child's . . . medical and dental care, and psychiatric, psychological, and surgical treatment . . ."). But this general right to consent to certain medically necessary procedures does not extend to elective (not medically necessary) procedures and treatments that infringe upon a minor child's constitutional right to procreate. Indeed, courts have analyzed the imposition of unnecessary medical procedures upon children in similar circumstances in the past to determine whether doing so constitutes child abuse.

One such situation that the law has addressed is often referred to as "Munchausen by proxy" or "factitious disorder imposed on another":

> [A] psychological disorder that is characterized by the intentional feigning, exaggeration, or induction of the symptoms of a disease or injury in oneself or another and that is accompanied by the seeking of excessive medical care from various doctors and medical facilities typically resulting in multiple diagnostic tests, treatments, procedures, and hospitalizations. Unlike the malingerer, who consciously induces symptoms to obtain something of value, the patient with a factitious disorder consciously produces symptoms for unconscious reasons, without identifiable gain.[13]

In situations such as this, an individual intentionally seeks to procure—often by deceptive means, such as exaggeration—unnecessary medical procedures or treatments either for themselves or others, usually their children. In Texas, courts have found that these "Munchausen by proxy" situations can constitute child abuse. *See generally Williamson v. State*, 356 S.W.3d 1, 19–21 (Tex. App.—Houston [1st Dist.] 2010, pet. ref'd) (recognizing that an unnecessary medical procedure

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[13] *Factitious disorder*, MERRIAM-WEBSTER.COM DICTIONARY, https://www merriam-webster.com/dictionary/factitious%20disorder.

may cause serious bodily injury, supporting a charge of injury to a child under section 22.04 of the Penal Code).[14]

In the context of elective sex change procedures for minors, the Legislature has not provided any avenue for parental consent, and no judicial avenue exists for the child to proceed with these procedures and treatments without parental consent. By comparison, Texas law respecting abortion requires parental consent and, in extenuating circumstances, permits non-parental consent for a minor to obtain an abortion. TEX. OCC. CODE § 164.052(19) (requiring written consent of a child's parent before a physician may perform an abortion on an unemancipated minor); TEX. FAM. CODE § 33.003 (authorizing judicial approval of a minor's abortion without parental consent in limited circumstances). But the Texas Legislature has not decided to make those same allowances for consent to sterilization, and thus a parent cannot consent to sterilization procedures or treatments that result in the permanent deprivation of a minor child's constitutional right to procreate.[15] Thus, no avenue exists for a child to consent to or obtain consent for an elective procedure or treatment that causes sterilization.

IV. The procedures and treatments you describe can constitute child abuse under the Family Code.

Having established the legal and cultural context of this opinion request, we now consider whether these procedures and treatments qualify as child abuse under the Family Code. *See* Request Letter at 1. Where, as a factual matter, one of these procedures or treatments cannot result in sterilization, a court would have to go through the process of evaluating, on a case-by-case basis, whether that procedure violates any of the provisions of the Family Code—and whether the procedure or treatment poses a similar threat or likelihood of substantial physical and emotional harm. Thus, where a factual scenario involving non-medically necessary, gender-based procedures or treatments on a minor causes or threatens to cause harm or irreparable harm[16] to the child—comparable to instances of Munchausen syndrome by proxy or criminal injury to a child—or demonstrates a lack of consent, etc., a court could find such procedures to constitute child abuse under section 261.001.

A. The Texas Legislature defines child abuse broadly.

Family Code chapter 261 provides for the reporting and investigation of abuse or neglect of a child. *See* TEX. FAM. CODE §§ 261.001–.505; *see also* TEX. PENAL CODE § 22.04 (providing for the offense of injury to a child). Section 261.001 defines abuse through a broad and nonexclusive list of acts and omissions. TEX. FAM. CODE § 261.001(1); *see also In re Interest of*

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[14] *See also* Tex. Dep't of Fam. & Protective Servs., Tex. Practice Guide for Child Protective Servs. Att'ys, § 7, at 15 (2018), https://www.dfps.state.tx.us/Child_Protection/Attorneys_Guide/default.asp.

[15] Federal Medicaid programs will not reimburse for these types of procedures on minors, regardless of whether the child or parent consents, because of the numerous concerns outlined in the Federal Register provisions discussed above. *See* 43 FED. REG. at 52,146–52,159.

[16] For example, a non-medically necessary procedure or treatment that seeks to alter a minor female's breasts in such a way that would or could prevent that minor female from having the ability to breastfeed her eventual children likely causes irreparable harm and could form the basis for a finding of child abuse.

S.M.R., 434 S.W.3d 576, 583 (Tex. 2014). Of course, this broad definition of abuse would apply to and include criminal acts against children, such as "female genital mutilation"[17] or "injury to a child."[18]

Your questions implicate several components of section 261.001(1). Subsection 261.001(1)(A) identifies "mental or emotional injury to a child that results in an observable and material impairment in the child's growth, development, or psychological functioning." Subsection 261.001(1)(B) provides that "causing or permitting the child to be in a situation in which the child sustains a mental or emotional injury that results in an observable and material impairment in the child's growth, development, or psychological functioning" is abuse. Subsection 261.001(1)(C) includes as abuse a "physical injury that results in substantial harm to the child, or the genuine threat of substantial harm from physical injury to the child." And subsection 261.001(1)(D) includes "failure to make a reasonable effort to prevent an action by another person that results in physical injury that results in substantial harm to the child."

Offering some clarity to the scope of "abuse" under subsection 261.001(1), the Texas Department of Family and Protective Services ("Department") adopted rules giving meaning to the key terms and phrases used in the definition. The Department acknowledges that emotional abuse is a subset of abuse that includes "[m]ental or emotional injury to a child that results in an observable and material impairment in the child's growth, development, or psychological functioning." 40 TEX. ADMIN. CODE § 707.453(a) (Tex. Dept. of Fam. & Protective Servs., What is Emotional Abuse?). The Department's rules provide that "[m]ental or emotional injury" means

> [t]hat a child of any age experiences significant or serious negative effects on intellectual or psychological development or functioning. . . . and exhibits behaviors indicative of observable and material impairment . . . . mean[ing] discernable and substantial damage or deterioration to a child's emotional, social, and cognitive development.

Id. § 707.453(b)(1)–(2).

With respect to physical injuries, the Department further clarified the meaning of the phrase "[p]hysical injury that results in substantial harm to the child," explaining that it means in relevant part a

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[17]A person commits an offense if the person: (1) knowingly circumcises, excises, or infibulates any part of the labia majora or labia minora or clitoris of another person who is younger than 18 years of age; (2) is a parent or legal guardian of another person who is younger than 18 years of age and knowingly consents to or permits an act described by Subdivision (1) to be performed on that person; or (3) knowingly transports or facilitates the transportation of another person who is younger than 18 years of age within this state or from this state for the purpose of having an act described by Subdivision (1) performed on that person. TEX. HEALTH & SAFETY CODE § 167.001.

[18]A person commits an offense if he intentionally, knowingly, recklessly, or with criminal negligence, by act or intentionally, knowingly, or recklessly by omission, causes to a child, elderly individual, or disabled individual: (1) serious bodily injury; (2) serious mental deficiency, impairment, or injury; or (3) bodily injury. TEX. PENAL CODE § 22.04.

> real and significant physical injury or damage to a child that includes but is not limited to . . . [a]ny of the following, if caused by an action of the alleged perpetrator directed toward the alleged victim: . . . *impairment of or injury to any bodily organ or function*; . . . .

Id. § 707.455(b)(2)(A) (emphasis added). The Department's rules also define a "[g]enuine threat of substantial harm from physical injury" to include the

> *declaring or exhibiting the intent or determination to inflict real and significant physical injury or damage to a child.* The declaration or exhibition does not require actual physical contact or injury.

Id. § 707.455(b)(1) (emphasis added).

Subsection 261.001(1) and these rules define "abuse" broadly to include mental or emotional injury in addition to a physical injury. To the extent the specific procedures about which you ask may cause mental or emotional injury or physical injury within these provisions, they constitute abuse.

Further, the Legislature has explicitly defined "female genital mutilation" and made such act a state jail felony. *See* TEX. HEALTH & SAFETY CODE § 167.001(a)–(b). While the Legislature has not elsewhere defined the phrase "genital mutilation", nor specifically for males of any age,[19] the Legislature's criminalization of a particular type of genital mutilation supports an argument that analogous procedures that include genital mutilation—potentially including gender reassignment surgeries—could constitute "abuse" under the Family Code's broad and non-exhaustive examples of child abuse or neglect.[20] *See* TEX. FAM. CODE § 261.001(1)(A)–(M); *see generally* Commissioner's Letter at 1 (concluding that genital "mutilation may cause a genuine threat of substantial harm from physical injury to the child"). Thus, many of the procedures and treatments you ask about can constitute "female genital mutilation," a standalone criminal act. But even where these procedures and treatments may not constitute "female genital mutilation" under Texas law, a court could still find that these procedures and treatments constitute child abuse under section 261.001 of the Family Code.

B. Each of these procedures and treatments can constitute abuse under Texas Family Code § 261.001(1)(A), (B), (C), or (D).

The Texas Family Code is clear—causing or permitting substantial harm to the child or the child's growth and development is child abuse. Courts have held that an unnecessary surgical

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[19]Your letter does not mention nor request an analysis under federal law. However, under federal law, there are at least two definitions of female genital mutilation, 8 U.S.C § 1374 and 18 U.S.C. § 116. For purposes of this opinion, we have not considered federal statutes, nor have we undertaken any analysis under state or federal constitutions beyond that included here.

[20]The Eighty-seventh Legislature considered multiple bills that would have amended Family Code subsection 261.001(1) to expressly include in the definition of abuse the performing of surgery or other medical procedures on a child for the purpose of gender transitioning or gender reassignment. Those bills did not pass. *See, e.g.*, Tex. H.B. 22, 87th Leg., 3d C.S. (2021).

procedure that removes a healthy body part from a child can constitute a real and significant injury or damage to the child. *See generally Williamson v. State*, 356 S.W.3d 1, 19–21 (Tex. App.—Houston [1st Dist.] 2010, pet. ref'd) (recognizing that an unnecessary medical procedure may cause serious bodily injury, supporting a charge of injury to a child under section 22.04 of the Penal Code). The *Williamson* case involved a "victim of medical child abuse, sometimes referred to as Munchausen Syndrome by Proxy." *Id.* at 5. Munchausen syndrome by proxy is "where an alleged perpetrator . . . attempts to gain medical procedures and issues for [their] child for secondary gain for themselves . . . . [A]s a result, the children are subjected to multiple diagnostic tests, therapeutic procedures, sometimes operative procedures, in order to treat things that aren't really there." *Williamson*, 356 S.W.3d at 11. In the *Williamson* case, the abuse was perpetrated on the child when he was five and six years old by his mother. *Id.* The evidence showed that two surgeries performed on the child "were not medically necessary and that [his mother] knowingly and intentionally caused the unnecessary procedures to be performed by fabricating, exaggerating, and inducing the symptoms leading to the surgeries." *Id.*

Similarly, in *Austin v. State*, a court of appeals upheld the conviction for felony injury of a child of a mother suffering from Munchausen syndrome by proxy who injected her son with insulin. *See* 222 S.W.3d 801, 804 (Tex. App.—Austin 2007, pet. ref'd); *see also In re McCabe*, 580 S.E.2d 69, 73 (N.C. Ct. App. 2003) (concluding that abuse through Munchausen syndrome by proxy was abuse under state statute defining abuse in a similar manner as chapter 261); *Matter of Aaron S.*, 625 N.Y.S.2d 786, 793 (Fam. Ct. 1993), *aff'd sub nom. Matter of Suffolk Cnty. Dep't of Soc. Servs on Behalf of Aaron S.*, 626 N.Y.S.2d 227 (App. Div. 1995) (finding that a mother neglected her son by subjecting him to a continuous course of medical treatment for condition which he did not have and that he was a neglected child under state statute governing abuse of a child). In guidance documents published for its child protective services attorneys, the Texas Department of Family and Protective Services explains that "Munchausen by proxy syndrome is relatively rare, but when it occurs, it is frequently a basis for a finding of child abuse."[21] Whether motivated by Munchausen syndrome by proxy or otherwise, it is clear that unnecessary medical treatment inflicted on a child by a parent can constitute child abuse under the Family Code.

By definition, procedures and treatments resulting in sterilization cause "physical injury that results in substantial harm to the child, or the genuine threat of substantial harm from physical injury to the child" by surgically altering key physical body parts of the child in ways that render entire body parts, organs, and the entire reproductive system of the child physically incapable of functioning. Thus, such procedures and treatments can constitute child abuse under section 261.001(1)(C). Even where the procedure or treatment does not involve the physical removal or alteration of a child's reproductive organs (*i.e.* puberty blockers), these procedures and treatments can cause "mental or emotional injury to a child that results in an observable and material impairment in the child's growth, development, or psychological functioning" by subjecting a child to the mental and emotional injury associated with lifelong sterilization—an impairment to

[21] TEX. DEP'T OF FAM. & PROTECTIVE SERVS., TEX. PRACTICE GUIDE FOR CHILD PROTECTIVE SERVS. ATT'YS, § 7, at 15 (2018), https://www.dfps.state.tx.us/Child_Protection/Attorneys_Guide/default.asp (citing *Reid v. State*, 964 S.W.2d 723 (Tex. App.—Amarillo 1998, pet. ref'd) (mem. op.) (expert testimony admitted regarding general acceptance of Munchausen diagnosis as a form of child abuse)).

one's growth and development. Therefore, a court could find these procedures and treatments to be child abuse under section 261.001(1)(A). Further, attempts by a parent to consent to these procedures and treatments on behalf of their child may, if successful, "cause or permit the child to be in a situation in which the child sustains a mental or emotional injury that results in an observable and material impairment in the child's growth, development, or psychological functioning[,]" and could be child abuse under section 261.001(1)(B). Additionally, the failure to stop a doctor or another parent from conducting these treatments and procedures on a minor child can constitute a "failure to make a reasonable effort to prevent an action by another person that results in physical injury that results in substantial harm to the child[,]" and this "failure to make a reasonable effort to prevent" can also constitute child abuse under section 261.001(1)(D). Any person that conducts or facilitates these procedures or treatments could be engaged in child abuse, whether that be parents, doctors, counselors, etc.

It is important to note that anyone who has "a reasonable cause to believe that a child's physical or mental health or welfare has been adversely affected by abuse or neglect by any person shall immediately make a report" as described in the Family Code. TEX. FAM. CODE § 261.101(a). Further, "[i]f a professional has reasonable cause to believe that a child has been abused or neglected or may be abused or neglected, or that a child is a victim of an offense under Section 21.11, Penal Code, and the professional has reasonable cause to believe that the child has been abused as defined by Section 261.001, the professional shall make a report not later than the 48th hour after the hour the professional first has reasonable cause to believe that the child has been or may be abused or neglected or is a victim of an offense under Section 21.11, Penal Code." TEX. FAM. CODE § 261.101(b). The term includes teachers, nurses, doctors, day-care employees, employees of a clinic or health care facility that provides reproductive services, juvenile probation officers, and juvenile detention or correctional officers. *Id.* A failure to report under these circumstances is a criminal offense. TEX. FAM. CODE § 261.109(a).

S U M M A R Y

Each of the "sex change" procedures and treatments enumerated above, when performed on children, can legally constitute child abuse under several provisions of chapter 261 of the Texas Family Code.

When considering questions of child abuse, a court would likely consider the fundamental right to procreation, issues of physical and emotional harm associated with these procedures and treatments, consent laws in Texas and throughout the country, and existing child abuse standards.

Very truly yours,

KEN PAXTON
Attorney General of Texas

BRENT E. WEBSTER
First Assistant Attorney General

LESLEY FRENCH
Chief of Staff

MURTAZA F. SUTARWALLA
Deputy Attorney General for Legal Counsel

AARON REITZ
Deputy Attorney General for Legal Strategy

RALPH M. MOLINA
Special Counsel to the First Assistant Attorney General

VIRGINIA K. HOELSCHER
Chair, Opinion Committee

CHARLOTTE M. HARPER
Assistant Attorney General, Opinion Committee

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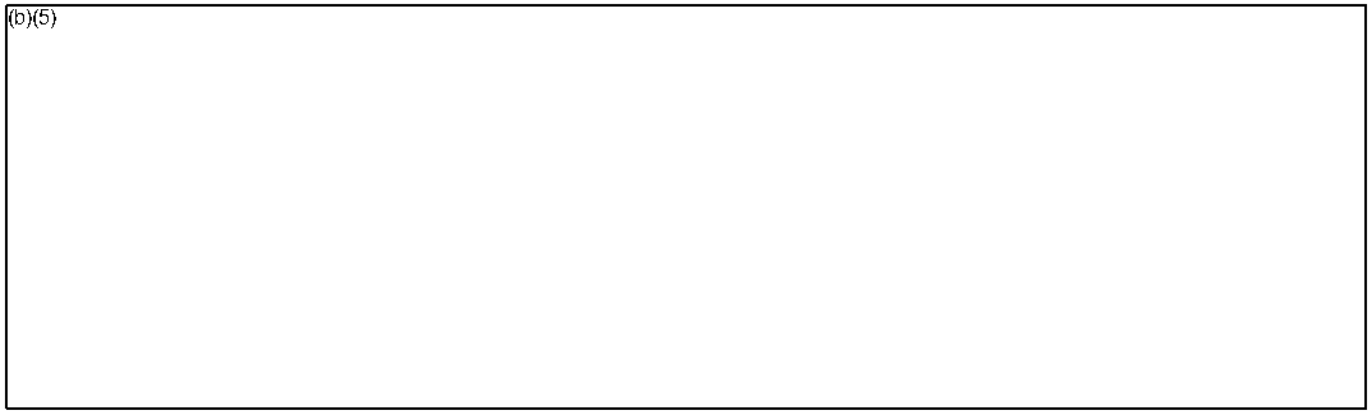
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AMA
AMERICAN MEDICAL ASSOCIATION

James L. Madara, MD
CEO, EXECUTIVE VICE PRESIDENT
[redacted]

April 26, 2021

Mr. Bill McBride
Executive Director
National Governors Association
Hall of States
444 North Capitol Street NW, Suite 267
Washington, DC 20001

Dear Mr. McBride:

On behalf of the American Medical Association (AMA) and our physician and medical student members, I write to urge the National Governors Association (NGA) and its member governors to oppose state legislation that would prohibit the provision of medically necessary gender transition-related care to minor patients. We believe this legislation represents a dangerous governmental intrusion into the practice of medicine and will be detrimental to the health of transgender children across the country.

Empirical evidence has demonstrated that trans and non-binary gender identities are normal variations of human identity and expression. For gender diverse individuals, standards of care and accepted medically necessary services that affirm gender or treat gender dysphoria may include mental health counseling, non-medical social transition, gender-affirming hormone therapy, and/or gender-affirming surgeries. Clinical guidelines established by professional medical organizations for the care of minors promote these supportive interventions based on the current evidence and that enable young people to explore and live the gender that they choose. Every major medical association in the United States recognizes the medical necessity of transition-related care for improving the physical and mental health of transgender people.

Arkansas' recently enacted SAFE Act and similar bills pending in several other states would insert the government into clinical decision-making and force physicians to disregard clinical guidelines. Decisions about medical care belong within the sanctity of the patient-physician relationship. As with all medical interventions, physicians are guided by their ethical duty to act in the best interest of their patients and must tailor recommendations about specific interventions and the timing of those interventions to each patient's unique circumstances. Such decisions must be sensitive to the child's clinical situation, nurture the child's short and long-term development, and balance the need to preserve the child's opportunity to make important life choices autonomously in the future. We believe it is inappropriate and harmful for any state to legislatively dictate that certain transition-related services are never appropriate and limit the range of options physicians and families may consider when making decisions for pediatric patients.

In addition, evidence has demonstrated that forgoing gender-affirming care can have tragic consequences. Transgender individuals are up to three times more likely than the general population to report or be diagnosed with mental health disorders, with as many as 41.5 percent reporting at least one diagnosis of a mental health or substance use disorder.[1] The increased prevalence of these mental health conditions is widely thought to be a consequence of minority stress, the chronic stress from coping with societal

[1] Sari Reisner, et al., *Psychiatric Diagnoses and Comorbidities in a Diverse, Multicity Cohort of Young Transgender Women: Baseline Findings from Project LifeSkills*, 170 J. Am. Med. Ass'n Pediatrics 5, 481–86 (May 2016).

stigma, and discrimination because of one's gender identity and expression. Because of this stress, transgender minors also face a significantly heightened risk of suicide.

Transgender children, like all children, have the best chance to thrive when they are supported and can obtain the health care they need. Studies suggest that improved body satisfaction and self-esteem following the receipt of gender-affirming care is protective against poorer mental health and supports healthy relationships with parents and peers.[2] Studies also demonstrate dramatic reductions in suicide attempts, as well as decreased rates of depression and anxiety.[3] Other studies show that a majority of patients report improved mental health and function after receipt of gender-affirming care. Medically supervised care can also reduce rates of harmful self-prescribed hormones, use of construction-grade silicone injections, and other interventions that have potential to cause adverse events.[4]

It is imperative that transgender minors be given the opportunity to explore their gender identity under the safe and supportive care of a physician. Arkansas's law and others like it would forestall that opportunity. This is a dangerous intrusion into the practice of medicine and we strongly urge the NGA and its member governors to oppose these troubling bills.

We thank you for the opportunity to express our views on this important issue. Please contact Annalia Michelman, JD, Senior Legislative Attorney, AMA Advocacy Resource Center at annalia.michelman@ama-assn.org to discuss this issue further and how our two organizations can work together.

Sincerely,

James L. Madara, MD

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[2] Ashli Owen-Smith, et al., *Association Between Gender Confirmation Treatments and Perceived Gender Congruence, Body Image Satisfaction, and Mental Health in a Cohort of Transgender Individuals*, 15 J Sexual Med 4, 591-600 (Apr. 2018); Michelle Marie Johns, et al., *Protective Factors Among Transgender and Gender Variant Youth: A Systematic Review by Socioecological Level*, 39 J Primary Prevention 3, 263-301 (Jun. 2018).

[3] M. Hassan Murad, et al., *Hormonal Therapy and Sex Reassignment: A Systematic Review and Meta-Analysis of Quality of Life and Psychosocial Outcomes*, 72 Clinical Endocrinology 2, 214-331 (Feb. 2010); Yolanda Smith, et al., *Sex Reassignment: Outcomes and Predictors of Treatment for Adult and Adolescent Transsexuals*, 35 Psychological Med. 1, 89-99 (Jan. 2005).

[4] Jessica Xavier, Admin. HIV and AIDS, D.C. Gov't, The Washington Transgender Needs Assessment Survey (2000); Wendy Bostwick & Gretchen Kenagy, *Health and Social Service Needs of Transgendered People in Chicago*, 8 Int'l J Transgenderism 2-3, 57-66 (Oct. 2008); Cathy Reback, et al., Los Angeles Transgender Health Study: Community Report (2001).

From:	(b)(6) (b)(6) (b)(6 (HHS/OCR) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0BDEC12AD0974EACABABE032F2B37C91-(b)(6)
To:	Richards, Jacob (OS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Richards, Jacob <Jacob.Richards@hhs.gov>; (b)(6) (b)(6 (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (b)(6) (b)(6 (b)(6) Coriell (she/her), Jen (CMS/CCIIO) <Jennifer.Coriell@cms.hhs.gov>; Fathi, Christina (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec51f513b4244d1e8a306a36651087f9-Fathi, Chri <Christina.Fathi@hhs.gov>
CC:	Ayon Verduzco, Brenda (HHS/OCR) (CTR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac7cd226ce1a4a78ad5f3539491326b1-0165c495-19 <Brenda.Ayonverduzco@hhs.gov>; Kelly, Genevieve (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d5689fc09ae4cbe85f58683ef3b521e-Kelly, Gene <Genevieve.Kelly@hhs.gov>; Durso, Laura (HHS/OCR) (CTR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c28ea748a394755ab47b20b85a43f5f-7a1f26c0-21 <Laura.Durso@hhs.gov>
Subject:	possible ADMIN RECORD: Recent comments related to coverage of gender-affirming care
Date:	2023/02/21 12:05:00
Priority:	Normal
Type:	Note

FYI

(b)(6) (b)(6) (b) (b)(6) Esq., MSW (she/her)
Senior Advisor to the Director
Phone: (b)(6) (b)(6)
Email: (b)(6)

From: Baker, Kellan <KBaker@whitman-walker.org>
Sent: Wednesday, February 8, 2023 4:34 PM
To: Rainer, Melanie Fontes (OS/OCR) <Melanie.Rainer@hhs.gov>; (b) (b)(6) (b)(6) (HHS/OCR) (b)(6) (b)(6) Keene, Jamie D. EOP/WHO (b)(6)
Subject: Recent comments related to coverage of gender-affirming care

Dear Melanie, (b)(6) Katie, and Jamie,

I hope you're well! I wanted to share the attached comments that relate to ongoing issues around coverage of gender-affirming care. I have shared these with colleagues at CMS as well but wanted to flag them for you all as well.

The comments cover the NBPP rule, particularly the proposal from CMS to create a risk adjustment HCC for gender dysphoria, and the EHB RFI. In the EHB RFI, we note that a scan we conducted earlier this year found blanket exclusions of gender-affirming care in 41 out of the 51 EHB benchmark plans. The language of these exclusions is reproduced in the comment for reference.

We look forward to working with the administration to address the pervasive problem of these exclusions, as well as to look for alternative means beyond risk adjustment to advance the accessibility and quality of coverage for transgender people.

All the best,
Kellan

Kellan E. Baker, PhD, MPH, MA
Executive Director, Whitman-Walker Institute
kbaker@whitman-walker.org | (202) 797-4417

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Sent Date:	2023/02/21 12:05:53
Delivered Date:	2023/02/21 12:05:00

From: (b)(6) (b)(6) (HHS/OCR) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0BDEC12AD0974EACABABE032F2B37C91-(b)(6)

To: (b)(6) (b)(6) (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (b)(6) (b)(6) (b)(6)
Mitchell, Steven M (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf53b56e8 <Steven.Mitchell@HHS.GOV>; Garcia, Art (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f3e15a704cd4274bb9916d41a1923a9-Garcia, Art <Art.Garcia@HHS.GOV>

Subject: RE: MW Region - GAC complaints

Date: 2022/11/15 17:11:00

Importance: High

Priority: Urgent

Type: Note

Hi folks – we are sorting through the implications of the *Neece v. Becerra* decision that was issued on Friday as it relates to our gender identity enforcement. I believe Melanie is sending an email this evening or tomorrow to flag this, but let's pull this down and/or reschedule for next week once we have clearer guidance from OGC. Thank you, (b)(6)

(b)(6) (b)(6) (b) (b)(6) Esq., MSW (she/her)
Senior Advisor to the Director
Phone: (b)(6) (b)(6)
Email: (b)(6)

-----Original Appointment-----
From: (b)(6) (b)(6) (HHS/OCR) (b)(6)
Sent: Tuesday, November 8, 2022 6:31 PM
To: (b)(6) (b)(6) (HHS/OCR); Mitchell, Steven M (HHS/OCR); Garcia, Art (HHS/OCR); (b) (b)(6) (b)(6) (HHS/OCR)
Subject: MW Region - GAC complaints
When: Wednesday, November 16, 2022 10:00 AM-10:45 AM (UTC-05:00) Eastern Time (US & Canada).
Where: Microsoft Teams Meeting

To discuss the following cases:

Insurance Cases:

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(b)(5)

(b)(5)

Medicaid Cases:

(b)(5)

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(b)(5)

Microsoft Teams meeting

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Mitchell, Steven M (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf53b56e8 <Steven.Mitchell@HHS.GOV>;
Garcia, Art (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f3e15a704cd4274bb9916d41a1923a9-Garcia, Art <Art.Garcia@HHS.GOV>

Sent Date: 2022/11/15 17:11:42

Delivered Date: 2022/11/15 17:11:00

From:	(b) (b)(6) (b)(6 (HHS/OCR) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0BDEC12AD0974EACABABE032F2B37C91(b)(6)
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CC:	Pino, Lisa (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90674352c007441b96f0f199cdd550c2-Pino, Lisa <Lisa.Pino@hhs.gov>; Barron, Pamela (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d55f83440f074842ac94e1f27f11fa9e-Barron, Pam <Pamela.Barron@hhs.gov>; Carter, Carla (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user71ef86df <Carla.Carter@HHS.GOV>; Noonan, Timothy (OS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12eb3ee8ced84516902ac690558270ef-Noonan, Tim <Timothy.Noonan@hhs.gov>; Smith, Marisa (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user200ad5a8 <Marisa.Smith@HHS.GOV>; Gordon-Nguyen, Marissa (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df972908cd4c4422945243f7db218a8f-Gordon-Nguy <Marissa.Gordon@hhs.gov>; Allen, Marc (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cc610a88e103410889da97b4a20e69b8-Allen, Marc <Marc.Allen@hhs.gov>; LaCheen, Cary (OS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=702cb75708c24b96b0bae6cfc454a7bf-LaCheen, Ca <Cary.LaCheen@hhs.gov>; Fitzpatrick, Ryan (HHS/OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=081046aa5db24293991cefa34997bd0b-Fitzpatrick <Ryan.Fitzpatrick@hhs.gov>; Jee, Lauren (HHS/ASL) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7771eca5c9448a8bb1f8860affd22c0-Jee, Lauren <Lauren.Jee@hhs.gov>
Subject:	RE: Texas Transgender 'Abuse' Policy Portends Biden Investigation [Bloomberg Law, 03/10/2022]
Date:	2022/03/10 09:43:00
Priority:	Normal
Type:	Note

Thanks so much, Rachel.

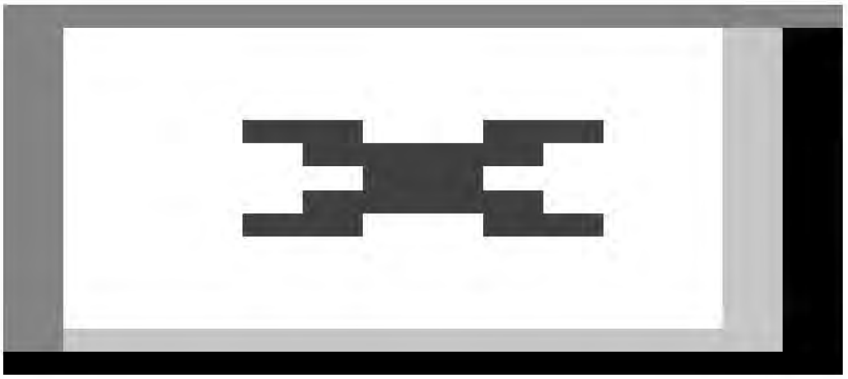
In case anyone has trouble accessing the NY AG letter to AG Garland:

Press Release
Letter

(b)(6) (b)(6) (b) (b)(6) Esq., MSW (she/her)
Phone: (b)(6) (b)(6)
Email: (b)(6)

From: Seeger, Rachel (HHS/OCR) <Rachel.Seeger@hhs.gov>
Sent: Thursday, March 10, 2022 9:13 AM
To: Rainer, Melanie Fontes (OS/IOS) <Melanie.Rainer@hhs.gov>; (b) (b)(6) (b)(6) (HHS/OCR) (b)(6) Schuham, Aaron (HHS/OGC) <Aaron.Schuham@hhs.gov>; Rodriguez, Paul (HHS/OGC) <PaulR.Rodriguez@hhs.gov>; Greenberg, Mark H (HHS/OGC) <MarkH.Greenberg@hhs.gov>
Cc: Pino, Lisa (HHS/OCR) <Lisa.Pino@hhs.gov>; Barron, Pamela (HHS/OCR) <Pamela.Barron@hhs.gov>; Carter, Carla (HHS/OCR) <Carla.Carter@HHS.GOV>; Noonan, Timothy (OS/OCR) <Timothy.Noonan@hhs.gov>; Smith, Marisa (HHS/OCR) <Marisa.Smith@HHS.GOV>; Gordon-Nguyen, Marissa (HHS/OCR) <Marissa.Gordon@hhs.gov>; Allen, Marc (HHS/OGC) <Marc.Allen@hhs.gov>; LaCheen, Cary (OS/OGC) <Cary.LaCheen@hhs.gov>; Fitzpatrick, Ryan (HHS/OGC) <Ryan.Fitzpatrick@hhs.gov>; Jee, Lauren (HHS/ASL) <Lauren.Jee@hhs.gov>
Subject: Texas Transgender 'Abuse' Policy Portends Biden Investigation [Bloomberg Law, 03/10/2022]

Texas Transgender 'Abuse' Policy Portends Biden Investigation: [Bloomberg Law (Shira Stein), 03/10/2022]



A person takes a picture of an Inclusive Pride flag and a rainbow flag at the Stonewall National Monument, the first US national monument dedicated to LGBTQ history and rights, marking the birthplace of the modern lesbian, gay, bisexual, transgender, and queer civil rights movement, on June 1, 2020 in New York City. ANGELA WEISS/AFP via Getty Images

Texas Transgender 'Abuse' Policy Portends Biden Investigation

March 10, 2022, 5:40 AM

- Biden administration says state policy violates federal law
- Options for HHS response are limited, but DOJ could intervene

The administration has just two options to stop Texas from investigating families for child abuse if they are suspected of seeking gender-affirming care for transgender children—pulling federal health funding or suing the state.

Attorneys say both options are likely being discussed at the Departments of Justice and Health and Human Services, especially in light of strong statements and guidance opposing the state's actions by President Joe Biden and his agencies March 2.

A Texas judge last week issued an injunction against the state's child protective services agency temporarily blocking it from investigating the parents of a transgender teen for alleged child abuse.

Opponents of the Texas policy are waiting for more federal actions. New York Attorney General Letitia James called on the DOJ Wednesday to investigate Texas Gov. Greg Abbott's policy.

Advocates and former HHS officials said the likely road for the administration is an HHS or DOJ investigation and possible DOJ involvement in the ongoing litigation. Withdrawal of federal health funds for an entire state agency is possible, but it would be a "nuclear option," said Leon Rodriguez, who ran the HHS's Office of Civil Rights (OCR) under President Barack Obama. He's now a partner as Seyfarth Shaw LLP.

The OCR enforces Section 1557 of the Affordable Care Act, which "prohibits discrimination on the basis of race, color, national origin, sex, age, and disability in covered health programs or activities." It typically handles complaints about actions of individual health providers or hospitals. It rarely uses its enforcement power against an entire state's policy.

"Short of litigating or initiating funding removal or withdrawal proceedings, there's not a whole lot in their toolkit said Joseph Wardenski, a former DOJ civil rights attorney.

A supporter of Texas's authority says the Biden administration is going too far by including transgender issues in the ACA's nondiscrimination clause. "I see no basis for them to be able to enforce Section 1557 against any state by reinterpreting sex to cover something that is not in the statute, which is what it sounds like they're trying to," said Roger Severino, former Trump administration OCR director. "They're on thin ice in their announcement suggesting they have an authority that is actually blocked by court injunctions."

But, other observers like Katie Keith, director of the health policy and the law initiative at Georgetown Law's O'Neill Institute, pointed out that the injunctions are fairly narrow and only applied to specific plaintiffs.

"I suspect the Administration is carefully weighing what else they can do and how quickly they can do it, looking for the widest positive impact while not creating challenges in other lawsuits," Laura Durso, who was OCR chief of staff until earlier this year, said in an email.

The HHS actions thus far "made crystal clear that any enforcement of this policy violates multiple federal laws. In addition, HHS also mobilized its own law enforcement arm and invited parents who are targeted by this policy to bring individual complaints to HHS," said Shannon Minter, legal director for the National Center for Lesbian Rights.

Gender-affirming care for children with gender dysphoria often includes puberty blocking drugs, which are reversible. Sex hormone treatment isn't recommended until around the age of 16, when a minor has the mental capacity to give informed consent, under the Endocrine Society's medical guidelines. And genital surgeries aren't recommended, and typically aren't available, until a patient has reached the age of 18.

Call for Complaints

HHS Secretary Xavier Becerra put out a rare call March 2 asking people in Texas to file complaints if they believe they were "being targeted by a child welfare investigation because of this discriminatory gubernatorial order."
This is the "clearest invitation I've ever seen to a marginalized population to file complaints," said Matthew Cortland, a senior resident fellow at Data for Progress working on disability and health care.

Getting these complaints would not only help the agency investigate allegations of federal law violations, but it could also help the agency as it prepares to come out with a new 1557 regulation.

Severino said a new regulation is the OCR's only option. "The only way I see for HHS to do anything in enforcement on gender identity is to pass a new regulation that would have to be upheld in court."

Regulations from both the Obama administration and Trump administration implementing Section 1557 are still tied up in court. Those court cases found that the word "sex" could not be interpreted to include gender identity in the regulations. However, the Biden administration announcedin May 2021 that it would interpret "sex" in the statute itself to include gender identity in light of the Supreme Court's finding in Bostock v. Clayton County.
Complaint data "would give OCR more of a record to come out more strongly in rulemaking if they got a bunch of complaints," said Keith. That could lead to policies that "more directly combat" the actions by Texas and others like it.

Once the agency receives a complaint, it can investigate. If the OCR finds a civil rights violation occurred, it can file a complaint with an HHS administrative law judge. If the judge finds a violation, the HHS then has the authority to order various streams of federal funding be withheld, said Rodriguez.

The option to remove federal funds has "almost never been used. We only used it once during the time that I was director," and that was against an individual, he said

What "makes it a really brutal penalty is that it's everything. So there's no sliding scale here, there's no sentencing guidelines. This is a 100% withhold if it is implemented," Rodriguez said.

Lawsuit Involvement

The Biden administration could get involved in one other major way—a lawsuit.

The DOJ is probably waiting to see what happens in the Texas courts before getting involved. The existing case, backed by the ACLU and Lambda Legal, is going well so far for the plaintiffs, Wardenski said.

"Part of why the guidance OCR released is so powerful is that every move they make on this issue is heavily scrutinized and will brought up in court," Durso said.

The DOJ could also file a statement of interest in this case, like it did in Arkansas when the state passed a law prohibiting gender-affirming care for transgender children, Keith said

The ACLU will be able to use the HHS guidance in its case, Cortland said. "HHS clearly staked out a position that providing supportive medical care to trans children is not abuse."

To contact the reporter on this story: Shira Stein in Washington
at sstein@bloomberglaw.com
To contact the editor responsible for this story: Fawn Johnson
at fjohnson@bloombergindustry.com

Other coverage from the Bulletin:

Texas Loses Appeal Over Investigation Of Family Of Transgender Teen, Files Lawsuit Against HHS.

The AP (3/9, DeMillo) reports, "A Texas court on Wednesday tossed out the state's appeal of an order preventing child welfare officials from investigating the parents of a transgender teenager over gender-confirming care the youth received." The court "dismissed Republican Attorney General Ken Paxton's appeal of the temporary order a judge issued last week halting the investigation by the Department of Family and Protective Services into the parents of the 16-year-old girl." Meanwhile, "Paxton on Wednesday also filed a challenge in federal court to guidance that President Joe Biden's administration issued in response to the Texas governor's directive."

CNN (3/9, Rose, Maxouris, 89.21M) reports, "On March 2, the US Department of Health and Human Services released guidance saying healthcare providers who report families seeking gender-affirming care or refuse to provide treatment may be violating federal law," with HHS Secretary Xavier Becerra adding in a statement, "HHS will take immediate action if needed." However, "in its federal court filing Wednesday, Texas argued federal protections over care for transgender youth are an 'erroneous interpretation of federal law' and said the guidance threatens state agencies with losing funding if they don't abide by the 'HHS's misinterpretation of their obligations' under the law."

The Hill (3/9, Dress, 5.69M) and the Texas Tribune (3/9, Park, 258K) also report.

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Subject: HHS Issues Guidance To Help Protect Transgender Youth | Health Affairs

Date: 2022/03/07 10:14:00

Priority: Normal

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Katie Keith's latest, highlighting our Guidance and (b)(5)

HHS Issues Guidance To Help Protect Transgender Youth
Katie Keith
March 7, 2022 10.1377/forefront.20220307.303712
https://www.healthaffairs.org/do/10.1377/forefront.20220307.303712/

On March 2, 2022, the Office for Civil Rights (OCR) within the Department of Health and Human Services (HHS) issued new guidance on civil rights protections for transgender youth, their families, and providers that offer gender-affirming health care services. The guidance explains how attempts to restrict access to gender-affirming care, or disclose patient information about this care, could violate federal nondiscrimination protections such as Section 1557 of the Affordable Care Act (ACA) and the Health Insurance Portability and Accountability Act (HIPAA), among others. OCR strongly encourages patients and providers who have faced discrimination to file a complaint here.

OCR was not alone in taking action: other HHS divisions also issued guidance or resources on protecting and supporting transgender young people and their families. For instance, the HHS Administration for

Children and Families issued a separate memorandum to agencies that serve LGBTQ young people in the child welfare system. HHS's announcements were highlighted in a statement from President Biden focused on responding to attacks on transgender youth and their families by leaders in Texas.

What Is Happening In Texas?

The OCR guidance itself does not name Texas, but statements from President Biden and Secretary Becerra do. Why the emphasis on Texas? On February 22, Governor Abbott directed the Texas Department of Family and Protective Services (DFPS), the state's child welfare agency, to investigate parents and providers in instances where a child receives gender-affirming care as "child abuse." Governor Abbott's directive is based on an advisory opinion from Attorney General Paxton that identifies medical procedures and treatments that he asserts qualify as "child abuse" under Texas law.

Under the directive, certain licensed professionals (e.g., doctors, nurses, teachers, etc.) and members of the general public are asked report any known instance of this "abuse"—or face penalties for the failure to do so. DFPS and other state agencies were also directed to follow the Attorney General's opinion. (Parts of the directive are reminiscent of Texas' law restricting abortion access, known as S.B. 8, where people are asked to report their neighbors and friends to the authorities for seeking highly personal health care services.)
Attorney General Paxton's advisory opinion grossly misstates the evidence base for gender-affirming care and repeatedly misrepresents this type of care as elective. As discussed below, every major medical association has affirmed that gender-affirming care is medically necessary to treat gender dysphoria. The advisory opinion also distastefully compares gender-affirming care (the provision of which is highly individualized and done in conjunction with a child's medical team) to our nation's horrific legacy of forced sterilization.

Investigations And Lawsuits

Gov. Abbott's directive has already sparked investigations by state officials into the parents of transgender young people and providers. One family was visited by DFPS on February 25 for interviews, only days after the directive was issued, and asked for access to their child's medical records.

On March 1, this family, along with a clinical psychologist, sued Governor Abbott and DFPS in state court. The plaintiffs are represented by the ACLU and Lambda Legal. In their complaint, the plaintiffs noted that the directive has caused "terror and anxiety … and singled out transgender youth and their families for discrimination and harassment." They went to great lengths to describe the medical standards in place for transgender youth by heavily citing clinical guidelines from the Endocrine Society and the World Professional Association for Transgender Health (WPATH). They also explained that puberty-delaying treatment is reversible and does not cause infertility (contrary to assertions in the advisory opinion) and underscored the benefits and strong evidence base for gender-affirming care.

On March 2, a Texas judge blocked DFPS from investigating the plaintiffs by issuing a temporary restraining order against the agency. This protects these parents and provider, but the court's order is limited only to those plaintiffs already under investigation. The court did not set aside Governor Abbott's entire directive, at least not yet—the court scheduled a hearing for March 11 to assess whether to block the directive more broadly.

A Note On Gender-Affirming Care

It is the overwhelming consensus among medical experts that gender-affirming care is medically necessary, effective, and safe when clinically indicated to alleviate a medical condition known as gender dysphoria (formerly known as gender identity disorder). According to the American Medical Association, untreated gender dysphoria "can result in clinically significant psychological distress, dysfunction, debilitating depression and, for some people without access to appropriate medical care and treatment, suicidality and death." Contrary to Attorney General Paxton's views, numerous studies and meta-analyses—including a comprehensive literature review on the issue—have demonstrated the significant benefits of gender-affirming care. This data and evidence base is cited in the lawsuit noted above.

WPATH has long maintained a set of evidence-based standards of care for transgender people. And experts on minor health like the American Academy of Pediatrics, the American Academy of Child and Adolescent Psychiatry, the American Counseling Association, the American Psychiatric Association, the American Psychological Association, the Endocrine Society, the National Association of Social Workers, the Pediatric Endocrine Society, and the Society for Adolescent Health and Medicine have issued statements and guidelines in support of access to care for transgender people, including young people. There are a range of clinical care programs that provide age-appropriate gender-affirming care for young people across the country, without the devastating impacts that Texas officials claim.

Major payers also view gender-affirming care as medically necessary. In a recent letter to federal officials, AHIP emphasized its strong support for "ensuring that appropriate gender-affirming care is available and accessible to enrollees." This is in addition to prior support for full nondiscrimination protections for LGBTQ people. Fortune 500 companies and state Medicaid programs have also adopted clear policies to require the coverage of gender-affirming care.

OCR's Guidance

OCR's guidance from March 2 underscores the importance of medically appropriate and necessary gender-affirming care for transgender young people and explains how efforts to restrict access to this type of care, like those announced by Texas, could violate federal civil rights laws and privacy protections. Care denials, restrictions on care, and reporting on those who access care could violate Section 1557 of the ACA, Section 504 of the Rehabilitation Act, the Americans with Disabilities Act, and HIPAA. OCR urges families and providers who have faced discrimination to file a complaint with OCR.

Per OCR, attempts to restrict or characterize gender-affirming care as "abuse" are dangerous, can discourage providers from offering this life-saving care, and will negatively affect the health and well-being of transgender and gender nonconforming youth. Overall, the goal of the guidance is to help ensure that young people can access care without discrimination and to respond to fear from families and providers about attempts to portray gender-affirming care as "abuse."

Section 1557

Section 1557 is the ACA's primary nondiscrimination provision and applies to any program or activity that is administered by a federal agency or any entity established under Title I of the ACA. Under Section 1557, an individual cannot be excluded from participation in, denied the benefits of, or subjected to discrimination based on race, color, national origin, age, disability, or sex by any health program or activity of which any part receives federal financial assistance. Per prior guidance from 2021, HHS interprets sex discrimination to include discrimination based on sexual orientation and gender identity.

What does sex discrimination mean in the context of actions like those in Texas? First, federally funded entities covered under Section 1557 cannot categorically refuse to treat someone based on their gender identity. Thus, someone cannot be turned away from care, including gender-affirming care, just because they are transgender. Second, covered entities cannot restrict a person's ability to receive medically necessary gender-affirming care solely because of their gender identity or sex assigned at birth. Efforts to restrict this type of care—by, say, preventing a doctor from providing or prescribing gender-affirming care—likely violate Section 1557.

As an example, a doctor or staff member that reports a parent or child to state authorities—after, say, the family comes in for a consultation for gender-affirming care—may violate Section 1557 if the doctor or facility receives federal financial assistance. Patients who have been denied care based on gender identity or providers who have been restricted from providing care based on a patient's gender identity can file a complaint with OCR.

Section 504

There may be further, independent protections for transgender young people under Section 504 of the Rehabilitation Act and Title II of the Americans with Disabilities Act. Section 504 prohibits discrimination based on disability in programs or activities that receive federal financial assistance, and Title II protects qualified individuals with disabilities from discrimination in state and local government programs. Gender dysphoria may qualify as a disability under these laws. Thus, restrictions that prevent individuals from accessing medically necessary care based on gender dysphoria, a gender dysphoria diagnosis, or perceived gender dysphoria may also violate Section 504 and Title II of the ADA.

HIPAA

HIPAA, among other provisions, requires health care providers and other entities to protect sensitive patient health information from being disclosed without a patient's consent or knowledge. Here, OCR cautions that disclosing protected health information—such as a patient's receipt of gender-affirming care—without a patient or guardian's consent may violate HIPAA. Said another way, HIPAA prohibits the disclosure of protected health information about gender-affirming care without consent except in limited circumstances.

One of these limited circumstances—where disclosure may be possible without a patient's consent—is when disclosure is required under another law. Here, OCR reminds covered entities that HIPAA permits, not requires, disclosure without consent. OCR also notes that the "required by law" exception is narrow, both in when it is required and the scope of the disclosure. Disclosure is permissible when "required by law" only in response to "a mandate contained in law that compels an entity to make a use or disclosure of PHI and that is enforceable in a court of law." Examples outlined in federal regulations include court orders, subpoenas or summons, grand jury requests, or lawsuits. The scope of the disclosure is also narrow and should be limited only to the relevant requirements of the law; disclosures that go beyond what is required may violate HIPAA.

OCR's guidance serves as a reminder that covered entities are merely permitted (not required) to disclose a patient's protected health information without their consent, including in response to Gov. Abbott's directive. The lawsuit noted above also argues that neither Gov. Abbott's directive nor Attorney General Paxton's advisory opinion are legally binding and that this new purported definition of

"child abuse" is inconsistent with state law, was not adopted using proper procedures, and is unconstitutional. These arguments raise real questions about whether any disclosure of sensitive patient information about gender-affirming care is truly "required by law" for purposes of this narrow HIPAA exception (and in general), such that providers and others should feel compelled to comply with it.

Overall, OCR cautions covered entities against voluntarily reporting protected health information related to gender-affirming care to state authorities except in the narrowest of circumstances and only when truly compelled to comply with a legally enforceable requirement. Providers who are concerned about their reporting obligations should seek legal advice. As with the statutes noted above, OCR encourages families to file a complaint with OCR if there has been a violation of a patient's health privacy rights.

Remedies

Complaints are important to enable OCR to investigate and enforce the laws noted above based on specific facts and circumstances. While the agency has other tools (such as compliance reviews), complaints will help OCR target its action, conduct thorough investigations, and maximally enforce federal laws. Complaints could also inform forthcoming rulemaking on Section 1557.

Specific complaints will also make clearer which federal laws apply to a given situation. While the laws cited above—Section 1557, Section 504, Title II, and HIPAA—are broad and powerful, they vary in scope, and each may not apply in every circumstance. In the context of Section 1557, questions about the scope of the law are exacerbated by dueling regulatory interpretations over who qualifies as a covered entity. There could, for instance, be questions about whether these laws theoretically apply to DFPS itself—whereas a specific complaint could underscore why these federal laws apply.

Setting aside these types of questions, OCR makes clear that federal protections apply to health care providers that receive federal funding. Medical facilities, for instance, should not direct doctors or staff to stop providing gender-affirming care or turn patients away. If OCR received a complaint about a situation like this, what might happen? The remedy would depend on the circumstances, but OCR would investigate and work to achieve voluntary compliance (through, say, a resolution agreement). Absent voluntary compliance, a violation of these laws would enable OCR to take enforcement actions such as levying financial penalties, terminating federal funding, or referring the entity to the Department of Justice for further legal action.

There is prior precedent for investigating state agencies in response to complaints about discrimination. A prominent recent example was a dispute between HHS OCR and California. In 2020, OCR issued a notice of violation to California, asserting that a state law requiring health insurance plans to cover abortion violated federal conscience protections. OCR later moved to disallow $800 million annually in California Medicaid funds, an action that now-Secretary of HHS (then-Attorney General of California) Becerra defended against. You can see other examples of action against state agencies, albeit under different laws, in recent resolution agreements in Alabama, Pennsylvania, and Oregon.

The Biden administration may also have other options at its disposal to protect transgender youth, although it is not clear what would be the most effective. Among other options, the Administration for Children and Families could open a compliance review for DFPS. That could lead to an improvement plan and potentially financial penalties. The Department of Justice could try to sue Texas, as the agency recently did over S.B. 8; alternatively, the department could at least file a "statement of interest" in the

pending litigation, as it has done in other litigation on gender-affirming care for young people, such as the lawsuit over Arkansas' legislative ban on gender-affirming care for minors.

(b)(6) (b)(6) (b) (b)(6) Esq., MSW (she/her)
Phone: (b)(6) (b)(6)
Email: (b)(6)

Sender: (b) (b)(6) (b)(6 (HHS/OCR) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0BDEC12AD0974EACABABE032F2B37C91-(b)(6)

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CC:	Lopez, Onelio (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user541e91e4 <Onelio.Lopez@HHS.GOV>
Subject:	RE: [MARKETING EMAIL]Teen Wins Blue Cross Bias Suit Challenging Trans Care Ban
Date:	2022/12/20 09:28:11
Priority:	Normal
Type:	Note

Hi (b)(6)

Please see the attached. We only have one Law360 subscription for the office, so please just let me know if you ever need anything. We have a very basic account, so not all content is accessible. That said, if I can pull an article and supporting materials, I will.

Best,
Rachel

From: (b) (b)(6) (b)(6) (HHS/OCR) (b)(6)
Sent: Tuesday, December 20, 2022 9:19 AM
To: Lopez, Onelio (HHS/OCR) <Onelio.Lopez@HHS.GOV>; Seeger, Rachel (HHS/OCR) <Rachel.Seeger@hhs.gov>
Subject: FW: [MARKETING EMAIL]Teen Wins Blue Cross Bias Suit Challenging Trans Care Ban

Hi Onelio,

Apologies if you have already pulled the below article – if you have, can you please resend, and if not are you able to either get this article or one discussing the same case? If I recall we may not have law360 access…

Also – (b)(6)

Thank you!
(b)(6)

(b)(6) (b)(6) (b) (b)(6) Esq., MSW (she/her)
Senior Advisor to the Director
Phone: (b)(6) (b)(6)
Email: (b)(6)

From: Benefits Law360 <news-alt@law360.com>
Sent: Tuesday, December 20, 2022 4:50 AM

To: (b) (b)(6) (b)(6) (HHS/OCR) (b)(6)
Subject: [MARKETING EMAIL]Teen Wins Blue Cross Bias Suit Challenging Trans Care Ban

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s Suit Challenging Trans Care Ban

londay sided with a transgender teenager who sued Blue Cross Blue Shield of Illinois for denying coverage for gender dysphoria- health care giant couldn't claim it was exempt from the Affordable Care Act's anti-bias policy.

cle »

er's Suit Over Pension Payments

red UPS driver's lawsuit claiming he was shorted on his monthly pension payments, saying that a lower court jumped the gun ate.

ticle »

ealth Coverage Policy Is Illegal

ender bias complaint against a turbomachinery company at a New Hampshire state agency, alleging the company's blanket ban er dysphoria-related treatments is unlawful discrimination.

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OMPLIANCE

ions, Cigna Says Everybody Does It

ral judge that the U.S. Department of Justice's False Claims Act lawsuit accusing it of defrauding Medicare Advantage by challenging an "industry-wide practice."

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ercharging For Vets' Tuition

atically cheated the U.S. Department of Veterans Affairs out of millions of dollars by inflating reimbursements for veteran Justice has claimed in a suit filed in Michigan federal court.

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K Of $25M Post-IPO Drop Suit Deal

reliminary approval to Lyft's $25 million deal to end an investor class action alleging the company concealed sexual assault of its 2019 initial public offering, ruling Friday that the settlement is well within the range of approval.

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nt Laws In 2022 And Beyond

er drowning out other topics in Pennsylvania employment law, 2022 instead saw a variety of worker-friendly changes introduced nd that may continue to grow in 2023 under Gov.-elect Josh Shapiro, say J.T. Holt and Claire Throckmorton at Reed Smith.

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r McKenzie's Bonus Scale

s Kellogg Hansen Todd Figel &Frederick PLLC are part of the latest round of law firms announcing their year-end bonuses, with rd set last month by Baker McKenzie.

To Refer Trump To DOJ

e Jan. 6 attack on the U.S. Capitol voted unanimously Monday to refer former President Donald Trump to the U.S. Department of the 2020 election, citing four criminal statutes it says he violated in the lead-up to and in the midst of the deadly insurrection.

Jackson To Take Senior Status

Jackson of the District of Columbia federal court will assume senior status in May, according to the Administrative Office of the udicial vacancies, giving President Joe Biden the opportunity to nominate another judge to the bench.

ct 'Supersized' Privilege Test

egal and nonlegal advice should not be shielded from grand jury subpoenas by a "supersized" attorney-client privilege unless the federal government told the U.S. Supreme Court.

e »

n Funder In Google Suit Fee Fight

e has backed a $1.8 million arbitration award in favor of a British litigation funder in its battle with a San Francisco law firm over patent infringement lawsuit against Google.

rticle »

e's Chancery Court

eady for the holidays this week, gifting one of their top justices to the Third Circuit, putting a bow on a multimillion-dollar fee c dispute for an arbitrator. Hope you enjoy the last wrap-up this year of last week's news from Delaware's Chancery Court.

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Recipient:	(b)(6) (b)(6) (b)(6 (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bdec12ad0974eacababe032f2b37c91(b)(6) (b)(6) Lopez, Onelio (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user541e91e4 <Onelio.Lopez@HHS.GOV>
Sent Date:	2022/12/20 09:27:40
Delivered Date:	2022/12/20 09:28:11

PRIVILEGED AND CONFIDENTIAL

MEMORANDUM

TO: (b)(6) HHS/OCR
(b)(6) HHS/OCR
(b)(6) HHS/OCR
Section 1557 Team, HHS/OCR

FROM: Vatsala Kumar, Intern, HHS/OCR

RE: Draft Responses to Expected NPRM Comments re Proposed Inclusion of Gender Affirming Care Provisions

DATE: June 24, 2022

I. QUESTION PRESENTED

(b)(5)

II. GENERAL COMMENTS AND DRAFT RESPONSES

(b)(5)

Comment: (b)(5)

(b)(5)

Response: (b)(5)

(b)(5)

PRIVILEGED AND CONFIDENTIAL

(b)(5)

(b)(5)

From: (b)(6) (b)(6 (HHS/OCR) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b)(6) (b)(6) (b)(6)

To: Mitchell, Steven M (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf53b56e8 <Steven.Mitchell@HHS.GOV>; (b) (b)(6) (b)(6 (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bdec12ad0974eacababe032f2b37c91-(b)(6) (b)(6) Kelly, Genevieve (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d5689fc09ae4cbe85f58683ef3b521e-Kelly, Gene <Genevieve.Kelly@hhs.gov>

CC: Roman, David (OS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user5d5a5775 <David.Roman@hhs.gov>

Subject: RE: (b)(5); (b)(7)(C)

Date: 2023/04/07 15:09:24

Priority: Normal

Type: Note

Hi all,

(b)(5); (b)(7)(C)

Thanks and have a good weekend, (b)(6)

From: Mitchell, Steven M (HHS/OCR) <Steven.Mitchell@HHS.GOV>
Sent: Thursday, April 6, 2023 11:52 AM
To: (b) (b)(6) (b)(6) (HHS/OCR) (b)(6) Kelly, Genevieve (HHS/OCR) <Genevieve.Kelly@hhs.gov>
Cc: (b)(6) (b)(6) (HHS/OCR) (b)(6) Roman, David (OS/OCR) <David.Roman@hhs.gov>
Subject: RE: (b)(5); (b)(7)(C)

(b)(5); (b)(7)(C)

From: (b) (b)(6) (b)(6) (HHS/OCR) (b)(6)
Sent: Thursday, April 6, 2023 8:38 AM
To: Mitchell, Steven M (HHS/OCR) <Steven.Mitchell@HHS.GOV>; Kelly, Genevieve (HHS/OCR) <Genevieve.Kelly@hhs.gov>
Cc: (b)(6) (b)(6) (HHS/OCR) (b)(6) Roman, David (OS/OCR)

<David.Roman@hhs.gov>
Subject: RE: (b)(5); (b)(7)(C)

(b)(5); (b)(7)(C)

(b)(6) (b)(6) (b) (b)(6) Esq., MSW (she/her)
Senior Advisor to the Director
Office for Civil Rights | U.S. Department of Health &Human Services
Phone: (b)(6) (b)(6)

From: Mitchell, Steven M (HHS/OCR) <Steven.Mitchell@HHS.GOV>
Sent: Thursday, April 6, 2023 9:35 AM
To: (b) (b)(6) (b)(6) (HHS/OCR) (b)(6) Kelly, Genevieve (HHS/OCR) <Genevieve.Kelly@hhs.gov>
Cc: (b)(6) (b)(6) (HHS/OCR) (b)(6) Roman, David (OS/OCR) <David.Roman@hhs.gov>
Subject: Re: (b)(5); (b)(7)(C)

(b)(5); (b)(7)(C)

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From: (b) (b)(6) (b)(6) (HHS/OCR) (b)(6)
Sent: Thursday, April 6, 2023 7:59:53 AM
To: Kelly, Genevieve (HHS/OCR) <Genevieve.Kelly@hhs.gov>; Mitchell, Steven M (HHS/OCR) <Steven.Mitchell@HHS.GOV>
Cc: (b)(6) (b)(6) (HHS/OCR) (b)(6) Roman, David (OS/OCR) <David.Roman@hhs.gov>
Subject: RE: (b)(5); (b)(7)(C)

(b)(5); (b)(7)(C)

(b)(6) (b)(6) (b) (b)(6) Esq., MSW (she/her)
Senior Advisor to the Director
Office for Civil Rights | U.S. Department of Health &Human Services
Phone: (b)(6) (b)(6)

From: Kelly, Genevieve (HHS/OCR) <Genevieve.Kelly@hhs.gov>
Sent: Wednesday, April 5, 2023 4:42 PM
To: Mitchell, Steven M (HHS/OCR) <Steven.Mitchell@HHS.GOV>; (b) (b)(6) (b)(6) (HHS/OCR) (b)(6)
Subject: Re: (b)(5); (b)(7)(C)

Thanks for sharing, Steve. (b)(5); (b)(7)(C)

(b)(5); (b)(7)(C)

(b)(5); (b)(7)(C)

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From: Mitchell, Steven M (HHS/OCR) <Steven.Mitchell@HHS.GOV>
Sent: Wednesday, April 5, 2023 3:51:25 PM
To: (b) (b)(6) (b)(6) (HHS/OCR) (b)(6) Kelly, Genevieve (HHS/OCR) <Genevieve.Kelly@hhs.gov>
Subject: (b)(5); (b)(7)(C)

(b)(5); (b)(7)(C)

Providing notice. Any guidance appreciated

Steven M. Mitchell
Regional Manager
Midwest Region
US Department of Health and Human Services, Office for Civil Rights
601 East 12th Street, Room 353
Kansas City, MO 64106
(816)426-7278 voice
(816)426-3686 fax
(816)426-7065 TDD

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Русский – Russian – Если вы говорите по- русски, наберите 1-800-368-1019. Для клиентов с ограниченными слуховыми и речевыми возможностями: 1-800-537-7697), и вас соединят с русскоговорящим переводчиком, который вам поможет с этим документом безвозмездно.

Sender: (b)(6) (b)(6) (HHS/OCR) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b)(6) (b)(6) (b)(6)

Recipient: Mitchell, Steven M (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf53b56e8 <Steven.Mitchell@HHS.GOV>; (b) (b)(6) (b)(6 (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bdec12ad0974eacababe032f2b37c91(b)(6) (b)(6)
Kelly, Genevieve (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d5689fc09ae4cbe85f58683ef3b521e-Kelly, Gene <Genevieve.Kelly@hhs.gov>;
Roman, David (OS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user5d5a5775 <David.Roman@hhs.gov>

Sent Date: 2023/04/07 15:08:50

Delivered Date: 2023/04/07 15:09:24

Gender Dysphoria Treatment

Policy Number: CS145.M
Effective Date: March 1, 2023

➲ Instructions for Use

Table of Contents

Related Community Plan Policies

- Brow Ptosis and Eyelid Repair
- Botulinum Toxins A and B
- Cosmetic and Reconstructive Procedures
- Gonadotropin Releasing Hormone Analogs
- Panniculectomy and Body Contouring Procedures
- Rhinoplasty and Other Nasal Surgeries
- Speech Language Pathology Services

Commercial Policy

- Gender Dysphoria Treatment

Application

This Medical Policy does not apply to the states listed below; refer to the state-specific policy/guideline, if noted:

State	Policy/Guideline
Indiana	Gender Dysphoria Treatment (for Indiana Only)
Kentucky	None
Louisiana	Gender Dysphoria Treatment (for Louisiana Only)
Nebraska	None
New Jersey	Gender Dysphoria Treatment (for New Jersey Only)
North Carolina	None
Ohio	Gender Dysphoria Treatment (for Ohio Only)
Pennsylvania	Gender Dysphoria Treatment (for Pennsylvania Only)
Tennessee	None
Virginia	Virginia Medicaid Department of Medical Assistance Services: Bulletin > Coverage of Gender Dysphoria Services

Coverage Rationale

➲ See Benefit Considerations

Note: This Medical Policy does not apply to individuals with ambiguous genitalia or disorders of sexual development.

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Surgical treatment for Gender Dysphoria may be indicated for individuals who provide the following documentation:

- For breast surgery, a written psychological assessment from at least one Qualified Behavioral Health Provider experienced in treating Gender Dysphoria* is required. The assessment must document that an individual meets all of the following criteria:
  - Persistent, well-documented Gender Dysphoria
  - Capacity to make a fully informed decision and to consent for treatment
  - Must be at least 18 years of age (age of majority)
  - Favorable psychosocial-behavioral evaluation to provide screening and identification of risk factors or potential postoperative challenges
- For genital surgery, a written psychological assessment from at least two Qualified Behavioral Health Providers experienced in treating Gender Dysphoria*, who have independently assessed the individual, is required. The assessment must document that an individual meets all of the following criteria:
  - Persistent, well-documented Gender Dysphoria
  - Capacity to make a fully informed decision and to consent for treatment
  - Must be at least 18 years of age (age of majority)
  - Favorable psychosocial-behavioral evaluation to provide screening and identification of risk factors or potential postoperative challenges
  - Complete at least 12 months of successful continuous full-time real-life involvement in the experienced gender
  - Complete 12 months of continuous hormone therapy appropriate for the experienced gender (unless medically contraindicated)
- Treatment plan that includes ongoing follow-up and care by a Qualified Behavioral Health Provider experienced in treating Gender Dysphoria*

When the above criteria are met, the following surgical procedures to treat Gender Dysphoria are medically necessary and covered as a proven benefit:

- Bilateral mastectomy or breast reduction*
- Clitoroplasty (creation of clitoris)
- Hysterectomy (removal of uterus)
- Labiaplasty (creation of labia)
- Laser or electrolysis hair removal in advance of genital reconstruction prescribed by a physician for the treatment of Gender Dysphoria
- Metoidioplasty (creation of penis, using clitoris)
- Orchiectomy (removal of testicles)
- Penectomy (removal of penis)
- Penile prosthesis
- Phalloplasty (creation of penis)
- Salpingo-oophorectomy (removal of fallopian tubes and ovaries)
- Scrotoplasty (creation of scrotum)
- Testicular prostheses
- Urethroplasty (reconstruction of female urethra)
- Urethroplasty (reconstruction of male urethra)
- Vaginectomy (removal of vagina)
- Vaginoplasty (creation of vagina)
- Vulvectomy (removal of vulva)

*When bilateral mastectomy or breast reduction is performed as a stand-alone procedure, without genital reconstruction procedures, completion of hormone therapy prior to the breast procedure is not required.

Certain ancillary procedures, including but not limited to the following, are considered cosmetic and not medically necessary, when performed as part of surgical treatment for Gender Dysphoria (check the federal, state or contractual requirements for benefit coverage**):

Refer to the Benefit Considerations section as member specific benefit plan language may vary.

- Abdominoplasty (also refer to the Medical Policy titled Panniculectomy and Body Contouring Procedures)

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- Blepharoplasty (also refer to the Medical Policy titled Brow Ptosis and Eyelid Repair)
- Body contouring (e.g., fat transfer, lipoplasty, panniculectomy) (also refer to the Medical Policy titled Panniculectomy and Body Contouring Procedures)
- Breast enlargement, including augmentation mammaplasty and breast implants
- Brow lift
- Calf implants
- Cheek, chin and nose implants
- Face/forehead lift and/or neck tightening
- Facial bone remodeling for facial feminization
- Hair transplantation
- Injection of fillers or neurotoxins (also refer to the Medical Benefit Drug Policy titled Botulinum Toxins A and B)
- Laser or electrolysis hair removal not related to genital reconstruction
- Lip augmentation
- Lip reduction
- Liposuction (suction-assisted lipectomy) (also refer to the Medical Policy titled Panniculectomy and Body Contouring Procedures)
- Mastopexy
- Pectoral implants for chest masculinization
- Rhinoplasty (also refer to the Medical Policy titled Rhinoplasty and Other Nasal Surgeries)
- Skin resurfacing (e.g., dermabrasion, chemical peels, laser)
- Thyroid cartilage reduction/reduction thyroid chondroplasty/trachea shave (removal or reduction of the Adam's apple)
- Voice modification surgery (e.g., laryngoplasty, glottoplasty or shortening of the vocal cords)
- Voice lessons and voice therapy

**Note: For New York plans, refer to the Benefit Considerations section for more information.

Definitions

Gender Dysphoria in Adolescents and Adults: A disorder characterized by the following diagnostic criteria [Diagnostic and Statistical Manual of Mental Disorders, 5th edition, Text Revison (DSM-5-TR™)]:

A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration, as manifested by at least two of the following:
   1. A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics (or in young adolescents, the anticipated secondary sex characteristics)
   2. A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender (or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics)
   3. A strong desire for the primary and/or secondary sex characteristics of the other gender
   4. A strong desire to be of the other gender (or some alternative gender different from one's assigned gender)
   5. A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender)
   6. A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender).
B. The condition is associated with clinically significant distress or impairment in social, occupational or other important areas of functioning.

Gender Dysphoria in Children: A disorder characterized by the following diagnostic criteria [Diagnostic and Statistical Manual of Mental Disorders, 5th edition, Text Revision (DSM-5-TR™)]:

A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration, as manifested by at least six of the following (one of which must be criterion A1):
   1. A strong desire to be of the other gender or an insistence that one is the other gender (or some alternative gender different from one's assigned gender).
   2. In boys (assigned gender), a strong preference for cross-dressing or simulating female attire; or in girls (assigned gender), a strong preference for wearing only typical masculine clothing and a strong resistance to the wearing of typical feminine clothing.

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3. A strong preference for cross-gender roles in make-believe play or fantasy play.
4. A strong preference for the toys, games or activities stereotypically used or engaged in by the other gender.
5. A strong preference for playmates of the other gender.
6. In boys (assigned gender), a strong rejection of typically masculine toys, games and activities and a strong avoidance of rough-and-tumble play; or in girls (assigned gender), a strong rejection of typically feminine toys, games and activities.
7. A strong dislike of ones' sexual anatomy.
8. A strong desire for the primary and/or secondary sex characteristics that match one's experienced gender.

B. The condition is associated with clinically significant distress or impairment in social, school or other important areas of functioning.

Qualified Behavioral Health Provider:

- Recommended minimum credentials for behavioral health providers working with adults presenting with gender dysphoria [World Professional Association for Transgender Health (WPATH) Guidelines, version 7, 2012]:
  - A minimum of a master's degree or its equivalent in a clinical behavioral science field. This degree should be granted by an institution accredited by the appropriate national or regional accrediting board. The behavioral health provider should have documented credentials from a relevant licensing board;
  - Competence in using the current version of the Diagnostic Statistical Manual of Mental Disorders (DSM) and/or the International Classification of Diseases (ICD) for assessment and diagnostic purposes;
  - Ability to recognize and diagnose coexisting mental health concerns and to distinguish these from gender dysphoria;
  - Documented supervised training and competence in psychotherapy or counseling;
  - Knowledgeable about gender nonconforming identities and expressions, and the evaluation and treatment of gender dysphoria;
  - Continuing education in the assessment and treatment of gender dysphoria;
  - Develop and maintain cultural competence to facilitate their work with transsexual, transgender, and gender nonconforming clients.
- Recommended minimum credentials for behavioral health providers working with children or adolescents presenting with gender dysphoria (WPATH Guidelines, version 7, 2012):
  - Meet the competency requirements for behavioral health providers working with adults, as outlined above;
  - Trained in childhood and adolescent developmental psychopathology;
  - Competent in diagnosing and treating the ordinary problems of children and adolescents.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
11950	Subcutaneous injection of filling material (e.g., collagen); 1 cc or less
11951	Subcutaneous injection of filling material (e.g., collagen); 1.1 to 5.0 cc
11952	Subcutaneous injection of filling material (e.g., collagen); 5.1 to 10.0 cc
11954	Subcutaneous injection of filling material (e.g., collagen); over 10.0 cc
14000	Adjacent tissue transfer or rearrangement, trunk; defect 10 sq cm or less
14001	Adjacent tissue transfer or rearrangement, trunk; defect 10.1 sq cm to 30.0 sq cm
14041	Adjacent tissue transfer or rearrangement, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; defect 10.1 sq cm to 30.0 sq cm
15734	Muscle, myocutaneous, or fasciocutaneous flap; trunk
15738	Muscle, myocutaneous, or fasciocutaneous flap; lower extremity
15750	Flap; neurovascular pedicle

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CPT Code	Description
15757	Free skin flap with microvascular anastomosis
15758	Free fascial flap with microvascular anastomosis
15769	Grafting of autologous soft tissue, other, harvested by direct excision (e.g., fat, dermis, fascia)
15771	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; 50 cc or less injectate
15772	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; each additional 50 cc injectate, or part thereof (List separately in addition to code for primary procedure)
15773	Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; 25 cc or less injectate
15774	Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; each additional 25 cc injectate, or part thereof (List separately in addition to code for primary procedure)
15775	Punch graft for hair transplant; 1 to 15 punch grafts
15776	Punch graft for hair transplant; more than 15 punch grafts
15780	Dermabrasion; total face (e.g., for acne scarring, fine wrinkling, rhytids, general keratosis)
15781	Dermabrasion; segmental, face
15782	Dermabrasion; regional, other than face
15783	Dermabrasion; superficial, any site (e.g., tattoo removal)
15788	Chemical peel, facial; epidermal
15789	Chemical peel, facial; dermal
15792	Chemical peel, nonfacial; epidermal
15793	Chemical peel, nonfacial; dermal
15819	Cervicoplasty
15820	Blepharoplasty, lower eyelid
15821	Blepharoplasty, lower eyelid; with extensive herniated fat pad
15822	Blepharoplasty, upper eyelid
15823	Blepharoplasty, upper eyelid; with excessive skin weighting down lid
15824	Rhytidectomy; forehead
15825	Rhytidectomy; neck with platysmal tightening (platysmal flap, P-flap)
15826	Rhytidectomy; glabellar frown lines
15828	Rhytidectomy; cheek, chin, and neck
15829	Rhytidectomy; superficial musculoaponeurotic system (SMAS) flap
15830	Excision, excessive skin and subcutaneous tissue (includes lipectomy); abdomen, infraumbilical panniculectomy
15832	Excision, excessive skin and subcutaneous tissue (includes lipectomy); thigh
15833	Excision, excessive skin and subcutaneous tissue (includes lipectomy); leg
15834	Excision, excessive skin and subcutaneous tissue (includes lipectomy); hip
15835	Excision, excessive skin and subcutaneous tissue (includes lipectomy); buttock
15836	Excision, excessive skin and subcutaneous tissue (includes lipectomy); arm
15837	Excision, excessive skin and subcutaneous tissue (includes lipectomy); forearm or hand
15838	Excision, excessive skin and subcutaneous tissue (includes lipectomy); submental fat pad
15839	Excision, excessive skin and subcutaneous tissue (includes lipectomy); other area

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CPT Code	Description
15847	Excision, excessive skin and subcutaneous tissue (includes lipectomy), abdomen (e.g., abdominoplasty) (includes umbilical transposition and fascial plication) (List separately in addition to code for primary procedure)
15876	Suction assisted lipectomy; head and neck
15877	Suction assisted lipectomy; trunk
15878	Suction assisted lipectomy; upper extremity
15879	Suction assisted lipectomy; lower extremity
17380	Electrolysis epilation, each 30 minutes
17999	Unlisted procedure, skin, mucous membrane and subcutaneous tissue
19303	Mastectomy, simple, complete
19316	Mastopexy
19318	Breast reduction
19325	Breast augmentation with implant
19340	Insertion of breast implant on same day of mastectomy (i.e., immediate)
19342	Insertion or replacement of breast implant on separate day from mastectomy
19350	Nipple/areola reconstruction
21120	Genioplasty; augmentation (autograft, allograft, prosthetic material)
21121	Genioplasty; sliding osteotomy, single piece
21122	Genioplasty; sliding osteotomies, 2 or more osteotomies (e.g., wedge excision or bone wedge reversal for asymmetrical chin)
21123	Genioplasty; sliding, augmentation with interpositional bone grafts (includes obtaining autografts)
21125	Augmentation, mandibular body or angle; prosthetic material
21127	Augmentation, mandibular body or angle; with bone graft, onlay or interpositional (includes obtaining autograft)
21137	Reduction forehead; contouring only
21138	Reduction forehead; contouring and application of prosthetic material or bone graft (includes obtaining autograft)
21139	Reduction forehead; contouring and setback of anterior frontal sinus wall
21172	Reconstruction superior-lateral orbital rim and lower forehead, advancement or alteration, with or without grafts (includes obtaining autografts)
21175	Reconstruction, bifrontal, superior-lateral orbital rims and lower forehead, advancement or alteration (e.g., plagiocephaly, trigonocephaly, brachycephaly), with or without grafts (includes obtaining autografts)
21179	Reconstruction, entire or majority of forehead and/or supraorbital rims; with grafts (allograft or prosthetic material)
21180	Reconstruction, entire or majority of forehead and/or supraorbital rims; with autograft (includes obtaining grafts)
21208	Osteoplasty, facial bones; augmentation (autograft, allograft, or prosthetic implant)
21209	Osteoplasty, facial bones; reduction
21210	Graft, bone; nasal, maxillary or malar areas (includes obtaining graft)
21270	Malar augmentation, prosthetic material
21899	Unlisted procedure, neck or thorax
30400	Rhinoplasty, primary; lateral and alar cartilages and/or elevation of nasal tip

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CPT Code	Description
30410	Rhinoplasty, primary; complete, external parts including bony pyramid, lateral and alar cartilages, and/or elevation of nasal tip
30420	Rhinoplasty, primary; including major septal repair
30430	Rhinoplasty, secondary; minor revision (small amount of nasal tip work)
30435	Rhinoplasty, secondary; intermediate revision (bony work with osteotomies)
30450	Rhinoplasty, secondary; major revision (nasal tip work and osteotomies)
31599	Unlisted procedure, larynx
31899	Unlisted procedure, trachea, bronchi
53410	Urethroplasty, 1-stage reconstruction of male anterior urethra
53430	Urethroplasty, reconstruction of female urethra
54125	Amputation of penis; complete
54400	Insertion of penile prosthesis; non-inflatable (semi-rigid)
54401	Insertion of penile prosthesis; inflatable (self-contained)
54405	Insertion of multi-component, inflatable penile prosthesis, including placement of pump, cylinders, and reservoir
54406	Removal of all components of a multi-component, inflatable penile prosthesis without replacement of prosthesis
54408	Repair of component(s) of a multi-component, inflatable penile prosthesis
54410	Removal and replacement of all component(s) of a multi-component, inflatable penile prosthesis at the same operative session
54411	Removal and replacement of all components of a multi-component inflatable penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue
54415	Removal of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis, without replacement of prosthesis
54416	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis at the same operative session
54417	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue
54520	Orchiectomy, simple (including subcapsular), with or without testicular prosthesis, scrotal or inguinal approach
54660	Insertion of testicular prosthesis (separate procedure)
54690	Laparoscopy, surgical; orchiectomy
55175	Scrotoplasty; simple
55180	Scrotoplasty; complicated
55970	Intersex surgery; male to female
55980	Intersex surgery; female to male
56625	Vulvectomy simple; complete
56800	Plastic repair of introitus
56805	Clitoroplasty for intersex state
57110	Vaginectomy, complete removal of vaginal wall
57335	Vaginoplasty for intersex state
58150	Total abdominal hysterectomy (corpus and cervix), with or without removal of tube(s), with or without removal of ovary(s)

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CPT Code	Description
58180	Supracervical abdominal hysterectomy (subtotal hysterectomy), with or without removal of tube(s), with or without removal of ovary(s)
58260	Vaginal hysterectomy, for uterus 250 g or less;
58262	Vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s)
58290	Vaginal hysterectomy, for uterus greater than 250 g
58291	Vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58541	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less
58542	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58543	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g
58544	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58550	Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 g or less
58552	Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58553	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g
58554	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58570	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less
58571	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58572	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g
58573	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58661	Laparoscopy, surgical; with removal of adnexal structures (partial or total oophorectomy and/or salpingectomy)
58720	Salpingo-oophorectomy, complete or partial, unilateral or bilateral (separate procedure)
58940	Oophorectomy, partial or total, unilateral or bilateral
64856	Suture of major peripheral nerve, arm or leg, except sciatic; including transposition
64892	Nerve graft (includes obtaining graft), single strand, arm or leg; up to 4 cm length
64896	Nerve graft (includes obtaining graft), multiple strands (cable), hand or foot; more than 4 cm length
67900	Repair of brow ptosis (supraciliary, mid-forehead or coronal approach)
92507	Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual
92508	Treatment of speech, language, voice, communication, and/or auditory processing disorder; group, 2 or more individuals

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Diagnosis Code	Description
F64.0	Transsexualism
F64.1	Dual role transvestism
F64.2	Gender identity disorder of childhood
F64.8	Other gender identity disorders
F64.9	Gender identity disorder, unspecified
Z87.890	Personal history of sex reassignment

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Description of Services

Gender Dysphoria is a condition in which there is a marked incongruence between an individual's experienced/expressed/alternative gender and assigned gender (DSM-5-TR). Treatment options include behavioral therapy, psychotherapy, hormone therapy, and surgery for gender transformation. Surgical treatments for gender dysphoria may include the following: clitoroplasty, hysterectomy, labiaplasty, mastectomy, orchiectomy, penectomy, phalloplasty or metoidioplasty (alternative to phalloplasty), placement of testicular and/or penile prostheses, salpingo-oophorectomy, scrotoplasty, urethroplasty, urethroplasty, vaginectomy, vaginoplasty and vulvectomy.

Other terms used to describe surgery for gender dysphoria include gender affirming surgery, sex transformation surgery, sex change, sex reversal, gender change, transsexual surgery, transgender surgery, and sex reassignment.

Benefit Considerations

Coverage Information

Benefit coverage for health services is determined by the federal, state or contractual requirements that may require coverage for a specific service.

Unless otherwise specified, if a plan covers treatment for Gender Dysphoria, coverage includes psychotherapy, hormone therapy, puberty suppressing medications and laboratory testing to monitor the safety of hormone therapy. This benefit also includes certain surgical treatments listed in the Coverage Rationale section. Refer to the Medical Benefit Drug Policy titled Gonadotropin Releasing Hormone Analogs.

Limitations and Exclusions

Certain treatments and services are not covered. Examples include, but are not limited to:

- Treatment received outside of the United States
- Reproduction services, including, but not limited to, sperm preservation in advance of hormone treatment or Gender Dysphoria surgery, cryopreservation of fertilized embryos, oocyte preservation, surrogate parenting, donor eggs, donor sperm and host uterus (refer to the federal, state or contractual requirements for benefit coverage)
- Transportation, meals, lodging or similar expenses
- Cosmetic procedures (refer to the Medical Policy titled Cosmetic and Reconstructive Procedures and the Coverage Rationale section). Refer to the section below for additional information on New York plans
- Reversal of genital surgery or reversal of surgery to revise secondary sex characteristics

Coverage does not apply to members who do not meet the indications listed in the Coverage Rationale section above.

For New York Plans Only

Certain ancillary procedures may be considered cosmetic and not medically necessary when performed as part of surgical treatment for Gender Dysphoria. Clinical review for medical necessity of ancillary procedures is conducted on a case-by-case basis.

Clinical Evidence

Almazan et al. (2021) conducted a secondary analysis of the 2015 United States Transgender Survey (USTS) that included 27,715 transgender and gender diverse (TGD) people to evaluate whether gender-affirming surgeries were associated with better mental health outcomes including psychological distress, substance use and suicide risk when compared to TGD people who do not undergo gender-affirming surgeries. The survey was conducted across all 50 states, Washington, DC, U.S. territories and U.S. military bases abroad. The exposure group included respondents who indicated they had undergone 1 or more gender-affirming surgeries at least 2 years prior to submitting survey responses. This group was compared to respondents who indicated a desire to undergo 1 or more types of gender-affirming surgeries but denied having had any gender-affirming surgeries. Of the 27,715 respondents, 3,559 (12.8%) indicated they had undergone 1 or more gender-affirming surgeries at least 2 years prior to the survey while 59.2% (n = 16,401) indicated a desire to undergo a gender-affirming surgery but had not done so as of the time they responded to the survey. Demographics of the respondents to the survey showed that

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81.1% (n = 16,182) were between the ages of 18 and 44 years, 82.1% (n = 16,386) identified as white, 38.8% (n = 7,751) identified as transgender women, 32.5% (n = 6,489) identified as transgender men and 26.6% (n = 5,300) identified as nonbinary. After adjusting for sociodemographic factors, the authors concluded that the analysis showed TGD people with a history of gender-affirming surgery had significantly lower odds of past-month psychological distress, past-year tobacco smoking, and past-year suicidal ideation compared with TGD people who did not have any gender-affirming surgery. Limitations noted by the authors included the nonprobability sampling of the database, the self-reporting structure of the measures, and the risk of confounding. The authors concluded that the study showed a positive association between gender-affirming surgery and improved mental health outcomes for TGD people who seek gender affirming surgical interventions.

Scandurra et al. (2019) performed a systematic review assessing the health of nonbinary and genderqueer (NBGQ) individuals compared to binary transgender (BT) and cisgender individuals. Eleven studies were included in the review. Results related to the difference in health between NBGQ and BT were mixed, with some finding a better health status while others a worse one. Results related to the differences in health between NBGQ and cisgender individuals highlighted higher health needs in NBGQ individuals compared with cisgender counterparts. The authors noted the need for research expansion in terms of both methodology and research contents.

Wernick et al. (2019) conducted a systematic review of the psychological benefits of gender-affirming surgery. Thirty-three studies were included in the analysis. Overall, most of the studies comparing pre- and post-operative data on quality of life, body image/satisfaction, and overall psychological functioning among individuals with gender dysphoria suggested that gender-affirming surgery leads to multiple, significant psychological benefits. Of the studies comparing psychological well-being between individuals who did or did not undergo surgery, most demonstrated a trend of better mental health among individuals who underwent surgery compared with those who did not. The authors encouraged future research to focus on standardizing the assessment of psychological functioning pre- and post-gender-affirming surgery to gather longitudinal data that will allow for more definitive conclusions to be made about factors that contribute to the psychological benefits of surgery.

Cohen et al. (2019) conducted a systematic review of surgical options and associated outcomes for transmasculine top surgery. Twenty-two studies were included (n = 2,447). The authors reported that future research is needed to improve patient selection, surgical decision making, and patient-reported outcomes for different chest contouring techniques.

Mahfouda et al. (2019) conducted a systematic review of the available published evidence on gender-affirming hormone and surgical interventions in transgender children and adolescents, amalgamating findings on mental health outcomes, cognitive and physical effects, side-effects, and safety variables. The small amount of available data suggest that when clearly indicated in accordance with international guidelines, gender-affirming hormone therapy and chest wall masculinization in transgender males are associated with improvements in mental health and quality of life. Evidence regarding surgical vaginoplasty in transgender females younger than age 18 years remains extremely scarce and conclusions cannot yet be drawn regarding its risks and benefits in this age group. Further research on an international scale is urgently warranted to clarify long-term outcomes on psychological functioning and safety.

A Hayes report on sex reassignment surgery (2018; updated 2021) for the treatment of gender dysphoria made the following conclusions:

- Studies suggest that following sex reassignment surgery, patients reported decreased gender dysphoria and improved body image satisfaction. However, results were mixed regarding effects of sex reassignment surgery on quality of life and psychological symptoms.
- Few studies compare outcomes in patients who received sex reassignment surgery with stand-alone hormone therapy. The results of these studies suggest that sex reassignment surgery may improve gender dysphoria, quality of life, body image and psychological symptoms to a greater extent than hormone therapy alone. However, the results were conflicting.
- Few studies compared outcomes in patients who received different components of sex reassignment surgery. For most outcome measures, there was only a single study available. This evidence is therefore insufficient to support definitive conclusions regarding the comparative effectiveness of different components of sex reassignment surgery for treating gender dysphoria.
- Not all studies reported all outcomes; the following findings therefore do not inform overall incidence of complications. Following sex reassignment surgery, there were very low rates of regret of surgery (0% to 6% per study) and suicide (2% to 3% per study). Complications following sex reassignment surgery were common, and some were serious.

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Dreher et al. (2018) conducted a systematic review and meta-analysis to evaluate the epidemiology, presentation, management, and outcomes of neovaginal complications in the MtF transgender reassignment surgery patients. Selected studies reported on 1,684 patients with an overall complication rate of 32.5% and a reoperation rate of 21.7% for non-esthetic reasons. The most common complication was stenosis of the neo-meatus (14.4%). Wound infection was associated with an increased risk of all tissue-healing complications. Use of sacrospinous ligament fixation (SSL) was associated with a significantly decreased risk of prolapse of the neovagina. The authors concluded that gender-affirmation surgery is important in the treatment of gender dysphoric patients, but there is a high complication rate in the reported literature. Variability in technique and complication reporting standards makes it difficult to assess the accurately the current state of MtF gender reassignment surgery. Further research and implementation of standards is necessary to improve patient outcomes.

Manrique et al (2018) conducted a systematic review of retrospective studies on the outcomes of MtF vaginoplasty to minimize surgical complications and improve patient outcomes for transgender patients. Forty-six studies met the authors eligibility criteria. A total of 3,716 cases were analyzed. The results showed the overall incidence of complications as follows: 2% fistula, 14% stenosis and strictures, 1% tissue necrosis, and 4% prolapse. Patient-reported outcomes included a satisfaction rate of 93% with overall results, 87% with functional outcomes, and 90% with esthetic outcomes. Ability to have orgasm was reported in 70% of patients. The regret rate was 1%. The authors concluded that multiple surgical techniques have demonstrated safe and reliable means of MtF vaginoplasty with low overall complication rates and with a significant improvement in the patient's quality of life. Studies using different techniques in a similar population and standardized patient-reported outcomes are required to further analyze outcomes among the different procedures and to establish best-practice guidelines.

Van Damme et al. (2017) conducted a systematic review of the effectiveness of pitch-raising surgery performed in MtF transsexuals. Twenty studies were included: eight using cricothyroid approximation, six using anterior glottal web formation and six using other surgery types or a combination of surgical techniques. A substantial rise in postoperative frequency was identified. The majority of patients seemed satisfied with the outcome. However, none of the studies used a control group and randomization process. Further investigation regarding long-term results using a stronger study design is necessary.

Gaither et al. (2017) retrospectively reviewed the records of 330 MtF patients from 2011 to 2015, to assess surgical complications related to primary penile inversion vaginoplasty. Complications included granulation tissue, vaginal pain, wound separation, labial asymmetry, vaginal stenosis, fistula formation, urinary symptoms including spraying stream or dribbling, infection, vaginal fissure or vaginal bleeding. Median age at surgery was 35 years, and median follow-up in all patients was 3 months. The results showed that 95 of the patients presented with a postoperative complication with the median time to a complication being 4.4 months. Rectoneovaginal fistulas developed in 3 patients, and 30 patients required a second operation. Age, body mass index and hormone replacement therapy were not associated with complications. The authors concluded that penile inversion vaginoplasty is a relatively safe procedure. Most complications due to this surgery develop within the first 4 months postoperatively. Age, body mass index and hormone replacement therapy are not associated with complications and, thus, they should not dictate the timing of surgery.

An ECRI special report systematically reviewed the clinical literature to assess the efficacy of treatments for gender dysphoria. The authors identified limited evidence from mostly low-quality retrospective studies. Evidence on gender reassignment surgery was mostly limited to evaluations of MtF individuals undergoing vaginoplasty, facial feminization surgery and breast augmentation. Outcomes included mortality, patient satisfaction, physical well-being, psychological-related outcomes, quality of life, sexual-related outcomes, suicide and adverse events. Concluding remarks included the need for standardized protocols and prospective studies using standardized measures for correct interpretation and comparability of data (ECRI, 2016).

Morrison et al. (2016) conducted a systematic review of the facial feminization surgery literature. Fifteen studies were included, all of which were either retrospective or case series/reports. The studies covered a variety of facial feminization procedures. A total of 1,121 patients underwent facial feminization surgery, with seven complications reported, although many studies did not explicitly comment on complications. Satisfaction was high, although most studies did not use validated or quantified approaches to address satisfaction. The authors noted that further studies are needed to better compare different techniques to more robustly establish best practices. Prospective studies and patient-reported outcomes are needed to establish quality of life outcomes for patients.

Frey et al. (2016) conducted a systematic review of metoidioplasty and radial forearm flap phalloplasty (RFFP) in FtM transgender genital reconstruction. Eighteen studies were included: 7 for metoidioplasty and 11 for RFFP. The quality of evidence was low to very low for all included studies. In studies examining metoidioplasty, the average study size and length of

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follow-up were 54 patients and 4.6 years, respectively [1 study did not report (NR)]. Eighty-eight percent underwent a single-stage reconstruction, 87% reported an aesthetic neophallus (3 NR) and 100% reported erogenous sensation (2 NR). Fifty-one percent of patients reported successful intercourse (3 NR) and 89% of patients achieved standing micturition (3 NR). In studies examining RFFP, the average study size and follow-up were 60.4 patients and 6.23 years, respectively (6 NR). No patients underwent single-stage reconstructions (8 NR). Seventy percent of patients reported a satisfactorily aesthetic neophallus (4 NR) and 69% reported erogenous sensation (6 NR). Forty-three percent reported successful penetration of partner during intercourse (6 NR) and 89% achieved standing micturition (6 NR). Compared with RFFP, metoidioplasty was significantly more likely to be completed in a single stage, have an aesthetic result, maintain erogenous sensation, achieve standing micturition and have a lower overall complication rate. The authors reported that, although the current literature suggests that metoidioplasty is more likely to yield an "ideal" neophallus compared with RFFP, any conclusion is severely limited by the low quality of available evidence.

Using a retrospective chart review, Buncamper et al. (2016) assessed surgical outcome after penile inversion vaginoplasty. Outcome measures were intraoperative and postoperative complications, reoperations, secondary surgical procedures and possible risk factors. Of 475 patients who underwent the procedure, 405 did not have additional full-thickness skin grafts while 70 did have grafts. Median follow-up was 7.8 years. The most frequently observed intraoperative complication was rectal injury (2.3 percent). Short-term postoperative bleeding that required transfusion (4.8 percent), reoperation (1.5 percent) or both (0.4 percent) occurred in some cases. Major complications were three (0.6 percent) rectoneovaginal fistulas, which were successfully treated. Revision vaginoplasty was performed in 14 patients (2.9 percent). Comorbid diabetes was associated with a higher risk of local infection, and use of psychotropic medication predisposed to postoperative urinary retention. Successful vaginal construction without the need for secondary functional reoperations was achieved in the majority of patients.

Bouman et al. (2016) prospectively assessed surgical outcomes of primary total laparoscopic sigmoid vaginoplasty in 42 transgender women with penoscrotal hypoplasia. Mean follow-up time was 3.2 ±2.1 years. The mean operative duration was 210 ±44 minutes. There were no conversions to laparotomy. One rectal perforation was recognized during surgery and immediately oversewn without long-term consequences. The mean length of hospitalization was 5.7 ±1.1 days. One patient died as a result of an extended-spectrum beta-lactamase-positive necrotizing fasciitis leading to septic shock, with multiorgan failure. Direct postoperative complications that needed laparoscopic reoperation occurred in three cases (7.1 percent). In seven cases (17.1 percent), long-term complications needed a secondary correction. After 1 year, all patients had a functional neovagina with a mean depth of 16.3 ±1.5 cm.

Despite the significant increase in genital gender affirming surgery (GAS) within the past 50 years, there is limited data regarding hair removal practices in preparation for genital GAS. Genital GAS involves reconstruction of the genitals to match a patient's identified sex. The use of hair-bearing flaps in this procedure may result in postoperative intra-vaginal and intra-urethral hair growth and associated complications, including lower satisfaction with genital GAS. In 2016, Zhang et al. conducted a literature review, recommendations from experience, and a practical laser hair removal (LHR) approach to hair removal prior to genital GAS.

Horbach et al. (2015) conducted a systematic review of vaginoplasty techniques in MtF individuals with gender dysphoria. Twenty-six studies were included (mostly retrospective case series of low to intermediate quality). Outcome of the penile skin inversion technique was reported in 1,461 patients and bowel vaginoplasty in 102 patients. Neovaginal stenosis was the most frequent complication in both techniques. Sexual function and patient satisfaction were overall acceptable, but many different outcome measures were used. Quality of life was only reported in one study. Comparison between techniques was difficult due to the lack of standardization. The authors concluded that the penile skin inversion technique is the most researched surgical procedure. Outcome of bowel vaginoplasty has been reported less frequently but does not seem to be inferior. The available literature is heterogeneous in patient groups, surgical procedure, outcome measurement tools and follow-up. There is a need for prospective studies with standardized surgical procedures, larger patient groups and longer follow-up periods. Uniformity in outcome measurement tools such as validated questionnaires and scores for sexual function and quality of life is mandatory for correct interpretation and comparability of data.

Bouman et al. (2014) conducted a systematic review of surgical techniques and clinical outcomes of intestinal vaginoplasty. Twenty-one studies were included (n = 894). All studies had a retrospective design and were of low quality. Prevalence and severity of procedure-related complications were low. The main postoperative complication was introital stenosis, necessitating surgical correction in 4.1% of sigmoid-derived and 1.2% of ileum-derived vaginoplasties. Neither diversion colitis nor cancer was reported. Sexual satisfaction rate was high, but standardized questionnaires were rarely used. Quality of life was not reported.

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The authors concluded that prospective studies, using standardized measures and questionnaires, are warranted to assess functional outcomes and quality of life.

Djordjevic et al. (2013) evaluated 207 patients who underwent single-stage metoidioplasty, comparing two different surgical techniques of urethral lengthening. The procedure included lengthening and straightening of the clitoris, urethral reconstruction and scrotoplasty with implantation of testicular prostheses. Buccal mucosa graft was used in all cases for dorsal urethral plate formation and joined with one of the two different flaps: longitudinal dorsal clitoral skin flap (n = 49) (group 1) and labia minora flap (n = 158) (group 2). The median follow-up was 39 months. The total length of reconstructed urethra ranged from 9.1 to 12.3 cm in group 1 and from 9.4 to 14.2 cm in group 2. Voiding while standing was significantly better in group 2 (93%) than in group 1 (87.82%). Urethral fistula occurred in 16 patients in both groups. Overall satisfaction was noted in 193 patients. The authors concluded that combined buccal mucosa graft and labia minora flap was the method of choice for urethroplasty in metoidioplasty, minimizing postoperative complications.

In a non-randomized study, Dhejne et al. (2011) evaluated mortality, morbidity and criminal rates after gender reassignment surgery in 324 individuals (MtF n = 191; FtM n = 133). Random population controls (10:1) were matched by birth year and birth sex or reassigned final sex. The authors reported substantially higher rates of overall mortality, death from cardiovascular disease and suicide, suicide attempts and psychiatric hospitalizations in sex-reassigned individuals (both MtF/FtM) compared to a healthy control population. FtMs had a higher risk for criminal convictions.

Murad et al. (2010) conducted a systematic review to evaluate the effects of hormone therapy on patients undergoing gender reassignment surgery. The authors identified 28 eligible studies, all of which were observational and most lacked controls. These studies enrolled 1,833 participants with gender dysphoria (1,093 MtF; 801 FtM). After gender reassignment surgery, individuals reported improvement in gender dysphoria (80%), psychological symptoms (78%), sexual function (72%) and quality of life (80%). The authors concluded that very low quality evidence suggests that gender reassignment, that includes hormonal interventions, is likely to improve gender dysphoria, psychological functioning and comorbidities, sexual function and overall quality of life.

Sutcliffe et al. (2009) systematically reviewed five individual procedures for MtF gender reassignment surgery: clitoroplasty, labiaplasty, orchiectomy, penectomy and vaginoplasty. Further evaluations were made of eight surgical procedures for FtM gender reassignment surgery: hysterectomy, mastectomy, metoidioplasty, phalloplasty, salpingo-oophorectomy, scrotoplasty/placement of testicular prostheses, urethroplasty and vaginectomy. Eighty-two published studies (38 MtF; 44 FtM) were included in the review. For MtF procedures, the authors found no evidence that met the inclusion criteria concerning labiaplasty, penectomy or orchiectomy. A large amount of evidence was available concerning vaginoplasty and clitoroplasty procedures. The authors reported that the evidence concerning gender reassignment surgery in both MtF and FtM individuals with gender dysphoria has several limitations including lack of controlled studies, lack of prospective data, high loss to follow-up and lack of validated assessment measures. Some satisfactory outcomes were reported, but the magnitude of benefit and harm for individual surgical procedures cannot be estimated accurately using the current available evidence.

World Professional Association for Transgender Health (WPATH)

WPATH, formerly known as the Harry Benjamin International Gender Dysphoria Association, is an advocacy group devoted to transgender health. WPATH guidelines (2012) present eligibility and readiness criteria for transition-related treatment, as well as competencies of health care providers. WPATH is currently reviewing their Standards of Care with an anticipated release date for their update of 2022.

WPATH describes the transition from one gender to another in the following three stages:

- Living in the gender role consistent with gender identity
- The use of hormone therapy after living in the new gender role for a least three months
- Gender-affirmation surgery after living in the new gender role and using hormonal therapy for at least 12 months

Clinical Practice Guidelines

American Academy of Pediatrics (AAP)

In a 2018 policy statement entitled Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents, the AAP states the following regarding surgery: Surgical approaches may be used to feminize or masculinize features, such as hair distribution, chest, or genitalia, and may include removal of internal organs, such as ovaries or the uterus

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(affecting fertility). These changes are irreversible. Although current protocols typically reserve surgical interventions for adults, they are occasionally pursued during adolescence on a case-by case basis, considering the necessity and benefit to the adolescent's overall health and often including multidisciplinary input from medical, mental health, and surgical providers as well as from the adolescent and family (Rafferty et al, 2018).

American College of Obstetrics and Gynecology (ACOG)

An ACOG committee opinion (2021) provides guidance on health care for transgender and gender diverse individuals. The document does not make specific recommendations regarding surgery but does provide an overview of surgical procedures and education for clinicians who care for transgender patients before and after surgery.

Endocrine Society

Endocrine Society practice guidelines (Hembree et al., 2017) addressing endocrine treatment of gender-dysphoric/ gender-incongruent persons makes the following recommendations regarding surgery for sex reassignment and gender confirmation:

- Suggest that clinicians delay gender-affirming genital surgery involving gonadectomy and/or hysterectomy until the patient is at least 18 years old or legal age of majority in his or her country (Recommendation based on low quality evidence).
- A patient pursue genital gender-affirming surgery only after the mental health practitioner (MHP) and the clinician responsible for endocrine transition therapy both agree that surgery is medically necessary and would benefit the patient's overall health and/or well-being (Strong recommendation based on low quality evidence).
- Surgery is recommended only after completion of at least one year of consistent and compliant hormone treatment unless hormone therapy is not desired or medically contraindicated (Ungraded Good Practice Statement).
- The physician responsible for endocrine treatment medically clears individual for surgery and collaborates with the surgeon regarding hormone use during and after surgery (Ungraded Good Practice Statement).
- Recommend that clinicians refer hormone treated transgender individuals for genital surgery when (Strong recommendation based on very low quality evidence):
  - The individual has had a satisfactory social role change
  - The individual is satisfied about the hormonal effects
  - The individual desires definitive surgical changes
- Suggest that clinicians determine the timing of breast surgery for transgender males based upon the physical and mental health status of the individual. There is insufficient evidence to recommend a specific age requirement (Recommendation based on very low quality evidence)

University of California, San Francisco (UCSF) Center of Excellence for Transgender Health

The UCSF Center of Excellence evidence-based guidelines for the primary and gender-affirming care of transgender and gender nonbinary people address various surgical procedures, including risks, complications, approaches and perioperative and postoperative care (Deutsch, 2016).

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Gender transformation surgeries are procedures, and therefore, not subject to FDA regulation. However, medical devices, drugs, biologics or tests used as a part of these procedures may be subject to FDA regulation. Refer to the following website to search by product name. Available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed July 12, 2022)

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Policy History/Revision Information

Date	Summary of Changes

03/01/2023	Coverage Rationale
	• Revised coverage criteria for genital surgery for Gender Dysphoria; replaced criterion requiring an individual must:
	  ○ "Complete at least 12 months of successful continuous full-time real-life *experience* in the *desired* gender" with "complete at least 12 months of successful continuous full-time real-life *involvement* in the *experienced* gender"
	  ○ "Complete 12 months of continuous *cross-sex* hormone therapy appropriate for the *desired* gender (unless medically contraindicated)" with "complete 12 months of continuous hormone therapy appropriate for the *experienced* gender (unless medically contraindicated)"
	• Added instruction to refer to the *Benefit Considerations* section [of the policy] as member specific benefit plan language may vary
	Supporting Information
	• Updated *Benefit Considerations*, *Clinical Evidence*, and *References* sections to reflect the most current information at the time of review
	• Archived previous policy version CS145.L

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

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To: (b) (b)(6) (b)(6) (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bdec12ad0974eacababe032f2b37c91-(b)(6) (b)(6)

Subject: NEED YOUR INPUT: (b)(5); (b)(7)(C) (b)(5);

Date: 2022/11/17 19:14:23

Priority: Normal

Type: Note

Hi (b)(6)

(b)(5); (b)(7)(C)

- • Case Summary:

(b)(5); (b)(7)(C)

Thanks, (b)(6)

From: (b)(6) (b)(6) (HHS/OCR) (b)(6)

Sent: Thursday, November 17, 2022 6:46 PM

To: (b)(6) (b)(6) (HHS/OCR) (b)(6)
Subject: (b)(5); (b)(7)(C)

(b)(5); (b)(7)(C)

From: Cameron, Emily (OS/OCR) <Emily.Cameron@hhs.gov>
Sent: Wednesday, November 16, 2022 5:29 PM
To: (b)(6) (b)(6) (HHS/OCR) (b)(6)
Subject: (b)(5); (b)(7)(C)

Hello,

(b)(5); (b)(7)(C)

Thanks for your help!

Emily Cameron, JD
She/Her
Supervisory Equal Opportunity Specialist
U.S. Department of Health &Human Services
Office for Civil Rights
Southwest Region • 1301 Young Street
Suite 106 - 1130 • Dallas, TX 75202
(214) 767-2010 • Toll Free – (800) 368-1019
Fax – (214) 767-0432 • TDD – (214) 767-8940
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Gender Dysphoria Treatment

Policy Number: 2021T0580L
Effective Date: November 1, 2021

➲ Instructions for Use

Table of Contents Page

Related Commercial Policies

- Blepharoplasty, Blepharoptosis and Brow Ptosis Repair
- Botulinum Toxins A and B
- Cosmetic and Reconstructive Procedures
- Gonadotropin Releasing Hormone Analogs
- Habilitative Services and Outpatient Rehabilitation Therapy
- Panniculectomy and Body Contouring Procedures
- Rhinoplasty and Other Nasal Surgeries

Community Plan Policy

- Gender Dysphoria Treatment

Coverage Rationale

➲ See Benefit Considerations

Notes:

- This Medical Policy does not apply to individuals with ambiguous genitalia or disorders of sexual development.
- This Medical Policy does not apply to fully-insured group plans in California. Refer to the Benefit Interpretation Policy titled Gender Dysphoria (Gender Identity Disorder) Treatment: CA.
- This Medical Policy does not apply to fully-insured group plans in the state of Washington. Refer to the Benefit Interpretation Policy titled Gender Dysphoria (Gender Identity Disorder) Treatment: WA.

Surgical treatment for Gender Dysphoria may be indicated for individuals who provide the following documentation:

- For breast surgery, a written psychological assessment from at least one Qualified Behavioral Health Provider experienced in treating Gender Dysphoria* is required. The assessment must document that an individual meets all of the following criteria:
  - Persistent, well-documented Gender Dysphoria
  - Capacity to make a fully informed decision and to consent for treatment
  - Must be at least 18 years of age (age of majority)
  - Favorable psychosocial-behavioral evaluation to provide screening and identification of risk factors or potential postoperative challenges
- For genital surgery, a written psychological assessment from at least two Qualified Behavioral Health Providers experienced in treating Gender Dysphoria*, who have independently assessed the individual, is required. The assessment must document that an individual meets all of the following criteria:
  - Persistent, well-documented Gender Dysphoria
  - Capacity to make a fully informed decision and to consent for treatment
  - Must be at least 18 years of age (age of majority)

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- Favorable psychosocial-behavioral evaluation to provide screening and identification of risk factors or potential postoperative challenges
- Complete at least 12 months of successful continuous full-time real-life experience in the desired gender
- Complete 12 months of continuous cross-sex hormone therapy appropriate for the desired gender (unless medically contraindicated)

- Treatment plan that includes ongoing follow-up and care by a Qualified Behavioral Health Provider experienced in treating Gender Dysphoria*

When the above criteria are met, the following surgical procedures to treat Gender Dysphoria are medically necessary and covered as a proven benefit:

- Bilateral mastectomy or breast reduction*
- Clitoroplasty (creation of clitoris)
- Hysterectomy (removal of uterus)
- Labiaplasty (creation of labia)
- Laser or electrolysis hair removal in advance of genital reconstruction prescribed by a physician for the treatment of Gender Dysphoria
- Metoidioplasty (creation of penis, using clitoris)
- Orchiectomy (removal of testicles)
- Penectomy (removal of penis)
- Penile prosthesis
- Phalloplasty (creation of penis)
- Salpingo-oophorectomy (removal of fallopian tubes and ovaries)
- Scrotoplasty (creation of scrotum)
- Testicular prostheses
- Urethroplasty (reconstruction of female urethra)
- Urethroplasty (reconstruction of male urethra)
- Vaginectomy (removal of vagina)
- Vaginoplasty (creation of vagina)
- Vulvectomy (removal of vulva)

*When bilateral mastectomy or breast reduction is performed as a stand-alone procedure, without genital reconstruction procedures, completion of hormone therapy prior to the breast procedure is not required.

Certain ancillary procedures, including but not limited to the following, are considered cosmetic and not medically necessary, when performed as part of surgical treatment for Gender Dysphoria:

Refer to the Benefit Considerations section as member specific benefit plan language may vary.

Note: For fully insured group policies in New York, refer to the Benefit Considerations section for more information.

- Abdominoplasty (also refer to the Coverage Determination Guideline titled Panniculectomy and Body Contouring Procedures)
- Blepharoplasty (also refer to the Coverage Determination Guideline titled Blepharoplasty, Blepharoptosis and Brow Ptosis Repair)
- Body contouring (e.g., fat transfer, lipoplasty, panniculectomy) (also refer to the Coverage Determination Guideline titled Panniculectomy and Body Contouring Procedures)
- Breast enlargement, including augmentation mammaplasty and breast implants
- Brow lift
- Calf implants
- Cheek, chin and nose implants
- Injection of fillers or neurotoxins (also refer to the Medical Benefit Drug Policy titled Botulinum Toxins A and B)
- Face/forehead lift and/or neck tightening
- Facial bone remodeling for facial feminization
- Laser or electrolysis hair removal not related to genital reconstruction
- Hair transplantation

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- Lip augmentation
- Lip reduction
- Liposuction (suction-assisted lipectomy) (also refer to the Coverage Determination Guideline titled Panniculectomy and Body Contouring Procedures)
- Mastopexy
- Pectoral implants for chest masculinization
- Rhinoplasty (also refer to the Coverage Determination Guideline titled Rhinoplasty and Other Nasal Surgeries)
- Skin resurfacing (e.g., dermabrasion, chemical peels, laser)
- Thyroid cartilage reduction/reduction thyroid chondroplasty/trachea shave (removal or reduction of the Adam's apple)
- Voice modification surgery (e.g., laryngoplasty, glottoplasty or shortening of the vocal cords)
- Voice lessons and voice therapy

Documentation Requirements

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The documentation requirements outlined below are used to assess whether the member meets the clinical criteria for coverage but do not guarantee coverage of the service requested.

CPT Codes*	Required Clinical Information
Gender Dysphoria Treatment	
14000, 14000, 14001, 14041, 15734, 15738, 15750, 15757, 15758, 15820, 15821, 15822, 15823, 15830, 15847, 15877, 15878, 15879, 17999, 19303, 19316, 19318, 19325, 19340, 19342, 19350, 21121, 21123, 21125, 21127, 21137, 21138, 21139, 21172, 21175, 21179, 21180, 21208, 21209, 21210, 30400, 30410, 30420, 30430, 30435, 30450, 53410, 53430, 54125, 54400, 54401, 54405, 54520, 54660, 54690, 55175, 55180, 55970, 55980, 56625, 56800, 56805, 57110, 57335, 58150, 58180, 58260, 58262, 58290, 58291, 58541, 58542, 58543, 58544, 58550, 58552, 58553, 58554, 58570, 58571, 58572, 58573, 58661, 58720, 58940, 64856, 64892, 64896, 67900	Medical notes documenting the following: • The history of medical conditions requiring treatment or surgical intervention • A well-defined physical/physiologic abnormality resulting in a medical condition that requires treatment • Recurrent or persistent functional deficit caused by the abnormality • Clinical studies/tests addressing the physical/physiologic abnormality confirming its presence and degree to which it causes impairment • Color photos, where applicable, of the physical and/or physiological abnormality • Physician plan of care with proposed procedures and whether this request is part of a staged procedure; indicate how the procedure will improve and/or restore function • For CPT codes 58260, 58262, 58290 and 58291, provide the additional information: o The history of medical conditions requiring treatment or surgical intervention o Physician plan of care with proposed procedures and whether this request is part of a staged procedure o A written psychological assessment from at least two Qualified Behavioral Health Providers experienced in treating Gender Dysphoria, who have independently assessed the individual. The assessment should include all of the following: ▪ The member is capable to make a fully informed decision and to consent for treatment ▪ The member must be at least 18 years of age (age of majority) ▪ If significant medical or mental health concerns are present, they must be reasonably well controlled ▪ The member has completed at least 12 months of successful continuous full-time real-life experience in the desired gender ▪ The member has completed 12 months of continuous cross-sex hormone therapy appropriate for the desired gender (unless medically contraindicated) o A treatment plan that includes ongoing follow-up and care by a Qualified Behavioral Health Provider experienced in treating Gender Dysphoria

**For code descriptions, see the Applicable Codes section.*

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Definitions

Gender Dysphoria in Adolescents and Adults: A disorder characterized by the following diagnostic criteria (Diagnostic and Statistical Manual of Mental Disorders, 5th edition [DSM-5]):

A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration, as manifested by at least two of the following:
   1. A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics [(or in young adolescents, the anticipated secondary sex characteristics)].
   2. A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender [or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics)].
   3. A strong desire for the primary and/or secondary sex characteristics of the other gender.
   4. A strong desire to be of the other gender (or some alternative gender different from one's assigned gender).
   5. A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender).
   6. A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender).
B. The condition is associated with clinically significant distress or impairment in social, occupational or other important areas of functioning.

Gender Dysphoria in Children: A disorder characterized by the following diagnostic criteria (Diagnostic and Statistical Manual of Mental Disorders, 5th edition [DSM-5]):

A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration, as manifested by at least six of the following (one of which must be criterion A1):
   1. A strong desire to be of the other gender or an insistence that one is the other gender (or some alternative gender different from one's assigned gender).
   2. In boys (assigned gender), a strong preference for cross-dressing or simulating female attire; or in girls (assigned gender), a strong preference for wearing only typical masculine clothing and a strong resistance to the wearing of typical feminine clothing.
   3. A strong preference for cross-gender roles in make-believe play or fantasy play.
   4. A strong preference for the toys, games or activities stereotypically used or engaged in by the other gender.
   5. A strong preference for playmates of the other gender.
   6. In boys (assigned gender), a strong rejection of typically masculine toys, games and activities and a strong avoidance of rough-and-tumble play; or in girls (assigned gender), a strong rejection of typically feminine toys, games and activities.
   7. A strong dislike of ones' sexual anatomy.
   8. A strong desire for the primary and/or secondary sex characteristics that match one's experienced gender.
B. The condition is associated with clinically significant distress or impairment in social, school or other important areas of functioning.

Qualified Behavioral Health Provider:

- Recommended minimum credentials for behavioral health providers working with adults presenting with gender dysphoria (World Professional Association for Transgender Health [WPATH] Guidelines, version 7, 2012):
  - A minimum of a master's degree or its equivalent in a clinical behavioral science field. This degree should be granted by an institution accredited by the appropriate national or regional accrediting board. The behavioral health provider should have documented credentials from a relevant licensing board;
  - Competence in using the current version of the Diagnostic Statistical Manual of Mental Disorders (DSM) and/or the International Classification of Diseases (ICD) for assessment and diagnostic purposes;
  - Ability to recognize and diagnose coexisting mental health concerns and to distinguish these from gender dysphoria;
  - Documented supervised training and competence in psychotherapy or counseling;
  - Knowledgeable about gender nonconforming identities and expressions, and the evaluation and treatment of gender dysphoria;
  - Continuing education in the assessment and treatment of gender dysphoria;
  - Develop and maintain cultural competence to facilitate their work with transsexual, transgender, and gender nonconforming clients.

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- Recommended minimum credentials for behavioral health providers working with children or adolescents presenting with gender dysphoria (WPATH Guidelines, version 7, 2012):
  - Meet the competency requirements for behavioral health providers working with adults, as outlined above;
  - Trained in childhood and adolescent developmental psychopathology;
  - Competent in diagnosing and treating the ordinary problems of children and adolescents.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
11950	Subcutaneous injection of filling material (e.g., collagen); 1 cc or less
11951	Subcutaneous injection of filling material (e.g., collagen); 1.1 to 5.0 cc
11952	Subcutaneous injection of filling material (e.g., collagen); 5.1 to 10.0 cc
11954	Subcutaneous injection of filling material (e.g., collagen); over 10.0 cc
14000	Adjacent tissue transfer or rearrangement, trunk; defect 10 sq cm or less
14001	Adjacent tissue transfer or rearrangement, trunk; defect 10.1 sq cm to 30.0 sq cm
14041	Adjacent tissue transfer or rearrangement, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; defect 10.1 sq cm to 30.0 sq cm
15734	Muscle, myocutaneous, or fasciocutaneous flap; trunk
15738	Muscle, myocutaneous, or fasciocutaneous flap; lower extremity
15750	Flap; neurovascular pedicle
15757	Free skin flap with microvascular anastomosis
15758	Free fascial flap with microvascular anastomosis
15769	Grafting of autologous soft tissue, other, harvested by direct excision (e.g., fat, dermis, fascia)
15771	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; 50 cc or less injectate
15772	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; each additional 50 cc injectate, or part thereof (List separately in addition to code for primary procedure)
15773	Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; 25 cc or less injectate
15774	Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet; each additional 25 cc injectate, or part thereof (List separately in addition to code for primary procedure)
15775	Punch graft for hair transplant; 1 to 15 punch grafts
15776	Punch graft for hair transplant; more than 15 punch grafts
15780	Dermabrasion; total face (e.g., for acne scarring, fine wrinkling, rhytids, general keratosis)
15781	Dermabrasion; segmental, face
15782	Dermabrasion; regional, other than face
15783	Dermabrasion; superficial, any site (e.g., tattoo removal)
15788	Chemical peel, facial; epidermal
15789	Chemical peel, facial; dermal
15792	Chemical peel, nonfacial; epidermal

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CPT Code	Description
15793	Chemical peel, nonfacial; dermal
15819	Cervicoplasty
15820	Blepharoplasty, lower eyelid
15821	Blepharoplasty, lower eyelid; with extensive herniated fat pad
15822	Blepharoplasty, upper eyelid
15823	Blepharoplasty, upper eyelid; with excessive skin weighting down lid
15824	Rhytidectomy; forehead
15825	Rhytidectomy; neck with platysmal tightening (platysmal flap, P-flap)
15826	Rhytidectomy; glabellar frown lines
15828	Rhytidectomy; cheek, chin, and neck
15829	Rhytidectomy; superficial musculoaponeurotic system (SMAS) flap
15830	Excision, excessive skin and subcutaneous tissue (includes lipectomy); abdomen, infraumbilical panniculectomy
15832	Excision, excessive skin and subcutaneous tissue (includes lipectomy); thigh
15833	Excision, excessive skin and subcutaneous tissue (includes lipectomy); leg
15834	Excision, excessive skin and subcutaneous tissue (includes lipectomy); hip
15835	Excision, excessive skin and subcutaneous tissue (includes lipectomy); buttock
15836	Excision, excessive skin and subcutaneous tissue (includes lipectomy); arm
15837	Excision, excessive skin and subcutaneous tissue (includes lipectomy); forearm or hand
15838	Excision, excessive skin and subcutaneous tissue (includes lipectomy); submental fat pad
15839	Excision, excessive skin and subcutaneous tissue (includes lipectomy); other area
15847	Excision, excessive skin and subcutaneous tissue (includes lipectomy), abdomen (e.g., abdominoplasty) (includes umbilical transposition and fascial plication) (List separately in addition to code for primary procedure)
15876	Suction assisted lipectomy; head and neck
15877	Suction assisted lipectomy; trunk
15878	Suction assisted lipectomy; upper extremity
15879	Suction assisted lipectomy; lower extremity
17380	Electrolysis epilation, each 30 minutes
17999	Unlisted procedure, skin, mucous membrane and subcutaneous tissue
19303	Mastectomy, simple, complete
19316	Mastopexy
19318	Breast reduction
19325	Breast augmentation with implant
19340	Insertion of breast implant on same day of mastectomy (i.e., immediate)
19342	Insertion or replacement of breast implant on separate day from mastectomy
19350	Nipple/areola reconstruction
21120	Genioplasty; augmentation (autograft, allograft, prosthetic material)
21121	Genioplasty; sliding osteotomy, single piece
21122	Genioplasty; sliding osteotomies, 2 or more osteotomies (e.g., wedge excision or bone wedge reversal for asymmetrical chin)
21123	Genioplasty; sliding, augmentation with interpositional bone grafts (includes obtaining autografts)
21125	Augmentation, mandibular body or angle; prosthetic material

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CPT Code	Description
21127	Augmentation, mandibular body or angle; with bone graft, onlay or interpositional (includes obtaining autograft)
21137	Reduction forehead; contouring only
21138	Reduction forehead; contouring and application of prosthetic material or bone graft (includes obtaining autograft)
21139	Reduction forehead; contouring and setback of anterior frontal sinus wall
21172	Reconstruction superior-lateral orbital rim and lower forehead, advancement or alteration, with or without grafts (includes obtaining autografts)
21175	Reconstruction, bifrontal, superior-lateral orbital rims and lower forehead, advancement or alteration (e.g., plagiocephaly, trigonocephaly, brachycephaly), with or without grafts (includes obtaining autografts)
21179	Reconstruction, entire or majority of forehead and/or supraorbital rims; with grafts (allograft or prosthetic material)
21180	Reconstruction, entire or majority of forehead and/or supraorbital rims; with autograft (includes obtaining grafts)
21208	Osteoplasty, facial bones; augmentation (autograft, allograft, or prosthetic implant)
21209	Osteoplasty, facial bones; reduction
21210	Graft, bone; nasal, maxillary or malar areas (includes obtaining graft)
21270	Malar augmentation, prosthetic material
21899	Unlisted procedure, neck or thorax
30400	Rhinoplasty, primary; lateral and alar cartilages and/or elevation of nasal tip
30410	Rhinoplasty, primary; complete, external parts including bony pyramid, lateral and alar cartilages, and/or elevation of nasal tip
30420	Rhinoplasty, primary; including major septal repair
30430	Rhinoplasty, secondary; minor revision (small amount of nasal tip work)
30435	Rhinoplasty, secondary; intermediate revision (bony work with osteotomies)
30450	Rhinoplasty, secondary; major revision (nasal tip work and osteotomies)
31599	Unlisted procedure, larynx
31899	Unlisted procedure, trachea, bronchi
53410	Urethroplasty, 1-stage reconstruction of male anterior urethra
53430	Urethroplasty, reconstruction of female urethra
54125	Amputation of penis; complete
54400	Insertion of penile prosthesis; non-inflatable (semi-rigid)
54401	Insertion of penile prosthesis; inflatable (self-contained)
54405	Insertion of multi-component, inflatable penile prosthesis, including placement of pump, cylinders, and reservoir
54406	Removal of all components of a multi-component, inflatable penile prosthesis without replacement of prosthesis
54408	Repair of component(s) of a multi-component, inflatable penile prosthesis
54410	Removal and replacement of all component(s) of a multi-component, inflatable penile prosthesis at the same operative session
54411	Removal and replacement of all components of a multi-component inflatable penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue
54415	Removal of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis, without replacement of prosthesis

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CPT Code	Description
54416	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis at the same operative session
54417	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue
54520	Orchiectomy, simple (including subcapsular), with or without testicular prosthesis, scrotal or inguinal approach
54660	Insertion of testicular prosthesis (separate procedure)
54690	Laparoscopy, surgical; orchiectomy
55175	Scrotoplasty; simple
55180	Scrotoplasty; complicated
55970	Intersex surgery; male to female
55980	Intersex surgery; female to male
56625	Vulvectomy simple; complete
56800	Plastic repair of introitus
56805	Clitoroplasty for intersex state
57110	Vaginectomy, complete removal of vaginal wall;
57335	Vaginoplasty for intersex state
58150	Total abdominal hysterectomy (corpus and cervix), with or without removal of tube(s), with or without removal of ovary(s)
58180	Supracervical abdominal hysterectomy (subtotal hysterectomy), with or without removal of tube(s), with or without removal of ovary(s)
58260	Vaginal hysterectomy, for uterus 250 g or less
58262	Vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s)
58290	Vaginal hysterectomy, for uterus greater than 250 g
58291	Vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58541	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less
58542	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58543	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g
58544	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58550	Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 g or less
58552	Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58553	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g
58554	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58570	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less
58571	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58572	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g
58573	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)

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CPT Code	Description
58661	Laparoscopy, surgical; with removal of adnexal structures (partial or total oophorectomy and/or salpingectomy)
58720	Salpingo-oophorectomy, complete or partial, unilateral or bilateral (separate procedure)
58940	Oophorectomy, partial or total, unilateral or bilateral
64856	Suture of major peripheral nerve, arm or leg, except sciatic; including transposition
64892	Nerve graft (includes obtaining graft), single strand, arm or leg; up to 4 cm length
64896	Nerve graft (includes obtaining graft), multiple strands (cable), hand or foot; more than 4 cm length
67900	Repair of brow ptosis (supraciliary, mid-forehead or coronal approach)
92507	Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual
92508	Treatment of speech, language, voice, communication, and/or auditory processing disorder; group, 2 or more individuals

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Diagnosis Code	Description
F64.0	Transsexualism
F64.1	Dual role transvestism
F64.2	Gender identity disorder of childhood
F64.8	Other gender identity disorders
F64.9	Gender identity disorder, unspecified
Z87.890	Personal history of sex reassignment

Description of Services

Gender Dysphoria is a condition in which there is a marked incongruence between an individual's experienced/expressed/alternative gender and assigned gender (DSM-5). Treatment options include behavioral therapy, psychotherapy, hormone therapy, and surgery for gender transformation. Surgical treatments for Gender Dysphoria may include the following: clitoroplasty, hysterectomy, labiaplasty, mastectomy, orchiectomy, penectomy, phalloplasty or metoidioplasty (alternative to phalloplasty), placement of testicular and/or penile prostheses, salpingo-oophorectomy, scrotoplasty, urethroplasty, urethroplasty, vaginectomy, vaginoplasty and vulvectomy.

Other terms used to describe surgery for Gender Dysphoria include gender affirming surgery, sex transformation surgery, sex change, sex reversal, gender change, transsexual surgery, transgender surgery, and sex reassignment.

Benefit Considerations

Coverage Information

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service.

This medical policy does not apply to fully-insured group plans in California. Refer to the Benefit Interpretation Policy titled Gender Dysphoria (Gender Identity Disorder) Treatment: CA.

This Medical Policy does not apply to fully-insured group plans in the state of Washington. Refer to the Benefit Interpretation Policy titled Gender Dysphoria (Gender Identity Disorder) Treatment: WA.

Unless otherwise specified, if a plan covers treatment for Gender Dysphoria, coverage includes psychotherapy, cross-sex hormone therapy, puberty suppressing medications and laboratory testing to monitor the safety of hormone therapy. This

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benefit also includes certain surgical treatments listed in the Coverage Rationale section. Refer to the Drug Policy titled Gonadotropin Releasing Hormone Analogs.

Limitations and Exclusions

Certain treatments and services are not covered. Examples include, but are not limited to:

- Treatment received outside of the United States
- Reproduction services, including, but not limited to, sperm preservation in advance of hormone treatment or Gender Dysphoria surgery, cryopreservation of fertilized embryos, oocyte preservation, surrogate parenting, donor eggs, donor sperm and host uterus (see the Reproduction exclusion in the member specific benefit plan document)
- Transportation, meals, lodging or similar expenses
- Cosmetic procedures (refer to the Coverage Determination Guideline titled Cosmetic and Reconstructive Procedures and the Coverage Rationale section). See below for additional information on New York fully insured group policies.
- Reversal of genital surgery or reversal of surgery to revise secondary sex characteristics

Coverage does not apply to members who do not meet the indications listed in the Coverage Rationale section above.

For Fully Insured Group Policies in New York Only

Certain ancillary procedures may be considered cosmetic and not medically necessary when performed as part of surgical treatment for Gender Dysphoria. Clinical review for medical necessity of ancillary procedures is conducted on a case-by-case basis.

Clinical Evidence

Scandurra et al. (2019) performed a systematic review assessing the health of nonbinary and genderqueer (NBGQ) individuals compared to binary transgender (BT) and cisgender individuals. Eleven studies were included in the review. Results related to the difference in health between NBGQ and BT were mixed, with some finding a better health status while others a worse one. Results related to the differences in health between NBGQ and cisgender individuals highlighted higher health needs in NBGQ individuals compared with cisgender counterparts. The authors noted the need for research expansion in terms of both methodology and research contents.

Wernick et al. (2019) conducted a systematic review of the psychological benefits of gender-affirming surgery. Thirty-three studies were included in the analysis. Overall, most of the studies comparing pre- and post-operative data on quality of life, body image/satisfaction, and overall psychological functioning among individuals with gender dysphoria suggested that gender-affirming surgery leads to multiple, significant psychological benefits. Of the studies comparing psychological well-being between individuals who did or did not undergo surgery, most demonstrated a trend of better mental health among individuals who underwent surgery compared with those who did not. The authors encouraged future research to focus on standardizing the assessment of psychological functioning pre- and post-gender-affirming surgery to gather longitudinal data that will allow for more definitive conclusions to be made about factors that contribute to the psychological benefits of surgery.

Cohen et al. (2019) conducted a systematic review of surgical options and associated outcomes for transmasculine top surgery. Twenty-two studies were included (n=2447). The authors reported that future research is needed to improve patient selection, surgical decision making, and patient-reported outcomes for different chest contouring techniques.

Mahfouda et al. (2019) conducted a systematic review of the available published evidence on gender-affirming cross-sex hormone (CSH) and surgical interventions in transgender children and adolescents, amalgamating findings on mental health outcomes, cognitive and physical effects, side-effects, and safety variables. The small amount of available data suggest that when clearly indicated in accordance with international guidelines, gender-affirming CSHs and chest wall masculinization in transgender males are associated with improvements in mental health and quality of life. Evidence regarding surgical vaginoplasty in transgender females younger than age 18 years remains extremely scarce and conclusions cannot yet be drawn regarding its risks and benefits in this age group. Further research on an international scale is urgently warranted to clarify long-term outcomes on psychological functioning and safety.

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A Hayes report on sex reassignment surgery (2018; updated 2021) for the treatment of gender dysphoria made the following conclusions:

- Studies suggest that following sex reassignment surgery, patients reported decreased gender dysphoria and improved body image satisfaction. However, results were mixed regarding effects of sex reassignment surgery on quality of life and psychological symptoms.

- Few studies compare outcomes in patients who received sex reassignment surgery with stand-alone hormone therapy. The results of these studies suggest that sex reassignment surgery may improve gender dysphoria, quality of life, body image and psychological symptoms to a greater extent than hormone therapy alone. However, the results were conflicting.

- Few studies compared outcomes in patients who received different components of sex reassignment surgery. For most outcome measures, there was only a single study available. This evidence is therefore insufficient to support definitive conclusions regarding the comparative effectiveness of different components of sex reassignment surgery for treating gender dysphoria.

- Not all studies reported all outcomes; the following findings therefore do not inform overall incidence of complications. Following sex reassignment surgery, there were very low rates of regret of surgery (0% to 6% per study) and suicide (2% to 3% per study). Complications following sex reassignment surgery were common, and some were serious.

Dreher et al. (2018) conducted a systematic review and meta-analysis to evaluate the epidemiology, presentation, management, and outcomes of neovaginal complications in the MtF transgender reassignment surgery patients. Selected studies reported on 1,684 patients with an overall complication rate of 32.5% and a reoperation rate of 21.7% for non-esthetic reasons. The most common complication was stenosis of the neo-meatus (14.4%). Wound infection was associated with an increased risk of all tissue-healing complications. Use of sacrospinous ligament fixation (SSL) was associated with a significantly decreased risk of prolapse of the neovagina. The authors concluded that gender-affirmation surgery is important in the treatment of gender dysphoric patients, but there is a high complication rate in the reported literature. Variability in technique and complication reporting standards makes it difficult to assess the accurately the current state of MtF gender reassignment surgery. Further research and implementation of standards is necessary to improve patient outcomes.

Manrique et al (2018) conducted a systematic review of retrospective studies on the outcomes of MtF vaginoplasty to minimize surgical complications and improve patient outcomes for transgender patients. Forty-six studies met the authors eligibility criteria. A total of 3716 cases were analyzed. The results showed the overall incidence of complications as follows: 2% fistula, 14% stenosis and strictures, 1% tissue necrosis, and 4% prolapse. Patient-reported outcomes included a satisfaction rate of 93% with overall results, 87% with functional outcomes, and 90% with esthetic outcomes. Ability to have orgasm was reported in 70% of patients. The regret rate was 1%. The authors concluded that multiple surgical techniques have demonstrated safe and reliable means of MtF vaginoplasty with low overall complication rates and with a significant improvement in the patient's quality of life. Studies using different techniques in a similar population and standardized patient-reported outcomes are required to further analyze outcomes among the different procedures and to establish best-practice guidelines.

Van Damme et al. (2017) conducted a systematic review of the effectiveness of pitch-raising surgery performed in MtF transsexuals. Twenty studies were included: eight using cricothyroid approximation, six using anterior glottal web formation and six using other surgery types or a combination of surgical techniques. A substantial rise in postoperative frequency was identified. The majority of patients seemed satisfied with the outcome. However, none of the studies used a control group and randomization process. Further investigation regarding long-term results using a stronger study design is necessary.

Gaither et al. (2017) retrospectively reviewed the records of 330 MtF patients from 2011 to 2015, to assess surgical complications related to primary penile inversion vaginoplasty. Complications included granulation tissue, vaginal pain, wound separation, labial asymmetry, vaginal stenosis, fistula formation, urinary symptoms including spraying stream or dribbling, infection, vaginal fissure or vaginal bleeding. Median age at surgery was 35 years, and median follow-up in all patients was 3 months. The results showed that 95 of the patients presented with a postoperative complication with the median time to a complication being 4.4 months. Rectoneovaginal fistulas developed in 3 patients, and 30 patients required a second operation. Age, body mass index and hormone replacement therapy were not associated with complications. The authors concluded that penile inversion vaginoplasty is a relatively safe procedure. Most complications due to this surgery develop within the first 4 months postoperatively. Age, body mass index and hormone replacement therapy are not associated with complications and, thus, they should not dictate the timing of surgery.

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An ECRI special report systematically reviewed the clinical literature to assess the efficacy of treatments for gender dysphoria. The authors identified limited evidence from mostly low-quality retrospective studies. Evidence on gender reassignment surgery was mostly limited to evaluations of MtF individuals undergoing vaginoplasty, facial feminization surgery and breast augmentation. Outcomes included mortality, patient satisfaction, physical well-being, psychological-related outcomes, quality of life, sexual-related outcomes, suicide and adverse events. Concluding remarks included the need for standardized protocols and prospective studies using standardized measures for correct interpretation and comparability of data (ECRI, 2016).

Morrison et al. (2016) conducted a systematic review of the facial feminization surgery literature. Fifteen studies were included, all of which were either retrospective or case series/reports. The studies covered a variety of facial feminization procedures. A total of 1121 patients underwent facial feminization surgery, with seven complications reported, although many studies did not explicitly comment on complications. Satisfaction was high, although most studies did not use validated or quantified approaches to address satisfaction. The authors noted that further studies are needed to better compare different techniques to more robustly establish best practices. Prospective studies and patient-reported outcomes are needed to establish quality of life outcomes for patients.

Frey et al. (2016) conducted a systematic review of metoidioplasty and radial forearm flap phalloplasty (RFFP) in FtM transgender genital reconstruction. Eighteen studies were included: 7 for metoidioplasty and 11 for RFFP. The quality of evidence was low to very low for all included studies. In studies examining metoidioplasty, the average study size and length of follow-up were 54 patients and 4.6 years, respectively (1 study did not report [NR]). Eighty-eight percent underwent a single-stage reconstruction, 87% reported an aesthetic neophallus (3 NR) and 100% reported erogenous sensation (2 NR). Fifty-one percent of patients reported successful intercourse (3 NR) and 89% of patients achieved standing micturition (3 NR). In studies examining RFFP, the average study size and follow-up were 60.4 patients and 6.23 years, respectively (6 NR). No patients underwent single-stage reconstructions (8 NR). Seventy percent of patients reported a satisfactorily aesthetic neophallus (4 NR) and 69% reported erogenous sensation (6 NR). Forty-three percent reported successful penetration of partner during intercourse (6 NR) and 89% achieved standing micturition (6 NR). Compared with RFFP, metoidioplasty was significantly more likely to be completed in a single stage, have an aesthetic result, maintain erogenous sensation, achieve standing micturition and have a lower overall complication rate. The authors reported that, although the current literature suggests that metoidioplasty is more likely to yield an "ideal" neophallus compared with RFFP, any conclusion is severely limited by the low quality of available evidence.

Using a retrospective chart review, Buncamper et al. (2016) assessed surgical outcome after penile inversion vaginoplasty. Outcome measures were intraoperative and postoperative complications, reoperations, secondary surgical procedures and possible risk factors. Of 475 patients who underwent the procedure, 405 did not have additional full-thickness skin grafts while 70 did have grafts. Median follow-up was 7.8 years. The most frequently observed intraoperative complication was rectal injury (2.3 percent). Short-term postoperative bleeding that required transfusion (4.8 percent), reoperation (1.5 percent) or both (0.4 percent) occurred in some cases. Major complications were three (0.6 percent) rectoneovaginal fistulas, which were successfully treated. Revision vaginoplasty was performed in 14 patients (2.9 percent). Comorbid diabetes was associated with a higher risk of local infection, and use of psychotropic medication predisposed to postoperative urinary retention. Successful vaginal construction without the need for secondary functional reoperations was achieved in the majority of patients.

Bouman et al. (2016) prospectively assessed surgical outcomes of primary total laparoscopic sigmoid vaginoplasty in 42 transgender women with penoscrotal hypoplasia. Mean follow-up time was 3.2 ± 2.1 years. The mean operative duration was 210 ± 44 minutes. There were no conversions to laparotomy. One rectal perforation was recognized during surgery and immediately oversewn without long-term consequences. The mean length of hospitalization was 5.7 ± 1.1 days. One patient died as a result of an extended-spectrum beta-lactamase-positive necrotizing fasciitis leading to septic shock, with multiorgan failure. Direct postoperative complications that needed laparoscopic reoperation occurred in three cases (7.1 percent). In seven cases (17.1 percent), long-term complications needed a secondary correction. After 1 year, all patients had a functional neovagina with a mean depth of 16.3 ± 1.5 cm.

Despite the significant increase in genital gender affirming surgery (GAS) within the past 50 years, there is limited data regarding hair removal practices in preparation for genital GAS. Genital GAS involves reconstruction of the genitals to match a patient's identified sex. The use of hair-bearing flaps in this procedure may result in postoperative intra-vaginal and intra-urethral hair growth and associated complications, including lower satisfaction with genital GAS. In 2016, Zhang et al. conducted a literature review, recommendations from experience, and a practical laser hair removal (LHR) approach to hair removal prior to genital GAS.

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Horbach et al. (2015) conducted a systematic review of vaginoplasty techniques in MtF individuals with gender dysphoria. Twenty-six studies were included (mostly retrospective case series of low to intermediate quality). Outcome of the penile skin inversion technique was reported in 1,461 patients and bowel vaginoplasty in 102 patients. Neovaginal stenosis was the most frequent complication in both techniques. Sexual function and patient satisfaction were overall acceptable, but many different outcome measures were used. Quality of life was only reported in one study. Comparison between techniques was difficult due to the lack of standardization. The authors concluded that the penile skin inversion technique is the most researched surgical procedure. Outcome of bowel vaginoplasty has been reported less frequently but does not seem to be inferior. The available literature is heterogeneous in patient groups, surgical procedure, outcome measurement tools and follow-up. There is a need for prospective studies with standardized surgical procedures, larger patient groups and longer follow-up periods. Uniformity in outcome measurement tools such as validated questionnaires and scores for sexual function and quality of life is mandatory for correct interpretation and comparability of data.

Bouman et al. (2014) conducted a systematic review of surgical techniques and clinical outcomes of intestinal vaginoplasty. Twenty-one studies were included (n=894). All studies had a retrospective design and were of low quality. Prevalence and severity of procedure-related complications were low. The main postoperative complication was introital stenosis, necessitating surgical correction in 4.1% of sigmoid-derived and 1.2% of ileum-derived vaginoplasties. Neither diversion colitis nor cancer was reported. Sexual satisfaction rate was high, but standardized questionnaires were rarely used. Quality of life was not reported. The authors concluded that prospective studies, using standardized measures and questionnaires, are warranted to assess functional outcomes and quality of life.

Djordjevic et al. (2013) evaluated 207 patients who underwent single-stage metoidioplasty, comparing two different surgical techniques of urethral lengthening. The procedure included lengthening and straightening of the clitoris, urethral reconstruction and scrotoplasty with implantation of testicular prostheses. Buccal mucosa graft was used in all cases for dorsal urethral plate formation and joined with one of the two different flaps: longitudinal dorsal clitoral skin flap (n=49) (group 1) and labia minora flap (n=158) (group 2). The median follow-up was 39 months. The total length of reconstructed urethra ranged from 9.1 to 12.3 cm in group 1 and from 9.4 to 14.2 cm in group 2. Voiding while standing was significantly better in group 2 (93%) than in group 1 (87.82%). Urethral fistula occurred in 16 patients in both groups. Overall satisfaction was noted in 193 patients. The authors concluded that combined buccal mucosa graft and labia minora flap was the method of choice for urethroplasty in metoidioplasty, minimizing postoperative complications.

In a non-randomized study, Dhejne et al. (2011) evaluated mortality, morbidity and criminal rates after gender reassignment surgery in 324 individuals (MtF n=191; FtM n=133). Random population controls (10:1) were matched by birth year and birth sex or reassigned final sex. The authors reported substantially higher rates of overall mortality, death from cardiovascular disease and suicide, suicide attempts and psychiatric hospitalizations in sex-reassigned individuals (both MtF/FtM) compared to a healthy control population. FtMs had a higher risk for criminal convictions.

Murad et al. (2010) conducted a systematic review to evaluate the effects of hormone therapy on patients undergoing gender reassignment surgery. The authors identified 28 eligible studies, all of which were observational and most lacked controls. These studies enrolled 1833 participants with gender dysphoria (1093 MtF; 801 FtM). After gender reassignment surgery, individuals reported improvement in gender dysphoria (80%), psychological symptoms (78%), sexual function (72%) and quality of life (80%). The authors concluded that very low quality evidence suggests that gender reassignment, that includes hormonal interventions, is likely to improve gender dysphoria, psychological functioning and comorbidities, sexual function and overall quality of life.

Sutcliffe et al. (2009) systematically reviewed five individual procedures for MtF gender reassignment surgery: clitoroplasty, labiaplasty, orchiectomy, penectomy and vaginoplasty. Further evaluations were made of eight surgical procedures for FtM gender reassignment surgery: hysterectomy, mastectomy, metoidioplasty, phalloplasty, salpingo-oophorectomy, scrotoplasty/placement of testicular prostheses, urethroplasty and vaginectomy. Eighty-two published studies (38 MtF; 44 FtM) were included in the review. For MtF procedures, the authors found no evidence that met the inclusion criteria concerning labiaplasty, penectomy or orchiectomy. A large amount of evidence was available concerning vaginoplasty and clitoroplasty procedures. The authors reported that the evidence concerning gender reassignment surgery in both MtF and FtM individuals with gender dysphoria has several limitations including lack of controlled studies, lack of prospective data, high loss to follow-up and lack of validated assessment measures. Some satisfactory outcomes were reported, but the magnitude of benefit and harm for individual surgical procedures cannot be estimated accurately using the current available evidence.

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World Professional Association for Transgender Health (WPATH)

WPATH, formerly known as the Harry Benjamin International Gender Dysphoria Association, is an advocacy group devoted to transgender health. WPATH guidelines (2012) present eligibility and readiness criteria for transition-related treatment, as well as competencies of health care providers.

WPATH describes the transition from one gender to another in the following three stages:

- Living in the gender role consistent with gender identity
- The use of cross-sex hormone therapy after living in the new gender role for a least three months
- Gender-affirmation surgery after living in the new gender role and using hormonal therapy for at least 12 months

Clinical Practice Guidelines

American Academy of Pediatrics (AAP)

In a 2018 policy statement entitled Ensuring Comprehensive Care and Support for Transgender and Gender- Diverse Children and Adolescents, the AAP states the following regarding surgery: Surgical approaches may be used to feminize or masculinize features, such as hair distribution, chest, or genitalia, and may include removal of internal organs, such as ovaries or the uterus (affecting fertility). These changes are irreversible. Although current protocols typically reserve surgical interventions for adults, they are occasionally pursued during adolescence on a case-by case basis, considering the necessity and benefit to the adolescent's overall health and often including multidisciplinary input from medical, mental health, and surgical providers as well as from the adolescent and family.

American College of Obstetrics and Gynecology (ACOG)

An ACOG committee opinion (2021) provides guidance on health care for transgender and gender diverse individuals. The document does not make specific recommendations regarding surgery but does provide an overview of surgical procedures and education for clinicians who care for transgender patients before and after surgery.

Endocrine Society

Endocrine Society practice guidelines (Hembree et al., 2017) addressing endocrine treatment of gender-dysphoric/ gender-incongruent persons makes the following recommendations regarding surgery for sex reassignment and gender confirmation:

- Suggest that clinicians delay gender-affirming genital surgery involving gonadectomy and/or hysterectomy until the patient is at least 18 years old or legal age of majority in his or her country (Recommendation based on low quality evidence).
- A patient pursue genital gender-affirming surgery only after the mental health practitioner (MHP) and the clinician responsible for endocrine transition therapy both agree that surgery is medically necessary and would benefit the patient's overall health and/or well-being (Strong recommendation based on low quality evidence).
- Surgery is recommended only after completion of at least one year of consistent and compliant hormone treatment unless hormone therapy is not desired or medically contraindicated (Ungraded Good Practice Statement).
- The physician responsible for endocrine treatment medically clears individual for surgery and collaborates with the surgeon regarding hormone use during and after surgery (Ungraded Good Practice Statement).
- Recommend that clinicians refer hormone treated transgender individuals for genital surgery when (Strong recommendation based on very low quality evidence):
  - The individual has had a satisfactory social role change
  - The individual is satisfied about the hormonal effects
  - The individual desires definitive surgical changes
- Suggest that clinicians determine the timing of breast surgery for transgender males based upon the physical and mental health status of the individual. There is insufficient evidence to recommend a specific age requirement (Recommendation based on very low quality evidence)

University of California, San Francisco (UCSF) Center of Excellence for Transgender Health

The UCSF Center of Excellence evidence-based guidelines for the primary and gender-affirming care of transgender and gender nonbinary people address various surgical procedures, including risks, complications, approaches and perioperative and postoperative care (Deutsch, 2016).

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U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Gender transformation surgeries are procedures, and therefore, not subject to FDA regulation. However, medical devices, drugs, biologics, or tests used as a part of these procedures may be subject to FDA regulation. See the following website to search by product name. Available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed August 24, 2021)

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Policy History/Revision Information

Date	Summary of Changes
11/01/2021	Documentation Requirements • Updated list of applicable CPT codes with associated documentation requirements; added 15878, 15879, 54400, 54401, and 54405 Supporting Information • Archived previous policy version 2021T0580K

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From: Jee, Lauren (HHS/OCR) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DC5A273E16824884903F0D2AFC8CB225-JEE, LAUREN <Lauren.Jee1@hhs.gov>

To: (b)(6) (b)(6) (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bdec12ad0974eacababe032f2b37c91-(b)(6) (b)(6)

CC: Barron, Pamela (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d55f83440f074842ac94e1f27f11fa9e-Barron, Pam <Pamela.Barron@hhs.gov>;
Kumar, Vatsala (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc510606a9034939ac2eb2c237dd8cf3-Kumar, Vats <Vatsala.Kumar@hhs.gov>;
Huggins, Michael (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9597596b8c4d4b8d9faf4922101a611b-Huggins, Mi <Michael.Huggins@hhs.gov>

Subject: RE: FOR FRIDAY - Background memo on Florida's General Medicaid Policy proposed rule (limiting gender affirming care)

Date: 2022/07/27 14:36:06

Priority: Normal

Type: Note

(b)(5)

From: (b)(6) (b)(6) (b)(6) (HHS/OCR) (b)(6)
Sent: Wednesday, July 27, 2022 12:56 PM
To: Jee, Lauren (HHS/OCR) <Lauren.Jee1@hhs.gov>
Cc: Barron, Pamela (HHS/OCR) <Pamela.Barron@hhs.gov>; Kumar, Vatsala (HHS/OCR) <Vatsala.Kumar@hhs.gov>; Huggins, Michael (HHS/OCR) <Michael.Huggins@hhs.gov>
Subject: FOR FRIDAY - Background memo on Florida's General Medicaid Policy proposed rule (limiting gender affirming care)

Hi Lauren,

(b)(5)

Please let us know if you have any questions.

Best,
(b)(6)

(b)(6) (b)(6) (b) (b)(6) Esq., MSW (she/her) | Section Chief
Office for Civil Rights
U.S. Department of Health &Human Services

200 Independence Ave. S.W., Room 532E
Washington, D.C. 20201
Phone: (b)(6) (b)(6)
Email: (b)(6)

Sender:	Jee, Lauren (HHS/OCR) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DC5A273E16824884903F0D2AFC8CB225-JEE, LAUREN <Lauren.Jee1@hhs.gov>
Recipient:	(b) (b)(6) (b)(6 (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bdec12ad0974eacababe032f2b37c91(b)(6) (b)(6) Barron, Pamela (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d55f83440f074842ac94e1f27f11fa9e-Barron, Pam <Pamela.Barron@hhs.gov>; Kumar, Vatsala (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc510606a9034939ac2eb2c237dd8cf3-Kumar, Vats <Vatsala.Kumar@hhs.gov>; Huggins, Michael (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9597596b8c4d4b8d9faf4922101a611b-Huggins, Mi <Michael.Huggins@hhs.gov>
Sent Date:	2022/07/27 14:35:38
Delivered Date:	2022/07/27 14:36:06

DELIBERATIVE

DATE: July 22, 2022

TO: Melanie Fontes Rainer, Director, Office for Civil Rights

THROUGH: (b)(6) (b) (b)(6) Section Chief

FROM: Vatsala Kumar, Intern

SUBJECT: INFORMATION MEMO – Florida Proposed Rule 59G-1.050

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1. Background

In June 2022, the Florida Agency for Health Care Administration proposed amendments to Florida Administrative Code Rule 59G-1.050, the General Medicaid Policy. 48 Fla. Admin. Reg. 2461–62 (June 17, 2022). The proposed rule states that certain gender-affirming procedures are not covered under Florida Medicare. *Id.*

This memorandum will first detail the content and timeline of the proposed rule, as well as the report used to justify promulgation. It will then explore the current status of the proposed rule and developments since its original publication. It will also note the work of Florida organizations on this rule, before turning to next steps on the proposed rule.

a. Timeline and Contents

The Florida Agency for Health Care Administration proposed an amendment to the Florida General Medicaid Policy in June 2022. The proposed amendment adds the following text:

> (7) Gender Dysphoria
> (a) Florida Medicaid does not cover the following services for the treatment of gender dysphoria:
> 1. Puberty blockers;
> 2. Hormones and hormone antagonists;
> 3. Sex reassignment surgeries; and
> 4. Any other procedures that alter primary or secondary sexual characteristics.
> (b) For the purpose of determining medical necessity, including Early and Periodic Screening, Diagnosis, and Treatment (EPSDT), the services listed in subparagraph (7)(a) do not meet the definition of medical necessity in accordance with Rule 59G-1.010, F.A.C.

48 Fla. Admin. Reg. 2461–62 (June 17, 2022). As rulemaking authority for promulgating this amendment, the agency cites Florida Statute § 409.919 and § 409.961, which some commenters have challenged as being insufficient for this proposal. *See infra* Appendix. Sections 409.919 and 409.961 both include the same language surrounding agency rulemaking. Both state that the agency "shall adopt any rules necessary to comply with or administer" Medicaid "and all rules necessary to comply with federal requirements." Fla. Stat. § 409.919 (2021); Fla. Stat. § 409.961

(2021).

The Florida Agency for Health Care Administration held a hearing on this proposed rule on July 8, 2022. Written comments were due to the agency on July 11, 2022, and they reportedly received approximately 1,200 total public comments. Forrest Saunders, *Agency for Health Care Administration Set to Decide on Medicaid Coverage of Gender Dysphoria Therapies*, WPTV (July 11, 2022). No further developments have yet ensued on the rule.

b. Florida Medicaid Report

In order for services to be covered under Florida Medicaid, they must be "medically necessary." Agency for Health Care Admin., *Florida Medicaid: Definitions Policy* 7 (2017). Part of this definition includes being "consistent with generally accepted professional medical standards" and not being "experimental or investigational." *Id.*

Shortly before the proposed rule was published, the Division of Florida Medicaid issued a report ("Florida Medicaid Report") concluding that gender-affirming care is not medically necessary because it is not "consistent with generally accepted professional medical standards" and it is "experimental or investigational." *See* Div. of Fla. Medicaid, *Florida Medicaid: Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria* (June 2022). In making this conclusion, the report opened the door for the Medicaid exclusion. The Florida Medicaid Report incorporates literature reviews on the etiology of gender dysphoria, desistance of gender dysphoria and puberty suppression, cross-sex hormones as a treatment for gender dysphoria, sex reassignment surgery, and the quality of available evidence and bioethical questions. *Id.* at 1. It also explores coverage policies domestically and in western Europe, and includes several attachments, including articles in support. *Id.* at 1–2.

The Florida Medicaid Report claims that "[a]vailable medical literature provides insufficient evidence that sex reassignment through medical intervention is a safe and effective treatment for gender dysphoria" and that studies focusing on the benefits "are either low or very low quality and rely on unreliable methods." *Id.* at 2. It claims that current evidence around gender-affirming care shows that it "cause[s] irreversible physical changes and side effects that can affect long-term health." *Id.* From the literature reviews conducted, the report states that "Florida Medicaid has determined that the research supporting sex reassignment treatment is insufficient to demonstrate efficacy and safety." *Id.* at 3.

Numerous critiques have been levied against the Florida Medicaid Report, both in public comments as described *infra* Part 2 and in external documents. Most comprehensively, faculty members from Yale and other universities[1] drafted a report reviewing the Florida Medicaid Report ("Critical Review"). *See* Meredithe McNamara et al., (July 8, 2022). The Critical Review

[1] Faculty members were from Yale Law School, Yale School of Medicine Child Study Center, Yale School of Medicine Department of Psychiatry, Yale School of Medicine Department of Pediatrics, University of Texas Southwestern, and University of Alabama at Birmingham. *See* Meredithe McNamara et al., *A Critical Review of the June 2022 Florida Medicaid Report on the Medical Treatment of Gender Dysphoria* (July 8, 2022), https://medicine.yale.edu/lgbtqi/research/gender-affirming-care/florida%20report%20final%20july%208%202022%20accessible_443048_284_55174_v3.pdf.

states that the Florida Medicaid Report "purports to be a review of the scientific and medical evidence but is, in fact, fundamentally unscientific" as it "makes false statements and contains glaring errors regarding science, statistical methods, and medicine." *Id.* at 2. The Critical Review is structured in five parts. It argues that "medical care for gender dysphoria is supported by a robust scientific consensus, meets generally accepted professional medical standards, and is neither experimental nor investigational"; that the Florida Medicaid Report is "a flawed analysis that ignores the scientific evidence and relies instead on pseudo-science" including experts who have been disqualified in court; that the Florida Medicaid Report "makes unfounded criticisms of robust and well-regarded clinical research and . . . cites sources with little or no scientific merit"; that the Florida Medicaid Report's "linchpin" is an analysis which is "extremely narrow in scope, inexpert, and so flawed it merits no scientific weight at all"; and that the Florida Medicaid Report "erroneously dismisses solid studies as 'low quality,'" which if followed regularly would mean that widely-used medications and common medical procedures would also have to be denied coverage. *Id.* at 3.

The Florida Agency for Health Care Administration responded to the Critical Review, stating that it is "another example of the left-wing academia propaganda machine arrogantly demanding you follow their words and not the clear evidence-based science sitting right in front of you" and that it is a "hodgepodge of baseless claims" without authority or credibility. Dara Kam, *Expert Report Condemns Florida's Plan to Ban Medicaid Coverage for Transgender Care*, Palm Coast Observer (July 17, 2022).

2. Current Status

a. July 8, 2022 Hearing

The Florida Agency for Health Care Administration held a lively public hearing on July 8, 2022 on the proposed rule. The hearing consisted mostly of public comments, a comprehensive summary of which is attached in the Appendix. The full hearing can be viewed online. 7/8/22 Agency for Health Care Administration Hearing on General Medicaid Policy Rule, Fla. Channel (July 8, 2022).

The hearing included a "panel of experts" consisting of Dr. Andre Van Mol, Dr. Quentin Van Meter, and Dr. Miriam Grossman. Dr. Van Meter has been found by a court unqualified to be an expert on the subject of gender-affirming care. *See* Stephen Caruso, *A Texas Judge Ruled This Doctor was Not an Expert. A Pennsylvania Republican Invited Him to Testify on Trans Health Care*, Penn. Capital-Star (Sept. 15, 2020). He is also the president of the American College of Pediatricians, an advocacy group whose primary focus is to advocate for conservative policies in medicine, which has been categorized by the Southern Poverty Law Center as a hate group. *See American College of Pediatricians*, Southern Poverty L. Ctr. (last visited July 22, 2022). Dr. Van Mol is also a member. *Andre Van Mol*, Pub. Discourse (last visited July 22, 2022). The panelists spoke at several times during the hearing, primarily to point the audience towards the Florida Medicaid Report. *See* Appendix.

Over the two-hour hearing period, fifty public commenters spoke. Forty-two of those commenters supported the proposed rule and eight opposed it. Of the forty-two in support, two

formerly identified as transgender but have since detransitioned, eight were representatives of the Christian Family Coalition, and at least ten mentioned God or the Bible as part of their rationale. Many supporters also raised concerns that children and teenagers are not mature or knowledgeable enough to choose these procedures, or that they are being unduly influenced by their peers and may later regret transitioning. Notably, the proposed rule would apply to gender-affirming care for individuals of all ages, not only youth. 48 Fla. Admin. Reg. 2461–62 (June 17, 2022). Several supporters also cited the Florida Medicaid Report as being well-researched and providing a strong basis for the rule; some opponents of the rule noted criticisms of the report including those raised by the Critical Review.

b. Florida Organizations and Individuals

The university faculty who wrote the Critical Review also wrote a significant public comment on the proposed rule. *See* Letter from Anne L. Alstott et al. to Simone Marstiller & Tom Wallace re Rule No. 59G-1.050: General Medicaid Policy (July 8, 2022). The letter highlights similar concerns, noting that the "complete absence of scientific foundation for the Proposed Rule renders it an arbitrary and capricious use of rulemaking power" and that it "cannot [be] characterize[d] . . . as a valid interpretation of the existing Florida regulations on generally accepted professional medical standards, because the [Florida Medicaid] Report fails to satisfy Florida's own regulatory requirements for scientific review." *Id.* at 2. It reiterates concerns about the Florida Medicaid Report, including the cited experts' bias and lack of expertise, errors about scientific research and medical regulation, and lack of scientific weight. *Id.* passim, 20.

Disability Rights Florida submitted a comment also opposing the proposed rule. *See* Letter from Peter P. Sleasman to Simone Marstiller re Proposed Amendments to Rule 59G-1.050. The letter focuses primarily on how this proposed rule "will cause unnecessary and disproportionate harm to individuals with disabilities living in Florida," especially those who are low-income. *Id.* at 1. It notes that transgender individuals "are more than twice as likely as the general population to live in poverty," and transgender individuals with disabilities are four times as likely. *Id.* at 2. Disability Rights Florida goes on to raise concerns about the agency's "apparent failure to take even minimal steps to ensure that the rulemaking workshop . . . is accessible to the very people with disabilities it will directly impact," citing to the lack of accommodations, contact information for seeking accommodations, and response regarding livestreaming. *Id.* at 3.

As did the Endocrine Society. *See* Letter from Ursula Kaiser to Agency for Health Care Administration re 59G-1.050: General Medicaid Policy (July 8, 2022). They note that their guidelines, "while not standards of care that clinicians are legally bound to follow, . . . provide a framework for best practices, and deviations must be justified." *Id.* at 1–2. They expound on how their guidelines were developed—using a "robust and rigorous process that adheres to the highest standards of trustworthiness and transparency" and with a "systematic review of the evidence that supports [clinical] questions"—in contrast to the Florida Medicaid Report, which "did not include endocrinologists with expertise in transgender medicine," "makes sweeping statements against gender affirming medical care that are not supported by evidence or references provided," and "does not acknowledge the data showing harm reduction and improvements in behavioral health issues" that result from gender affirming care. *Id.* at 2–3. The letter goes on to state that this proposed rule would cause irreparable harm to transgender youth,

including putting their lives at risk. *Id.* at 6.

Equality Florida advocated against the rule as well. Equality Florida, Press Release, Equality Florida Decries Proposed Rule to Eliminate Medicaid Coverage for Gender Affirming Care (June 17, 2022). They note that this will affect approximately 9,000 transgender Floridians insured with Medicaid, and that "major medical and mental health associations recognize the critical importance of gender affirming care." *Id.*

The Florida Coalition for Trans Liberation has also put together a short policy brief around the proposed rule. *See* Fla. Coal. for Trans Liberation, *Stop Rule 59G-1.050* (2022). They note that this proposed rule contravenes all major medical advice, pushes a political agenda, and can be life-threatening. *Id.*

Florida Policy Institute also submitted a comment. *See* Letter from Anne Swerlick to Thomas Wallace re Proposed Rule 59G-1.050, Florida Administrative Code (July 7, 2022). They note that the proposed rule would "bar transgender patients from accessing essential care and reverse current Medicaid policies which have been in effect for years. *Id.* at 1. They also point out that this is counter to established standards of care, inconsistent with antidiscrimination laws, and exacerbates the challenges that transgender individuals already face. *Id.* It closes by noting that this rule seems to be "weaponiz[ing] [the Medicare program] as a tool for promoting a particular political agenda." *Id.*

While the majority of public comments during the July 8 hearing were in support of the rule, few comments posted online seem to be, and Florida Medicaid has not made all of the comments publicly available. Christian Family Coalition, who was also heavily represented at the July 8 hearing, did make a public statement, stating that this rule was "important and necessary" to protect Floridians, "especially minors, from harmful transgender surgeries, hormone blockers, and other unnatural therapies." *CFC Florida to Testify in Support of DeSantis Administration Rule Banning Medicaid Funding for Transgender Surgeries and Puberty Blockers*, Best Things Fla. (July 8, 2022).

3. Next Steps

Several nonprofit groups in Florida are prepared to push back against the proposed rule. Lambda Legal, the National Health Law Program, the Florida Health Justice Project, and Southern Legal Counsel issued a statement criticizing the Florida Medicaid Report and stating that they "stand ready to defend the rights of transgender people in Florida." *LGBTQ Groups to Fight Florida Over Medicaid Ban for Trans Treatments*, CBS Miami (June 6, 2022).

One potential avenue for doing so may be seeking an administrative determination. Florida law says that any person "substantially affected by a . . . proposed rule may seek an administrative determination of the invalidity of the rule on the ground that the rule is an invalid exercise of delegated legislative authority. Fla. Stat. § 120.56 (2022). If a complaint is properly filed, the state must assign an administrative law judge (ALJ) to conduct a hearing within thirty days. *Id.* at (1)(c). The ALJ may declare the proposed rule wholly or partially invalid, and the rule then may not be adopted unless the judgment is reversed on appeal. *Id.* at (2)(b).

Appendix: Summary from July 8, 2022 Hearing

This appendix will detail the public comments made at the July 8 hearing regarding the proposed changes to 59G-1.050. There is no readily available transcript of the proceedings, so please note that names below may be missing or misspelled. Each speaker was met with audience applause at the end of their remarks, but any audience reactions during remarks are noted below.

The meeting opened with introductions of the panelists and representatives and a brief summary of the rule before opening the floor for public comments. Public commenters were asked to state their name and organization and to limit comments to two minutes, focusing only on the proposed rule language. The agency also noted that comments could be submitted via email.

The first speaker was Chloe Cole, a 17-year-old detransitioner from California. Cole began medical transition at the age of 13. In retrospect, she states that she was not becoming a man, but was just "fleeing from the uncomfortable feeling of being [a] wom[a]n." Chloe states that she "really didn't understand all of the ramifications of any of the medical decisions that [she] was making" when she chose to undergo a double mastectomy at the age of 15. She lamented that she will never be able to breastfeed, has blood clots in her urine, cannot fully empty her bladder, and does not know if she can ever give birth.[2]

The next speaker was Sophia Galvin, also a detransitioner. She states that she had a history of mental illness, including self-harm and suicidal ideation, and that her desire to transition was "all in an effort to escape the fear of being a woman in this society." Galvin stated that she had no support when she chose to detransition; her doctor told her to stop taking hormones but she did not see a mental health counselor. She said that "this is not good for children" and she "was harmed by this, and it should not be covered under Medicaid."

Next, the mother of a transgender boy spoke. She said that a physician gave her son testosterone at the age of 16 without her consent or knowledge, and that Medicaid covered her son's double mastectomy, hysterectomy, and vaginoplasty. She states that her son had private insurance but it was bypassed. She said that it is "impossible to change one's biological sex" and that doctors should not be affirming the "lie that biological sex is changeable." She characterized these lies as "child abuse," at which point the crowd began to applaud, and said that "amputating the healthy body parts of a child whose brain has not reached full decision-making maturity is simply criminal." This lead to more applause. She further characterized gender-affirming care as a "medical experiment."

The next speaker, Jeanette Cooper, spoke on behalf of Partners for Ethical Care. Cooper stated that "we need to make space in the public sphere for ethical therapists by removing the medical treatment option" and characterized gender identity affirmation as a "poisoned bandage on the

[2] Several news sources also reported on Chloe and her testimony. *See, e.g.*, Tyler O'Neil, *California Ex-Trans Teen Backs Florida Ban on Medicaid Funds for Transgender Medical Interventions*, Fox News (July 10, 2022), https://www.foxnews.com/health/california-ex-trans-teen-backs-florida-ban-medicaid-funds-transgender-medical-interventions. In one article, she urged individuals to "wait until you are a fully developed adult" prior to transitioning. *Id.* Notably, the Florida proposed rule is not only a prohibition on gender-affirming procedures for minors, but prohibits Medicaid funding for any gender-affirming procedures regardless of age.

skin of children causing permanent psychological and physical harm." The audience applauded when Cooper said "everyone knows what a woman is, but some people are afraid to say it." Cooper went on to state that "the state has no business using taxpayer funding to turn children into permanent medical patients" and "assisting doctors in selling disabilities to vulnerable suffering children." She further said that gender-affirming care is "not real healthcare" and that the state should instead fund "legitimate care" that addresses trans children's "actual needs." She likened the satisfaction children get from gender-affirming care to "a street drug that needs to be injected every day." Cooper closed by stating that the medical is "failing these families" and that her organization supports the proposed rule.

Donna Lambert, on behalf of Concerned Parents, also supported the rule. She said that "the healthcare professionals are presenting many [parents] with a false and painful choice: accept what we know will permanently harm our children, or lose them to suicide." She stated that "there is no data to prove that medically transitioning minors prevents suicide" and that parents lose their children down this "dangerous medical path permanently harming their healthy bodies with off-label drugs and experimental surgeries." Lambert said that transgender children "become angry and hostile and resentful; they begin lashing out at anyone who will not agree with their newfound identity." She described this as a "destructive social phenomenon" which "cuts parents out of the equation."

A Christian pastor spoke next, stating that the Bible teaches that "God makes people made and female" and to try and transition people "is a sin" and "should be a criminal abuse of children, especially when they're not at the age when they can properly process what they're doing to themselves." He said that the "one goal" of doctors who provide gender-affirming care is to "cut[ ] back on the birth rate." He supported the proposed rule and said Florida should "go further" and classify aiding in this case as "extreme child abuse."

Brandy Hendricks stated that gender-affirming procedures "have been shown to be extremely harmful, especially to minors." She lamented that children are being allowed to "change their genders before they've even reached puberty or shortly after." She said that pharmaceutical companies are advertising puberty blockers to children and unethically enriching themselves. She too characterized gender-affirming care as "child abuse" and as "experimental."

Sabrina Hartsfield, an alumna of Florida State University and a born-again Christian, spoke against the rule. Hartsfield said that "without gender-affirming healthcare, transgender and gender nonconforming individuals will die." She said that, "according to every major legitimate medical organization, gender-affirming care is the treatment for gender dysphoria." She said gender affirming care is "medically necessary and lifesaving treatment" that should not be decided by big government overreach. An audience member shouted something indiscernible at this point in Hartsfield's comment. Hartsfield went on to state that the proposed rule violates the Affordable Care Act and Medicaid Act's nondiscrimination provisions. She noted that denying gender-affirming care can be life-threatening.

Simone Chris, an attorney and the director of the Transgender Rights Initiative at Southern Legal Council, "vehemently oppose[d]" the proposed rule. She stated that her organization's experience working with hundreds of transgender individuals has evinced "the tremendous

benefits that access to [gender-affirming] care provides." Chris went on to state that "the insidiousness of this rule is exacerbated by the fact that it places in its crosshairs the individuals in our state who are already disproportionately likely" to face poverty, homelessness, poor health outcomes, and limited access to healthcare. She noted that every major medical association supports gender-affirming care, and that the proposed changes would "cause significant harm" by depriving individuals of "critical, lifesaving medical care." Chris went on to state that the changes to the rule substitute the state's judgment for that of the patient and their doctor, and that it is a "shameful waste of state resources." She cited to nationwide litigation which has struck down similar laws as inconsistent with the guarantees provided by the Medicaid Act, the Equal Protection Clause of the Fourteenth Amendment, and the Affordable Care Act, and noted that Florida will undoubtedly face similar challenges, wasting taxpayer money.

The next speaker, Matthew Benson, a pediatrician and pediatric endocrinologist, agreed with the proposed changes, stating that the data used to support gender-affirming care "is not scientific." He cited to a Swedish study from 2016 which found that the mortality rates of transgender individuals who received gender-affirming care were three times that of the general population, and that they attempted suicide five times more often than the general population. He also cited a similar study from Denmark wherein 10 percent of the study population died over the 20-year study period. Benson said we need better data and longer-term trials "to justify these kinds of very aggressive therapies."

Karen Schoen, a former teacher, spoke on behalf of Florida Citizens Alliance. She opened by stating that she would like to know "why 0.03 percent of the population is dictating to 99.97 percent of the population" that their elective surgeries should be paid for. This was met with audience applause. Schoen said that "kids change their minds" and that they become fearful of maturing. She lamented that thirteen-year-olds cannot drive a car, have a drink, or shoot a gun, but are "in charge" when it comes to changing their gender. This was met with audience laughter and applause.

The next speaker was Bill Snyder. Snyder first told a story about "reality disease," stating that "the further we move from reality, the further we move from morality" and that "the further we move from virtue, the more secular we become." Secularity leads to less freedom, he said, and then urged Florida to approve the changes to the rule.

Avery Fork with Christian Family Coalition, a college counselor, also spoke in support of the proposed rule. She characterized gender-affirming procedures as "unnatural therapies being promoted by radical gender ideals and with no basis in science." She said the proposed rule would prevent taxpayers from having to pay for "highly unethical and dangerous procedures."

Richard Carlins also spoke in support of the rule. He said that our Constitution was founded on "biblical principles." Carlins said children are being indoctrinated through commercials, Disney World, Coca-Cola commercials, and restaurants, and that gender-affirming procedures are a "horrendous evil." He said that "God raises up nations and he brings down nations," which was met with audience vocal support, and that this is a recent phenomenon. He said we've been "living in Judeo Christian principles" for 1500 years, and "it's just recently that we're throwing any mention of God [or] the Bible under the bus."

Amber Hand with the Body of Christ grew up with two queer parents. She said she had been considering gender transition for most of her life, but that "we have to teach these kids right from wrong" and that it is wrong to teach children they can make these decisions. Hand said that she is glad she never transitioned because she recently realized she wanted children. She went on to quote the Bible and that it's "not okay to change your identity."

The next speaker, Ms. Hazen, also supported the rule. She said that children are being pressured at a young age to identify as transgender, and that much of the pressure comes from the internet. She cited a follow-up study of individuals who transitioned, which found that the suicide rate in those individuals was twenty times the general population. She said that this evinces the "deep regret" they face after "mutilating" their bodies. She said that children "don't understand that they will never be able to procreate ever again" when we "mutilate these children's bodies at an early age."

Leonard Lord also spoke in favor of the proposed changes. He said that he was also uncomfortable in his body as a child but was able to get comfortable by becoming closer with God. The audience murmured in approval. He said that "either we're playing games, or we really believe there's a God and the Bible is true," and that this "problem" happens because we don't believe in God. Lord said that, with regard to mental health issues, "God's spirit is the answer to what's missing in their lives," again leading to audience applause and cheers. He said that by taking God, the Bible, and prayer out of schools, we are removing ourselves of power, love, and a sound mind. The audience again applauded. He said the "devil is the author of confusion" (the audience cheered) and that "if you spend your life trying to figure out if you're a man or a woman you'll never know why you're here" (again, audience applause).

The next speaker, Pam, also supported "stopping Medicaid from paying for children and teenagers to have such changes." She said that children are "confused" and likened gender-affirming procedures to "paying for [children] to have furry animal body parts," to which the audience cheered. She said she is thankful that Florida will "stop the madness" for "the sake of the children."

Jon Harris Maurer, the public policy director for Equality Florida, spoke next against the proposed rule. Maurer said that the proposed changes are without scientific or legal basis and are "clearly discriminatory." He cited to numerous experts and organizations who endorse gender-affirming care. Maurer also said that the agency "lacks the specific delegated rule-making authority to adopt the proposed rule" and that the statute cited "grants no authority" for the agency to usurp the role of healthcare providers. He said the rule is discriminatory and targets the transgender community, and that it would harm the 9,000 transgender Floridians on Medicaid. An audience member began to shout, and the audience began to speak over Maurer. He said that the proposed rule is politically calculated and urged them to reject the rule.

Anthony Verdugo spoke on behalf of the Christian Family Coalition as the Executive Director. Verdugo supported the rule. He said that "they call it gender-affirming care" but "they don't care, and it's not affirming." He called Chloe Cole and Sophia Galvin "heroes," and said that this is a "war on children and this is a crime against humanity." Verdugo said that "groomers" are pressuring children to undergo gender-affirming procedures. He cites to the warning label on a

package of hormones which states that emotional instability is a side effect. He said that the organizations Maurer listed "have been discredited" and cited to "more renowned" organizations who believe that "the suppression of normal puberty, the use of disease-causing cross sex hormones, and the surgical mutilation and sterilization of children" are "atrocities" and "not health care."

The next speaker, a veteran and police officer, said that doctors, parents, teachers, and scientists have been wrong before, but that detransitioners are the "evidence" we need. He said we need to "stop being ignorant" and that churches are bigger than any organization and in support of the proposed change. The audience met this with cheers and applause throughout.

Michael Haller, a doctor and professor of medicine at the University of Florida, spoke on his own behalf. After establishing himself as an expert, he said that this proposed rule makes "numerous false claims, uses biased reviews of the literature, and relies on more so-called experts who actually lack actual expertise" in caring for transgender youth. He said that the state's assertion that gender-affirming care is not safe or effective is "patently false" and that nearly every major medical organization supports this care. He says the state is "either unwilling or willfully chooses to ignore the totality of evidence for gender-affirming care." He said that the state's experts are unqualified. Haller noted that the proposal is "poorly-conceived," likely to cause harm, and should be rejected.

At this point, a member of the panel, Dr. Van Meter, made a comment. He said that the Endocrine Society guidelines are not standards of care, but merely guidelines, drafted by "ideologues" from the World Professional Association for Transgender Health. He said that this group excluded "world renowned experts in the field" and did not include their input "on purpose." He said that we "have to stop using the term 'standards of care' when there are absolutely no standards of care in this instance that have been addressed."

Robert Youelis spoke next, lamenting that gender-affirming care was not on anyone's radar even five years ago. He said that this is man "proclaim[ing] himself as God" and that there is only one truth. Youelis said we are "philosophically and morally" going down a slippery slope when we start considering gender-affirming care. He said that brains are not fully developed until the age of twenty-five, and children cannot make other decisions in life, so we should not be educating anyone about gender identities until they are in twelfth grade.

The next speaker, Keith Claw of Florida Citizens Alliance, spoke next. He said that children in public schools are "purposefully confused, desensitized, and even pressured into abnormal sexual behavior" and that "gender idealogues are coaching kids to be into this dysphoria." He said that there is ongoing debate as to whether gender dysphoria is biological or psychological. He said that taxpayers should not have to pay for gender-affirming care.

Robert Roper spoke next, also in support of the rule. He said that it "serves to protect the children." He said "gender confusion is the only disorder that comes with a false assertion that a child can be born in the wrong body" and that it is "impossible" to become the opposite gender. He went on to say that gender dysphoria is the only "disorder [where] the body is mangled to conform to the thoughts of the mind" and where "the child actually dictates his or her medical

care . . . instead of the other way around." He called this a "social media epidemic manufactured by social media influencers making a lot of money off the very vulnerable element of our society." He likened gender-affirming procedures to giving drugs to a drug addict or alcohol to an alcoholic and cited to a Reddit post where 35,000 individuals expressed regret of transitioning.

Karl Charles of Lambda Legal spoke against the proposed rule. He said that this care is "essential and in some cases lifesaving," "clinically effective," "evidence based," and "widely accepted." Charles said that exclusions such as this one cause "serious immediate and irreparable harm" to those who already experience "well-documented and pervasive stigma" and barriers to healthcare. He said that he is particularly concerned by the agency's characterization of this care as "experimental and ineffective," and that this is contrary to available medical evidence and misrepresents studies. He notes that the so-called experts relied on have been discredited and do not treat transgender patients. He noted that no one on the panel was a transgender Medicaid recipient in Florida, and that singling out transgender Medicaid participants violates Equal Protection and ACA § 1557.

A panelist at this point referred everyone to the appendices to the Florida Medicaid Report, including Dr. Cantor's reports cited to on page thirty-nine, which discusses each organization that has supported gender-affirming care.

Ed Wilson spoke in support of the proposed rule, saying that it would "protect children who are not mature enough to be comfortable in their own bodies" from "making mistakes that will destroy their lives." He said that taxpayer money should "never be used to destroy innocent lives" and that gender-affirming care "never actually succeed[s]" but does cause harm. He characterized it as "mutilation" and an "atrocit[y]" to be banned, "not healthcare."

Suzanne Zimmerman, a relative of a gender dysphoric youth, spoke next. She "pray[ed]" that the state "not make it easy" for this youth's parents to be persuaded towards gender-affirming care. She pointed to the testimony of detransitioners to state that "God doesn't make mistakes" (the audience said "amen"). She urged them to support the changes.

Jean Halloran also supports the changes. She said that Medicaid should not be supporting or paying for gender-affirming care. She likened gender-affirming care to cosmetic changes to make her look younger, receiving audience applause and laughter.

Ezra Stone, a clinical social worker, pointed to research that medical transition is safe and effective. They pointed to clients who have "expressed tremendous relief" and an increased sense of safety when they are able to access medical care. They said that "understanding and being seen as [one's] true sel[f] creates a sense of belonging, which is a fundamental human need." They pointed to the political climate in Florida as causing harm and anxiety to "transgender, nonbinary, questioning, and gender-diverse Floridians." Their patients "worry about their access to medical care" and experience fear of violence daily, which supports the minority stress model that says that expecting harm and violence has a negative impact on mental health and well-being. They said that this proposed change will create an atmosphere of fear and take away medically necessary care.

Peggy Joseph shared the thoughts of Ryan T. Anderson, author of *When Harry Became Sally*. She cited to the Obama Administration's refusal to mandate coverage of gender-affirming surgeries under Medicaid, which said that there was "not enough evidence" to determine whether it improved health outcomes. She said that studies with positive outcomes were exploratory, without follow-up, which "could be pointing to suicide." She cited to the Swedish study regarding suicide rates, as well. She said the "minimal standard of care should be with a standard of normality" and that gender dysphoric thoughts are "misguided and cause harm."

A panelist again interjected to note that the report on pages 35–36 and 42–45 discusses the international consensus.

Jack Walton with the Christian Family Coalition is a pastor. He said he has counseled queer individuals for thirty-seven years. He believes that "gender dysphoria should be labeled as child abuse" and the doctors who prescribe gender-affirming care are "tear[ing] the child apart and call[ing] it health care." Walton says that gender-affirming care is "not science" and that any such procedures "should be labeled criminal." He said that "nearly 90 percent of those that escape from that life do it by the time they reach the end of puberty because they come back to their senses that they were created male and female by God." Walton expressed that suicide happens when a transgender person transitions but "still do[es]n't find the completion that they thought they felt." He said that many individuals transition because of child abuse they faced as children or because they were not accepted by others. He closed by saying there are "two genders, male and female; women bear children, women breastfeed, women have menstrual cycles, men do not." He said he "would not provide the anorexic with food and [he] would not say give money to do something that would harm a child."

Another member of the Christian Family Coalition, Jose, also supported the changes. He characterized gender-affirming care as "mutilation" and said that transgender individuals need "counseling" and should not be given a "destructive choice." He said that everyone will have to "stand before our living God and give account for where we stand on this and other issues." He thanked Chloe Cole and Sophia Galvin for their testimonies.

The panel then asked that members of the same organization be mindful of their time.

Bob Johnson, an attorney, spoke next. He thanked the agency for putting together the report, noting that it is "thorough," and said the "case is compelling." He strongly supports the rule change, and this is in large part due to the report making the case. He noted that the "FDA does not approve any medication as clinically indicated for gender dysphoria" and lamented the lack of randomized controlled trials and long-term data for puberty suppression medication.

Sandy Westad also spoke on behalf of Christian Family Coalition. She said that her heart is "breaking for what these kids are going through" and that "the parents need to stay in control." She said that kids "play house" and "pretend," but they "don't want to be or understand or even know what it is to change from one sex to another." She said, "children cannot make those kinds of decisions" and "cannot decide who they are."

Gayle Carlins also spoke from Christian Family Coalition. She said her beliefs are based on the

Bible, which is "the only truth that there is," and which says that "God created male and female." She went on to "bring science into it," stating that females have two X chromosomes and males have an X and a Y chromosome, and that "it's an impossibility to change from one to the other" "no matter what kind of mutilation or anything is done to a person."

Dorothy Barron spoke next, also from Christian Family Coalition. She first thanked Florida's "great governor," eliciting audience cheers and applause, and thanked Chloe Cole and Sophia Galvin for not "going along with what you were trying to be brainwashed into" (also eliciting audience cheers and applause). She said "they're definitely targeting our youngest," and lamented that "we can't seem to find baby formula anywhere but yet Medicaid can fund this nonsense." Barron said it "has to be left up to the parents," and that "whatever you choose to practice in the privacy of your own home is your business"; she is "not discriminating against any genders or whatever." She said that it needs to be "taken out of the schools." She said Michael Haller's testimony was "shameful" and is "why we're in this bloody mess right now," to which the audience also cheered and applauded.

The panel reminded the public to be focused on the rule and respectful of other speakers.

Troy Peterson, the president of Warriors of Faith, supported Christian Family Coalition, and came from the Tampa Bay area. He said that he represents "thousands that stand in agreement" with the proposed change. He thanked the doctors for the report and said that "when [he] saw the evidence, [he] could clearly see that we need this rule." He quoted from Genesis and said that God created male and female, and he is opposed to Michael Haller as well. He said that "if [he] had any authority in the medical field, [he] would have [Michael Haller's] license revoked." The audience whistled and verbally approved. He said that the most thorough follow-up of transgender individuals in Sweden said that "the suicide rate is twenty times that of the comparable peers" and that "50 percent of the gender identity confused children have thoughts of suicide."

Janet Rath spoke next. She said that "fifty years ago, as parents, we were smarter than what's going on today," and that parents are being left out of their children's lives. She said some of this is the fault of parents and some is the fault of teachers. She said her granddaughter, a teacher, has told her that "if she has a child that comes in and identifies as a cat, she must have a litterbox there and a bowl of water." Rath said that our country is going "absolutely insane," and the audience murmured in agreement. She said that Dr. Fauci is "nothing but a money-grabbing liar" and "we have been hoodwinked ever since." Rath went on to say that "Chinese children in third grade are learning advanced calculus" but "our third graders are learning which bathroom to use."

Gerald Lomer drove 3.5 hours to attend the hearing. He supported the proposed rule and "the best governor in the United States," to which the audience cheered and applauded. He told "stories" of a girl who wanted to spend more time with her father and thought that being a boy was the best way to do so and a boy who wanted to spend more time with his mother and thought that being a girl was the best way to do so. He said that thirteen-year-olds cannot drive a car, drink a beer, or smoke a cigarette, but are able to take hormones and obtain surgeries for gender-affirming care. He characterized gender-affirming surgeries as "mutilating."

A pastor from Florida spoke next on behalf of Protect Our Children Project, Duval Country Charter House, and Christian Family Coalition. She supported the rule prohibiting funding for "unnatural therapies" and does not want taxpayers to subsidize transgender care. She said that "transgenderism is driven by unethical pharmaceutical companies enriching themselves with puberty blockers" and that this is child abuse. She cited to Swedish psychiatrist Dr. Christopher Gillberg, who has said that "pediatric transition is possibly one of the greatest scandals in medical history."

Paul Aarons, a physician, spoke next. He said he has transgender patients and friends. He said that he opposes the proposed change, because it "conflicts with the preponderance of medical science and practice and would do irreparable harm" to transgender Floridians of all ages. He said that the American Academy of Pediatrics and its Florida chapter have directly refuted the agency's report. Aarons said that, "contrary to an earlier comment, the Endocrine Society has stated, 'medical intervention for transgender youth and adults, including puberty suppression hormone therapy, and medically indicated surgery, has been established as their standard of care. Federal and private insurers should cover such interventions as prescribed by a physician.'" He said gender dysphoria is "very real" and that people should meet and speak to transgender individuals, which will help them realize that denial of care "at any age would be inhumane and a violation of human rights." He said that gender-affirming care is "generally accepted professional medical standards" and that this rule would put the health and lives of transgender people in danger. He said that "it feels like Medicaid is crossing into a political lane by seeking to preempt provider/patient/family decision-making." He said that, if the agency still wants to address this topic, they should "at least convene an appropriate panel of experts including transgender community members to inform yourselves and the public about the overwhelming evidence against denying coverage for gender affirming care."

A doctor on the panel then encouraged everyone to read the report and its attachments. He said that the report focuses on studies which have been brought up, and "specifically the flaws" in those studies. He also encouraged audience members not to interrupt when others are speaking. He went on to say that the Endocrine Society's 2017 guidelines "are guidelines, just that," and they "do not guarantee an outcome" and "do not establish a standard of care." He also referred to international reviews which "all came to the same conclusion" that "this should not be going on in minors at all," to which the audience applauded. He said that children need "strong psychological support" and that four decades of literature point to the "overwhelming probability of mental health problems after these childhood events" and "problems like autism spectrum disorder." He said that in other nations, having "psychological instability . . . blocks you from the transition pathway" and that "those things be taken care of first because transition simply won't fix them." He said that the report is a "very well-researched document" and addresses a lot of the concerns raised in comment letters.

Another panelist then referred everyone to Attachment C of the report and Dr. Hruz's *Deficiencies in Scientific Evidence for Medical Management of Gender Dysphoria*.

January Littlejohn, a mental health counselor, spoke next. Her child expressed that they were experiencing gender dysphoria in 2020, shortly after three of their friends had started identifying as transgender. She said that the middle school had "socially transitioned [her child] without

their knowledge or consent"[3] and that her child's "mental health spiraled." She said that she has worked with a psychologist to help address her child's low self-esteem and anxiety, and has "given [her child] more one-on-one time, in-person activities away from trans influences, limited [her child's] internet use, and declined to affirm [her child's] newly-chosen name and pronouns." She said that they set "appropriate boundaries" and allowed her child to choose hairstyle and clothing but "denied harmful requests such as breast binders, puberty blockers, cross-sex hormones, and surgeries." She said it was "clear from [their] conversations" that her child was uncomfortable with their developing body and had "an intense fear of being sexualized." Littlejohn said that her child was "filled with self-loathing and was in true emotional pain," but "had been led by peers and influencers to believe that gender was the source of [their] pain." She said that her child needed to be "remind[ed] that hormones and surgeries can never change [their] sex or resolve [their] issues." She said that she "shudder[s] to think what could have happened if [they] had affirmed [her child's] false identity and consented to medical treatment" as opposed to "lovingly affirm [her child] as [they are], beautifully unique and irreplaceable and undeniably female." She said that her child has "desisted and is on a path to self-love" but unfortunately gender dysphoric children are "being encouraged to activism peer pressure to disassociate from their bodies and to believe their body parts can be simply removed, modified, or replaced." Littlejohn said that "the irreversible consequences of medically transitioning, including loss of sexual and reproductive function, cannot be fully understood by children or teens who lack the necessary maturity or experience."

Kendra Barris, a mental health attorney, spoke next. She first addressed the comment about the lack of peer-reviewed standards of care, saying that this lack means that "a lot of people who are harmed or experience bad outcomes from these surgeries or other interventions have no ability to sue." She said that "they have had decades to create peer-reviewed standards of care and they have not," and she suspects that some people do not want to standards because it would open them up to lawsuits, which is not currently happening. She went on to say that "when you put a female on testosterone, within about five years [they are] going to have to have a hysterectomy," which for teens could mean a potential hysterectomy before the age of twenty. She said that "hysterectomy is correlated with negative mental health outcomes and cognitive decline" and that this is worse the earlier a hysterectomy is performed. She said that "essentially, the earlier you do the hysterectomy, the earlier the onset of dementia." She is "very concerned about" how in a few decades "we're going to have an absolute wave of young females, 40–50 years old, with early-onset cognitive decline" in assisted-living facilities. She said that "some people who are trans and have dementia forget that they're trans" and if they don't have written consent to continue their transition, they "might be cut off." She worries that "we have not considered all of the implications of this."

The next speaker was Nathan Bruemmer, Florida's LGBTQ Consumer Advocate. He opposed the proposed rule "on behalf of healthcare consumers," saying that consumers "must be provided with accurate information, education, choice, safety, representation, and regress." He said that

[3] Note that news organizations have reported that Ms. Littlejohn was aware of her child's choice to change names and pronouns at school and told the school she would not stop them from doing so. She later filed a lawsuit against the school. *See, e.g.*, Leyla Santiago, *Fact Check: Emails Show One of Desantis's Stories Backing the Rationale for So-Called 'Don't Say Gay' Law Didn't Happen as the Governor Says*, CNN Politics (Apr. 6, 2022), https://www.cnn.com/2022/04/06/politics/fact-check-desantis-dont-say-gay-family-narrative/index.html.

"documented, well-researched standards of care have been established, are based on a wide range of evidence, and conclude that gender-affirming medical care is medically necessary and safe and effective." In other words, "gender-affirming care *is* the standard of care." Bruemmer said that the proposed rule would "deny health care consumers . . . access to the standard of care." He said that agencies must defend the rights of all Floridians, including transgender Floridians, and that this includes the right to non-discriminatory healthcare coverage. He said we should work to increase access to healthcare, not lessen or remove it. Bruemmer said that he is "one of . . . tens of thousands of transgender Floridians" who have had access to gender-affirming care, and who are "happy, and successful, and thriving." He said that transgender Floridians "deserve the rights and benefits afforded to all."

The next speaker's name was inaudible, but he also spoke in support of the proposed rule. He told examples of his fifteen-year-old son making bad decisions, including speeding on his dirt bike and wanting to leave home, as proof that "these kids can['t] make a decision on what they want that's going to be with them for the rest of life." He said that the doctors who spoke previously "are despicable," "need to have their licenses taken away," and "are a disgrace to the human race."

A panelist thanked him for his comment and said, "we respect everybody's comments, including the doctors that you referenced."

Dottie McPherson spoke next on behalf of the Florida Federation of Republican Women. She said that even at the age of eighteen "children don't have the maturity to handle certain responsibilities given them" like driving and alcohol, and that "even older adults don't." She said that state programs include "programs for abused and neglected children, but not gender decisions." She urged the panel to "prevent funding the destruction of children's genitalia and hormonal balance." McPherson urged the panel to consider unintended consequences, such as "taxpayer money that will need to be used for lawsuits by those whose lives were ruined from surgeries that they got while they were immature or too young to understand," parents whose "parental rights were denied to protect their children's future." She said that "life isn't fair" and we have to "stop giving in to the 'poor pitiful me' syndrome." McPherson said that government "has no business funding these things."

Maria Caulkins spoke next in support of the proposed rule. She said that taxpayer money should not be spent on funding surgeries that are "unnecessarily and tremendously harmful." She said that there is "a war on our children" and that we need to "protect our children" and "support our governor" by being on the "right side" of this war.

James Caulkins also spoke in support of the rule, saying that we're "in a battle in this country." He said that the people of Florida "have spoken" by electing "the greatest governor in the United States," to which the audience cheered and applauded. Caulkins said that we "don't need this stuff, this evil, this Medicaid funding for transgender surgery" and that Florida should lead other states against "this evil."

The final speaker, whose name was also inaudible, spoke in support of the proposed rule. She said that, years ago, she was told by a doctor that she needed to undergo hormone therapy, but

she "saw the risks involved." She said that hormone therapy is an attempt to "prevent . . . natural things from occurring," such as menstruation, and we can't expect it not to have any problems. She cited to Bill Maher, who pointed out that transgender procedures were only occurring in major cities where "social engineering is happening and where people are being influenced" but not in the rest of the country. She lamented that she can't go to the media and say anything against transgender individuals because it will be "criticized and condemned" which "isn't fair." She said that "the government should not be involved in supporting any kind of procedure to these young kids."

A panelist thanked everyone for their comments and then clarified the purpose of the rule. He said that it is *not* "a ban on treatment for gender dysphoria," but rather lack of Medicaid coverage for services mentioned in the proposed rule. He also said that "there are other comprehensive coverage of services for gender dysphoria currently in the Florida Medicaid program" before reading some of those services (community-based services, psychiatric services, emergency services and inpatient services, and behavioral health services in schools).

From: (b)(6) (b)(6) (HHS/OCR) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b)(6) SUS (b)(6)

To: (b) (b)(6) (b)(6 (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bdec12ad0974eacababe032f2b37c91-Dekervor, D (b)(6)
Roman, David (OS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user5d5a5775 <David.Roman@hhs.gov>

Subject: FW: GAC Case Against Maryland Medicaid MCO - (b)(6) notes

Date: 2022/06/21 23:18:57

Priority: Normal

Type: Note

Hi (b)(6) and David,

(b)(5); (b)(7)(C)

(b)(5); (b)(7)(C)

(b)(5), (b)(7)(C)

(b)(5); (b)(7)(C)

(b)(5); (b)(7)(C)

(b)(5); (b)(7)(C)

(b)(5); (b)(7)(C)

(b)(5); (b)(7)(C)

From: (b) (b)(6) (b)(6) (HHS/OCR) (b)(6)
Sent: Tuesday, June 14, 2022 6:56 AM
To: Roman, David (OS/OCR) <David.Roman@hhs.gov>
Subject: RE: GAC Case Against Maryland Medicaid MCO

(b)(5); (b)(7)(C)

(b)(6) (b)(6) (b) (b)(6) Esq., MSW (she/her)
Phone: (b)(6) (b)(6)
Email: (b)(6)

From: (b) (b)(6) (b)(6) (HHS/OCR)
Sent: Tuesday, June 14, 2022 9:33 AM
To: Roman, David (OS/OCR) <David.Roman@hhs.gov>
Subject: RE: GAC Case Against Maryland Medicaid MCO

Hi David,

(b)(5); (b)(7)(C)

Thank you!
(b)(6)

(b)(6) (b)(6) (b) (b)(6) Esq., MSW (she/her)
Phone: (b)(6) (b)(6)
Email: (b)(6)

From: Roman, David (OS/OCR) <David.Roman@hhs.gov>
Sent: Monday, June 13, 2022 4:25 PM
To: (b) (b)(6) (b)(6) (HHS/OCR) (b)(6)
Subject: FW: GAC Case Against Maryland Medicaid MCO

Hi (b)(6)

My proposed responses to Alisha's questions are attached below.

Best, David

From: Welch, Alisha (HHS/OCR) <Alisha.Welch@hhs.gov>
Sent: Thursday, June 9, 2022 12:39 PM
To: (b) (b)(6) (b)(6) (HHS/OCR) (b)(6) Roman, David (OS/OCR) <David.Roman@hhs.gov>
Cc: Rahn Ballay, Jamie (HHS/OCR) <Jamie.Rahn@hhs.gov>; Smith, Marisa (HHS/OCR) <Marisa.Smith@HHS.GOV>
Subject: RE: GAC Case Against Maryland Medicaid MCO

Thanks. Will do!

From: (b) (b)(6) (b)(6) (HHS/OCR) (b)(6)
Sent: Thursday, June 9, 2022 3:39 PM
To: Welch, Alisha (HHS/OCR) <Alisha.Welch@hhs.gov>; Roman, David (OS/OCR) <David.Roman@hhs.gov>
Cc: Rahn Ballay, Jamie (HHS/OCR) <Jamie.Rahn@hhs.gov>; Smith, Marisa (HHS/OCR) <Marisa.Smith@HHS.GOV>
Subject: RE: GAC Case Against Maryland Medicaid MCO

Thanks, Alisha!

(b)(5); (b)(7)(C)

(b)(6) (b)(6) (b) (b)(6) Esq., MSW (she/her)

Phone: (b)(6) (b)(6)
Email: (b)(6)

From: Welch, Alisha (HHS/OCR) <Alisha.Welch@hhs.gov>
Sent: Thursday, June 9, 2022 3:25 PM
To: (b) (b)(6) (b)(6) (HHS/OCR) (b)(6) Roman, David (OS/OCR) <David.Roman@hhs.gov>
Cc: Rahn Ballay, Jamie (HHS/OCR) <Jamie.Rahn@hhs.gov>; Smith, Marisa (HHS/OCR) <Marisa.Smith@HHS.GOV>
Subject: GAC Case Against Maryland Medicaid MCO

Hi (b)(6) and David:

(b)(5); (b)(7)(C)

(b)(5); (b)(7)(C)

(b)(5); (b)(7)(C)

We would be happy to set up a time to discuss this complaint further

Thanks!

Alisha Welch
Acting Deputy Regional Manager
DHHS, Office for Civil Rights, Mid-Atlantic Region

801 Market Street, Suite 9300

Philadelphia, PA 19107

215-861-4439 (voice)

1-800-537-7697 (TTY)

215-861-4431 (fax)

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Sender:	(b)(6) (b)(6) (HHS/OCR) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b)(6) SUS (b)(6)
Recipient:	(b) (b)(6) (b)(6 (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bdec12ad0974eacababe032f2b37c91-Dekervor, D (b)(6) Roman, David (OS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user5d5a5775 <David.Roman@hhs.gov>
Sent Date:	2022/06/21 23:17:59
Delivered Date:	2022/06/21 23:18:57

STATE OF MARYLAND
DHMH
Maryland Department of Health and Mental Hygiene
Larry Hogan, Governor - Boyd Rutherford, Lt. Governor - Van Mitchell, Secretary

Office of Health Services
Medical Care Programs

MARYLAND MEDICAL ASSISTANCE PROGRAM
Managed Care Organizations Transmittal No. 110
March 10, 2016

TO: Managed Care Organizations

FROM: Susan J. Tucker, Executive Director
Office of Health Services

RE: Gender Transition: Covered Services, Coverage Criteria, Limitations and Exclusions

NOTE: Please ensure that appropriate staff members in your organization are informed of the contents of this transmittal

****

The purpose of this transmittal is to reinforce that, in addition to hormone therapy, HealthChoice Managed Care Organizations (MCOs) are now responsible for covering medically necessary gender transition services including gender reassignment surgery. The Department promulgated regulations effective December 10, 2015 to COMAR 10.09.02.05 to add coverage for gender reassignment surgery. The Department is also amending COMAR 10.09.02.05, .06, 10.09.03.06, 10.09.06.06, 10.09.09.05, 10.09.67.26-2 and 10.90.67.27 to reflect current policy.

When reviewing requests for gender transition services, MCOs will be responsible for the attached list of services. Gender reassignment surgery requires a behavioral health diagnosis of gender dysphoria. MCOs should verify that behavioral health treatment has taken place prior to gender reassignment surgery in accordance with the attached authorization criteria.

Please see the attached optional templates for providers that may be used prior to authorizing gender transition services.

If you have questions regarding this transmittal, please contact Dr. Tiffany Wedlake, Physician Specialist for Managed Care, at Tiffany.wedlake@maryland.gov or (410)767-6250.

Attachments

GENDER TRANSITION SERVICES UNDER
THE MARYLAND MEDICAID PROGRAM
Covered Services and Limitations
Effective 12/10/15

Covered Services:

1) **Outpatient psychotherapy/mental health services for gender dysphoria and associated co-morbid psychiatric diagnoses**. The benefits are the same as any other outpatient mental health service covered by Behavioral Health.

2) **Continuous hormone replacement therapy.** Includes hormones injected by a medical provider in an office setting and oral and self-injected hormones covered under the pharmacy benefit.

3) **Outpatient Laboratory testing to monitor continuous hormone therapy**.

4) **Gender reassignment surgery:**

Male-to-Female Transition	Female-to-Male Transition
Orchiectomy	Vaginectomy
Penectomy	Hysterectomy
Clitoroplasty	Mastectomy
Labiaplasty	Salpingo-oophorectomy
Vaginoplasty	Ovariectomy
Thyroid Chondroplasty	Metoidioplasy
	Phalloplasty
	Scrotoplasty
	Placement of Testicular Protheses
Urethroplasty for both types of transition	

For individuals planning to undergo gender reassignment surgery, all of the following criteria must be met:

a. The individual is at least 18 years of age; and

b. The individual has capacity to make fully informed decisions and consent for treatment; and

c. The individual has been **diagnosed with gender dysphoria** and exhibits all of the following:

   1. The desire to live and be accepted as a member of the opposite sex, usually accompanied by the wish to make his or her body as congruent as possible with the preferred sex through surgery and hormone treatment; and

2. The gender dysphoria (pre and post diagnosis) has been present persistently for at least two years; and

3. The gender dysphoria is not a symptom of another mental disorder; and

4. The gender dysphoria causes clinically significant distress or impairment in social, occupational, or other important areas of functioning; and

d. The individual regularly participates in psychotherapy and/or ongoing clinical treatment throughout the real-life experience may be required when recommended by a treating medical or behavioral health practitioner or when medically necessary; and

e. If the individual has significant medical or mental health issues present, they must be reasonably well controlled. If the individual is diagnosed with severe psychiatric disorders and impaired reality testing (e.g., psychotic episodes, bipolar disorder, dissociative identity disorder, borderline personality disorder), an effort must be made to improve these conditions with psychotropic medications and/or psychotherapy before surgery is contemplated; and

f. The individual will require two referrals from qualified mental health professionals who have independently assessed the individual. If the first referral is from the individual's psychotherapist, the second referral should be from a person who has only had an evaluative role with the individual. Two separate letters, or one letter signed by both (e.g., if practicing within the same clinic) are required; and

g. At least one of the professionals submitting a letter must have a doctoral degree (Ph.D., M.D., Ed.D., D.Sc., D.S.W., or Psy.D) and be capable of adequately evaluating co-morbid psychiatric conditions. One letter is sufficient if signed by two providers, one of whom has met the doctoral degree specifications, in addition to the specifications set forth above. One letter signed by an appropriate provider is sufficient to support benefits for a mastectomy. The medical documentation should include the start date of living full time in the new gender, when applicable; and

h. The individual has undergone a minimum of 12 months of continuous hormonal therapy when recommended by a mental health professional and provided under the supervision of a physician, unless the individual has a medical contraindication; and

i. Documentation that the individual is required to have completed 12 months of continuous hormonal therapy prior to hysterectomony/salpingo-oophorectomy, orchiectomy, vaginectomy or vaginoplasty procedures; and

j. Hormonal therapy **is not required** as a prerequisite to a mastectomy.

5) **Augmentation mammoplasty**. Provided the criteria above for gender reassignment surgery have been satisfied, augmentation mammoplasty (including breast prosthesis if necessary) may be covered for male-to-femal transgender individuals if the Physician prescribing hormones and the treating surgeon have documented that, after undergoing hormone treatment for 12 months, breast size continues to cause clinically significant distress in social, occupational, or other areas of functioning.

Post Transition Services. Gender-specific services may be medically necessary for transgender persons appropriate to their anatomy. Examples include:

- **Breast cancer screening** may be medically necessary for female to male transgender persons who have not undergone a mastectomy;
- **Prostate cancer screening** may be medically necessary for male to female transgender individuals who have retained their prostate.

Coverage Limitations and Exclusions

The surgeries and procedures identified below are excluded from coverage. (This list may not be all-inclusive):

1) Abdominoplasty
2) Blepharoplasty
3) Breast enlargement procedures, except in connection with a covered augmentation mammoplasty
4) Brow lift
5) Cheek implants
6) Chin/nose implants
7) Collagen injections
8) Cryopreservation, storage, and thawing of reproductive tissue (i.e., oocytes, ovaries, testicular tissue) and the charged associated therewith (e.g., office, hospital, ultrasounds, laboratory test, etc.)
9) Electrolysis
10) Face/forehead lifts
11) Hair removal/hairplasty/hair transplantation
12) Facial bone reconstruction
13) Hair removal/hairplasty/hair transplantation
14) Jaw shortening/sculpturing/facial bone reduction
15) Laryngoplasty
16) Lip reduction/enhancement
17) Liposuction
18) Mastopexy
19) Neck tightening
20) Nipple/areola reconstruction, except in connection with a covered augmentation Mammoplasty or mastectomy
21) Penile prosthesis (non-inflatable/inflatable), except in connection with a covered phalloplasty (implantation of the prosthesis shall not be considered a second state

phalloplasty) in a female-to-male transition (subsequent replacement or correction of such prosthesis subject to rules and limitations applicable to all prosthetic devises)

22) Removal or redundant skin, except in connection with a covered surgery
23) Replacement of tissue expander with permanent prosthesis testicular insertion, except as a component of a covered placement of a testicular prosthesis
24) Reversal of genital or breast surgery or reversal of surgery to revise secondary sex characteristics
25) Rhinoplasty
26) Second stage phalloplasty
27) Surgical correction of hydraulic abnormality of inflatable (multi-component) prosthesis including pump and/or cylinders and/or reservoir
28) Testicular prostheses, except as a component of a covered placement of a testicular Prosthesis (subsequent replacement or correction of such prosthesis subject to rules and Limitations applicable to all prosthetic devises)
29) Testicular expanders, except as a component of a covered placement of a testicular prosthesis
30) Voice modification surgery
31) Voice therapy/voice lessons

Amerigroup
An Anthem Company

Clinical UM Guideline

Subject: Gender Affirming Surgery
Guideline #: CG-SURG-27
Status: Revised

Publish Date: 05/20/2021
Last Review Date: 05/13/2021

Description

This document addresses gender affirming surgery (also known as sex affirmation surgery, gender or sex reassignment surgery, gender or sex confirmation surgery). Gender affirming surgery is a treatment option for gender dysphoria, a condition in which a person experiences persistent incongruence between gender identity and sexual anatomy at birth. Gender affirming surgery is not an isolated intervention; it is part of a complex process involving multiple medical, psychiatric and psychologic, and surgical specialists working in conjunction with each other and the individual to achieve successful behavioral and medical outcomes. Before undertaking gender affirming surgery, medical and psychological evaluations, medical therapies and behavioral trials are undertaken to help ensure that surgery is an appropriate treatment choice for the individual.

Note: Please refer to the following documents for additional information, including the use of these and other procedures for individuals with gender dysphoria that *are not related to gender affirming surgery*:

- ANC.00007 Cosmetic and Reconstructive Services: Skin Related
- ANC.00008 Cosmetic and Reconstructive Services of the Head and Neck
- ANC.00009 Cosmetic and Reconstructive Services of the Trunk and Groin
- CG-SURG-12 Penile Prosthesis Implantation
- SURG.00023 Breast Procedures; including Reconstructive Surgery, Implants and Other Breast Procedures

Note: Voice therapy is not addressed in this document, as it is not a surgical procedure.

Medically Necessary: In this document, procedures are considered medically necessary if there is a significant functional impairment AND the procedure can be reasonably expected to improve the functional impairment.

Reconstructive: In this document, procedures are considered reconstructive when intended to address a significant variation from normal related to accidental injury, disease, trauma, treatment of a disease or a congenital defect.

Note: Not all benefit contracts/certificates include benefits for reconstructive services as defined by this document. Benefit language supersedes this document.

Cosmetic: In this document, procedures are considered cosmetic when intended to change a physical appearance that would be considered within normal human anatomic variation. Cosmetic services are often described as those that are primarily intended to preserve or improve appearance.

Clinical Indications

NOTE: Procedures to address postoperative complications of gender affirming surgery procedures (for example, stenosis, scarring, chronic infection, or pain) are not considered separate gender affirming surgery procedures.

NOTE: Reversal of a prior gender affirming surgery procedure is considered gender affirming surgery and the medical necessity criteria below apply.

Medically Necessary:

Gender affirming pelvic or gonadal surgery (which may consist of a combination of the following: *hysterectomy, orchiectomy, ovariectomy, or salpingo-oophorectomy*), is considered **medically necessary** when *all* of the following

criteria are met:

A. The individual is at least 18 years of age; **and**
B. The individual has capacity to make fully informed decisions and consent for treatment; **and**
C. The individual has been diagnosed with gender dysphoria (see Discussion section for diagnostic criteria); **and**
D. For individuals without a medical contraindication or intolerance, the individual has undergone a minimum of 12 months of continuous hormonal therapy when recommended by a mental health professional and provided under the supervision of a physician; **and**
E. If the individual has significant medical or mental health issues present, they must be reasonably well controlled. If the individual is diagnosed with severe psychiatric disorders and impaired reality testing (for example, psychotic episodes, bipolar disorder, dissociative identity disorder, borderline personality disorder), an effort must be made to improve these conditions with psychotropic medications and/or psychotherapy before surgery is contemplated; **and**
F. Two referrals from qualified mental health professionals* who have independently assessed the individual. If the first referral is from the individual's psychotherapist, the second referral should be from a person who has only had an evaluative role with the individual. Two separate letters, or one letter signed by both (for example, if practicing within the same clinic) are required. The letter(s) must have been signed within 12 months of the request submission.

Gender affirming genital surgery (which may consist of a combination of the following: *clitoroplasty, labiaplasty, metoidioplasty, penectomy, phalloplasty, scrotoplasty, urethroplasty, vaginectomy, vaginoplasty, or placement of penile or testicular prostheses*), is considered **medically necessary** when *all* of the following criteria are met:

A. The individual is at least 18 years of age; **and**
B. The individual has capacity to make fully informed decisions and consent for treatment; **and**
C. The individual has been diagnosed with gender dysphoria (see Discussion section for diagnostic criteria); **and**
D. For individuals without a medical contraindication or intolerance, the individual has undergone a minimum of 12 months of continuous hormonal therapy when recommended by a mental health professional and provided under the supervision of a physician; **and**
E. Documentation** that the individual has completed a minimum of 12 months of successful continuous full time real-life experience in the new gender, across a wide range of life experiences and events that may occur throughout the year (for example, family events, holidays, vacations, season-specific work or school experiences). This includes coming out to partners, family, friends, and community members (for example, at school, work, and other settings); **and**
F. Regular participation in psychotherapy throughout the real-life experience when recommended by a treating medical or behavioral health practitioner; **and**
G. If the individual has significant medical or mental health issues present, they must be reasonably well controlled. If the individual is diagnosed with severe psychiatric disorders and impaired reality testing (for example, psychotic episodes, bipolar disorder, dissociative identity disorder, borderline personality disorder), an effort must be made to improve these conditions with psychotropic medications and/or psychotherapy before surgery is contemplated; **and**
H. Two referrals from qualified mental health professionals* who have independently assessed the individual. If the first referral is from the individual's psychotherapist, the second referral should be from a person who has only had an evaluative role with the individual. Two separate letters, or one letter signed by both (for example, if practicing within the same clinic) are required. The letter(s) must have been signed within 12 months of the request submission.

*At least one of the professionals submitting a letter must have a doctoral degree (for example, Ph.D., M.D., Ed.D., D.Sc., D.S.W., or Psy.D) or a master's level degree in a clinical behavioral science field (for example, M.S.W., L.C.S.W., Nurse Practitioner [N.P.], Advanced Practice Nurse [A.P.R.N.], Licensed Professional Counselor [L.P.C.], and Marriage and Family Therapist [M.F.T.]) and be capable of adequately evaluating co-morbid psychiatric conditions. One letter is sufficient if signed by two providers, one of whom has met the specifications set forth above.

**The medical documentation should include the start date of living full time in the new gender. Verification via communication with individuals who have related to the individual in an identity-congruent gender role, or requesting documentation of a legal name change, may be reasonable in some cases.

The use of hair removal procedures to treat tissue donor sites for a planned phalloplasty or vaginoplasty procedure is considered **medically necessary.**

Reconstructive

Gender affirming chest surgery (*augmentation, mastectomy, or reduction*) is considered **reconstructive** when *all* of the following criteria have been met:

A. The individual is at least 18 years of age (see *Further Considerations* section below for individuals under 18 years of age); **and**
B. The individual has capacity to make fully informed decisions and consent for treatment; **and**
C. The individual has been diagnosed with gender dysphoria (see Discussion section for diagnostic criteria); **and**
D. If the individual has significant medical or mental health issues present, they must be reasonably well controlled. If the individual is diagnosed with severe psychiatric disorders and impaired reality testing (for example, psychotic episodes, bipolar disorder, dissociative identity disorder, borderline personality disorder), an effort must be made to improve these conditions with psychotropic medications and/or psychotherapy before surgery is contemplated; **and**
E. *For gender affirming breast augmentation procedures only*: for individuals without a medical contraindication or intolerance, the individual has undergone a minimum of 12 months of continuous hormonal therapy when recommended by a mental health professional and provided under the supervision of a physician, and insufficient breast development has occurred; **and**
F. Existing chest appearance demonstrates significant variation from normal appearance for the experienced gender (note: each procedure requested should be considered separately as some procedures may be cosmetic and others may be reconstructive); **and**
G. One letter, signed by the referring qualified mental health professional* who has independently assessed the individual, is required; the letter must have been signed within 12 months of the request submission.

Nipple reconstruction, including tattooing, following a gender affirming mastectomy that meets the reconstructive criteria above is considered **reconstructive.**

Gender affirming facial surgery† is considered **reconstructive** when *all* of the following criteria have been met:

A. The individual is at least 18 years of age; **and**
B. The individual has capacity to make fully informed decisions and consent for treatment; **and**
C. The individual has been diagnosed with gender dysphoria (see Discussion section for diagnostic criteria); **and**
D. For individuals without a medical contraindication or intolerance, the individual has undergone a minimum of 12 months of continuous hormonal therapy when recommended by a mental health professional and provided under the supervision of a physician; **and**
E. If the individual has significant medical or mental health issues present, they must be reasonably well controlled. If the individual is diagnosed with severe psychiatric disorders and impaired reality testing (for example, psychotic episodes, bipolar disorder, dissociative identity disorder, borderline personality disorder), an effort must be made to improve these conditions with psychotropic medications and/or psychotherapy before surgery is contemplated; **and**
F. Existing facial appearance demonstrates significant variation from normal appearance for the experienced gender; **and**
G. The procedure directly addresses variation from normal appearance for the experienced gender (note: each procedure requested should be considered separately as some procedures may be cosmetic and others may be reconstructive); **and**
H. One letter, signed by the referring qualified mental health professional* who has independently assessed the individual, is required; the letter must have been signed within 12 months of the request submission.

†See Discussion section for a list of procedures included in this group of procedures

Gender affirming voice modification surgery is considered **reconstructive** when *all* of the following criteria have been met:

A. The individual is at least 18 years of age; **and**
B. The individual has capacity to make fully informed decisions and consent for treatment; **and**
C. The individual has been diagnosed with gender dysphoria (see Discussion section for diagnostic criteria); **and**
D. *For gender masculinization only:* for individuals without a medical contraindication or intolerance, the individual has undergone a minimum of 12 months of continuous hormonal therapy when recommended by a mental health professional and provided under the supervision of a physician; **and**
E. If the individual has significant medical or mental health issues present, they must be reasonably well controlled. If the individual is diagnosed with severe psychiatric disorders and impaired reality testing (for example, psychotic

episodes, bipolar disorder, dissociative identity disorder, borderline personality disorder), an effort must be made to improve these conditions with psychotropic medications and/or psychotherapy before surgery is contemplated; **and**

F. Existing vocal presentation demonstrates significant variation from normal for the experienced gender; **and**
G. One letter, signed by the referring qualified mental health professional* who has independently assessed the individual, is required; the letter must have been signed within 12 months of the request submission.

Not Medically Necessary:

The following gender affirming surgical procedures are considered **not medically necessary** when one or more of the medical necessary or reconstructive criteria above have not been met:

A. Clitoroplasty
B. Hysterectomy
C. Labiaplasty
D. Metoidioplasty
E. Orchiectomy
F. Ovariectomy
G. Penectomy
H. Phalloplasty
I. Salpingo-Oophorectomy
J. Scrotoplasty
K. Urethroplasty
L. Vaginectomy
M. Vaginoplasty

Cosmetic and Not Medically Necessary:

The following procedures, when requested alone or in combination with other procedures, are considered **cosmetic and not medically necessary** when applicable reconstructive criteria above have not been met, or when used to improve the gender specific appearance of an individual who has undergone or is planning to undergo gender affirming surgery, including, but not limited to, the following:

A. Abdominoplasty
B. Bilateral mastectomy
C. Blepharoplasty
D. Breast augmentation
E. Brow lift
F. Calf implants
G. Face liff
H. Facial bone reconstruction
I. Facial implants
J. Gluteal augmentation
K. Hair removal (for example, electrolysis or laser) and hairplasty, when the criteria above have not been met
L. Jaw reduction (jaw contouring)
M. Lip reduction/enhancement
N. Lipofilling/collagen injections
O. Liposuction
P. Nose implants
Q. Pectoral implants
R. Rhinoplasty
S. Thyroid cartilage reduction (chondroplasty)
T. Voice modification surgery

Further Considerations:

A provider with experience treating adolescents with gender dysphoria may request further consideration of a gender affirming chest procedure case in an individual under 18 years old when they meet all other gender affirming chest procedure criteria above (including prior mental health evaluation) by contacting a Medical Director. *(Further information is*

available in the Discussion/General Information section of this document titled 'Gender Affirming Surgery in Individuals Under the Age of 18').

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

CPT

17380	Electrolysis epilation, each 30 minutes [when done to treat tissue donor sites for a planned phalloplasty or vaginoplasty procedure]
17999	Unlisted procedure, skin, mucous membrane and subcutaneous tissue [when specified as permanent hair removal by laser to treat tissue donor sites for a planned phalloplasty or vaginoplasty procedure]
53410	Urethroplasty, 1-stage reconstruction of male anterior urethra
53420	Urethroplasty, 2-stage reconstruction or repair of prostatic or membranous urethra; first stage
53425	Urethroplasty, 2-stage reconstruction or repair of prostatic or membranous urethra; second stage
53430	Urethroplasty, reconstruction of female urethra
54125	Amputation of penis; complete
54400	Insertion of penile prosthesis; non-inflatable (semi-rigid)
54401	Insertion of penile prosthesis; inflatable (self-contained)
54405	Insertion of multi-component, inflatable penile prosthesis, including placement of pump, cylinders, and reservoir
54520	Orchiectomy, simple (including subcapsular), with or without testicular prosthesis, scrotal or inguinal approach
54660	Insertion of testicular prosthesis
54690	Laparoscopy, surgical; orchiectomy
55180	Scrotoplasty; complicated
55899	Unlisted procedure, male genital system [when specified as metoidioplasty or phalloplasty with penile prosthesis]
56625	Vulvectomy, simple; complete
56800	Plastic repair of introitus
57110	Vaginectomy, complete removal of vaginal wall;
57291	Construction of artificial vagina; without graft
57292	Construction of artificial vagina; with graft
57295	Revision (including removal) of prosthetic vaginal graft; vaginal approach
57296	Revision (including removal) of prosthetic vaginal graft; open abdominal approach
57426	Revision (including removal) of prosthetic vaginal graft, laparoscopic approach
58150	Total abdominal hysterectomy (corpus and cervix), with or without removal of tube(s), with or without removal of ovary(s);
58552	Laparoscopy, surgical, with vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58554	Laparoscopy, surgical, with vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)
58570	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less;
58571	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)
58572	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g;
58573	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)

HCPCS

C1813	Prosthesis, penile, inflatable

C2622	Prosthesis, penile, non-inflatable
L8699	Prosthetic implant, not otherwise specified [when specified as testicular or penile prosthesis]

ICD-10 Procedure

0HDSXZZ	Extraction of hair, external approach [when done to treat tissue donor sites for a planned phalloplasty or vaginoplasty procedure]
0UQG0ZZ	Repair vagina, open approach
0UQJ0ZZ-0UQJXZZ	Repair clitoris [by approach; includes codes 0UQJ0ZZ, 0UQJXZZ]
0UT20ZZ-0UT2FZZ	Resection of bilateral ovaries [by approach; includes codes 0UT20ZZ, 0UT24ZZ, 0UT27ZZ, 0UT28ZZ, 0UT2FZZ]
0UT70ZZ-0UT7FZZ	Resection of bilateral fallopian tubes [by approach; includes codes 0UT70ZZ, 0UT74ZZ, 0UT77ZZ, 0UT78ZZ, 0UT7FZZ]
0UT90ZZ-0UT9FZZ	Resection of uterus [by approach; includes codes 0UT90ZZ, 0UT94ZZ, 0UT97ZZ, 0UT98ZZ, 0UT9FZZ]
0UTC0ZZ-0UTC8ZZ	Resection of cervix [by approach; includes codes 0UTC0ZZ, 0UTC4ZZ, 0UTC7ZZ, 0UTC8ZZ]
0UTG0ZZ-0UTG8ZZ	Resection of vagina [by approach; includes codes 0UTG0ZZ, 0UTG4ZZ, 0UTG7ZZ, 0UTG8ZZ]
0UTJ0ZZ-0UTJXZZ	Resection of clitoris [by approach; includes codes 0UTJ0ZZ, 0UTJXZZ]
0UTM0ZZ-0UTMXZZ	Resection of vulva [by approach; includes codes 0UTM0ZZ, 0UTMXZZ]
0VRC0JZ	Replacement of bilateral testes with synthetic substitute, open approach
0VTC0ZZ-0VTC4ZZ	Resection of bilateral testes [by approach; includes codes 0VTC0ZZ, 0VTC4ZZ]
0VTS0ZZ-0VTSXZZ	Resection of penis [by approach; includes codes 0VTS0ZZ, 0VTS4ZZ, 0VTSXZZ]
0VUS07Z-0VUSX7Z	Supplement penis with autologous tissue substitute [by approach, includes codes 0VUS07Z, 0VUS47Z, 0VUSX7Z]
0VUS0JZ-0VUSXJZ	Supplement penis with synthetic substitute [by approach; includes codes 0VUS0JZ, 0VUS4JZ, 0VUSXJZ]
0VUS0KZ-0VUSXKZ	Supplement penis with nonautologous tissue substitute [by approach; includes codes 0VUS0KZ, 0VUS4KZ, 0VUSXKZ]
0W4M070	Creation of vagina in male perineum with autologous tissue substitute, open approach
0W4M0J0	Creation of vagina in male perineum with synthetic substitute, open approach
0W4M0K0	Creation of vagina in male perineum with nonautologous tissue substitute, open approach
0W4N071	Creation of penis in female perineum with autologous tissue substitute, open approach
0W4N0J1	Creation of penis in female perineum with synthetic substitute, open approach
0W4N0K1	Creation of penis in female perineum with nonautologous tissue substitute, open approach

ICD-10 Diagnosis

F64.0-F64.9	Gender identity disorders
Z87.890	Personal history of sex reassignment

When services are Not Medically Necessary:
For the procedure and diagnosis codes listed above when criteria are not met.

When services may be Reconstructive when criteria are met:

CPT

11920-11922	Tattooing, intradermal introduction of insoluble opaque pigments to correct color defects of skin, including micropigmentation; 6.0 sq cm or less [when specified for nipple/areola reconstruction after breast surgery; includes codes 11920, 11921, 11922]
11950-11954	Subcutaneous injection of filling material (eg, collagen) [includes codes 11950, 11951, 11952, 11954]
15769	Grafting of autologous soft tissue, other, harvested by direct excision (eg, fat, dermis, fascia)
15771-15772	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs
15773-15774	Grafting of autologous fat harvested by liposuction technique to face, eyelids, mouth, neck, ears, orbits, genitalia, hands, and/or feet
15876	Suction assisted lipectomy, head and neck
15877	Suction assisted lipectomy, trunk [when specified as breast liposuction for breast reduction]
17999	Unlisted procedure, skin, mucous membrane and subcutaneous tissue [when specified as

	injection of a dermal soft tissue filler]
19303	Mastectomy, simple, complete
19318	Breast reduction
19325	Breast augmentation with implant
19350	Nipple/areola reconstruction
21120-21123	Genioplasty [includes codes 21120, 21121, 21122, 21123]
21125	Augmentation, mandibular body or angle; prosthetic material
21127	Augmentation, mandibular body or angle; with bone graft, onlay or interpositional (includes obtaining autograft)
21137-21139	Reduction forehead [includes codes 21137, 21138, 21139]
21172	Reconstruction superior-lateral orbital rim and lower forehead, advancement or alteration, with or without grafts (includes obtaining autografts)
21188	Reconstruction midface, osteotomies (other than LeFort type) and bone grafts (includes obtaining autografts)
21193-21194	Reconstruction of mandibular rami, horizontal, vertical, C, or L osteotomy [with or without bone graft]
21195-21196	Reconstruction of mandibular rami and/or body, sagittal split [with or without internal rigid fixation]
21198	Osteotomy, mandible, segmental
21208	Osteoplasty, facial bones; augmentation (autograft, allograft, or prosthetic implant)
21209	Osteoplasty, facial bones; reduction
21210	Graft, bone; nasal, maxillary or malar areas (includes obtaining graft)
21215	Graft, bone; mandible (includes obtaining graft)
21230	Graft; rib cartilage, autogenous, to face, chin, nose or ear (includes obtaining graft)
21235	Graft; ear cartilage, autogenous, to nose or ear (includes obtaining graft)
21270	Malar augmentation, prosthetic material
30400-30420	Rhinoplasty, primary [includes codes 30400, 30410, 30420]
30430-30450	Rhinoplasty, secondary [includes codes 30430, 30435, 30450]
31599	Unlisted procedure, larynx [when specified as thyroid cartilage chondroplasty, tracheal shave, or voice modification surgery such as anterior glottal web formation, cricothyroid approximation, vocal cord shortening]

HCPCS

L8600	Implantable breast prosthesis, silicone or equal
Q2026	Injection, Radiesse, 0.1 ml
Q2028	Injection, sculptra, 0.5 mg

ICD-10 Procedure

0H0V07Z-0H0V0KZ	Alteration of bilateral breast, open approach; [with autologous tissue substitute, synthetic substitute, or nonautologous tissue substitute; includes codes 0H0V07Z, 0H0V0JZ, 0H0V0KZ]
0HBV0ZZ-0HBV8ZZ	Excision of breast, bilateral [by approach; includes codes 0HBV0ZZ, 0HBV3ZZ, 0HBV7ZZ, 0HBV8ZZ]
0HRW07Z-0HRXXKZ	Replacement of nipple [by approach; includes codes 0HRW07Z, 0HRW0JZ, 0HRW0KZ, 0HRW3JZ, 0HRW3KZ, 0HRW37Z, 0HRWX7Z, 0HRWXJZ, 0HRWXKZ, 0HRX07Z, 0HRX0JZ, 0HRX0KZ, 0HRX3JZ, 0HRX3KZ, 0HRX37Z, 0HRXX7Z, 0HRXXJZ, 0HRXXKZ]
0NB10ZZ	Excision of frontal bone, open approach
0NBB0ZZ	Excision of nasal bone, open approach
0NBM0ZZ	Excision of right zygomatic bone, open approach
0NBN0ZZ	Excision of left zygomatic bone, open approach
0NBR0ZZ	Excision of maxilla, open approach
0NBT0ZZ	Excision of right mandible, open approach
0NBV0ZZ	Excision of left mandible, open approach
0NU107Z-0NU10KZ	Supplement frontal bone, open approach; [with autologous tissue substitute, synthetic substitute, or nonautologous tissue substitute; includes codes 0NU107Z, 0NU10JZ, 0NU10KZ]
0NUB07Z-0NUB0KZ	Supplement nasal bone, open approach; [with autologous tissue substitute, synthetic substitute, or nonautologous tissue substitute; includes codes 0NUB07Z, 0NUB0JZ,

	0NUB0KZ]
0NUM07Z-0NUN0KZ	Supplement zygomatic bone, open approach; [right or left, with autologous tissue substitute, synthetic substitute, or nonautologous tissue substitute; includes codes 0NUM07Z, 0NUM0JZ, 0NUM0KZ, 0NUN07Z, 0NUN0JZ, 0NUN0KZ]
0NUR07Z-0NUR0KZ	Supplement maxilla, open approach; [with autologous tissue substitute, synthetic substitute, or nonautologous tissue substitute; includes codes 0NUR07Z, 0NUR0JZ, 0NUR0KZ]
0NUT07Z-0NUV0KZ	Supplement mandible, open approach; [right or left, with autologous tissue substitute, synthetic substitute, or nonautologous tissue substitute; includes codes 0NUT07Z, 0NUT0JZ, 0NUT0KZ, 0NUV07Z, 0NUV0JZ, 0NUV0KZ]
0W0407Z-0W040KZ	Alteration of upper jaw, open approach [with autologous tissue substitute, synthetic substitute, or nonautologous tissue substitute; includes codes 0W0407Z, 0W040JZ, 0W040KZ]
0W040ZZ	Alteration of upper jaw, open approach
0W0507Z-0W050KZ	Alteration of lower jaw, open approach [with autologous tissue substitute, synthetic substitute, or nonautologous tissue substitute; includes codes 0W0507Z, 0W050JZ, 0W050KZ]
0W050ZZ	Alteration of lower jaw, open approach
0WU407Z-0WU40KZ	Supplement lower jaw, open approach [with autologous tissue substitute, synthetic substitute, or nonautologous tissue substitute; includes codes 0WU407Z, 0WU40JZ, 0WU40KZ]
0WU507Z-0WU50KZ	Supplement lower jaw, open approach [with autologous tissue substitute, synthetic substitute, or nonautologous tissue substitute; includes codes 0WU507Z, 0WU50JZ, 0WU50KZ]

ICD-10 Diagnosis

F64.0-F64.9	Gender identity disorders
Z87.890	Personal history of sex reassignment

When services are Cosmetic and Not Medically Necessary:
For the procedure and diagnosis codes listed above when reconstructive criteria are not met or when the code describes a procedure designated in the Clinical Indications section as cosmetic and not medically necessary.

Discussion/General Information (Return to Clinical Indications)

The American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders, Fifth edition (DSM-5) provides criteria for the diagnosis of gender dysphoria. The DSM-5 criteria are widely recognized as the community standard by which individuals suspected of gender dysphoria are evaluated and diagnoses are confirmed. The DSM-5 criteria for gender dysphoria are as follows:

Gender dysphoria in Children*

A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months duration, as manifested by at least six of the following (one of which must be Criterion A1):
   1. A strong desire to be of the other gender or an insistence that one is the other gender (or some alternative gender, different from one's assigned gender).
   2. In boys (assigned gender), a strong preference for cross dressing or simulating female attire; or in girls (assigned gender), a strong preference for wearing only typical masculine clothing and a strong resistance to wearing of typical feminine clothing.
   3. A strong preference for cross-gender roles in make-believe play or fantasy play.
   4. A strong preference for toys, games, or activities stereotypically used or engaged in by the other gender.
   5. A strong preference for playmates of the other gender.
   6. In boys (assigned gender), a strong rejection of typically masculine toys, games and activities and a strong avoidance of rough and tumble play; or in girls (assigned gender), a strong rejection of typically feminine toys, games and activities.
   7. A strong dislike of one's sexual anatomy.
   8. A strong desire for the primary and/or secondary sex characteristics that match one's experienced gender.

B. The condition is associated with clinically significant distress or impairment in social, school, or other important areas of functioning.
   Specify if:
   With a disorder of sex development (e.g., a congenital adrenogenital disorder such as 2.55.2 [E25.0] congenital adrenal hyperplasia or 259.0 [E34.50] androgen insensitivity syndrome)
   Coding note: Code the disorder of sex development as well as gender dysphoria.

Gender dysphoria in Adolescents and Adults*

A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months duration, as manifested by at least two of the following:
   1. A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics (on in young adolescents, the anticipated secondary sex characteristics).
   2. A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender (or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics).
   3. A strong desire for the primary and /or secondary sex characteristics of the other gender.
   4. A strong desire to be of the other gender (or some alternative gender different from one's assigned gender).
   5. A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender).
   6. A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender).

B. The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.

   Specify if:

   With a disorder of sex development (e.g., a congenital adrenogenital disorder such as 2.55.2 [E25.0] congenital adrenal hyperplasia or 259.0 [E34.50] androgen insensitivity syndrome)

   Coding note: Code the disorder of sex development as well as gender dysphoria.

   Specify if:

   Post transition: The individual has transitioned to full-time living in the desired gender (with or without legalization of gender change) and has undergone (or is preparing to have) at least one cross-sex medical procedure or treatment regimen- namely regular cross-sex treatment or gender reassignment surgery confirming the desired gender (e.g., appendectomy, vaginoplasty in the natal male; mastectomy or phalloplasty in the natal female).

   *From: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition. DSM-5. American Psychiatric Association. Washington, DC. May 2013. Page 451-459.

The World Professional Association for Transgender Health's (WPATH) Standards of Care (SOC) for the Health of Transsexual, Transgender, and Gender Nonconforming People, Seventh Version (2012) provides recommendations for care of individuals with gender dysphoria. The SOC states,

> The SOC are intended to be flexible in order to meet the diverse health care needs of transsexual, transgender, and gender-nonconforming people. While flexible, they offer standards for promoting optimal health care and guiding the treatment of people experiencing gender dysphoria.

and

> Clinical departures from the *SOC* may come about because of a patient's unique anatomic, social, or psychological situation; an experienced health professional's evolving method of handling a common situation; a research protocol; lack of resources in various parts of the world; or the need for specific harm-reduction strategies.

Any variations from recommendations by WPATH within this guideline may reflect where SOC standards are, for example, not based on published medical evidence.

Procedures for the chest, also known as "top surgery", and those for the groin and reproductive organs, also known as "bottom surgery", do not need to be done in conjunction. Additionally, individuals undergoing top surgery do not need to subsequently undergo bottom surgery, or vice versa. The selection of appropriate procedures should be based on the needs of the individual in relation to the treatment of their diagnosis of gender dysphoria. The WPATH SOC addresses this issue, "The SOC do not specify an order in which different surgeries should occur. The number and sequence of surgical procedures may vary from patient to patient, according to their clinical needs."

Gender Affirming Pelvic and Gonadal Procedures

Procedures addressing pelvic and gonadal anatomy in individuals with gender dysphoria are conducted to achieve the desired physical anatomy and function aligning with the individual's experienced gender. Gender affirming pelvic and gonadal procedures have been shown in many studies to provide significant functional improvement in multiple areas (Becker, 2018; Butler, 2019; Cardoso da Silva, 2016; Castellano, 2015; De Cuypere, 2005; de Vries, 2014; Djordjevic,

2009; Guss, 2015; Hage, 2006; Jellestad, 2018; Lawrence, 2006; Miller, 2019; Murad, 2010; Olson-Kennedy, 2018; Owen-Smith, 2018; Papadopulos, 2015; Simbar, 2018; Terrier, 2014; Tucker, 2018; van [b] Grift, 2017; Weigert, 2013; Wernick, 2019; Wierckx, 2011). These improvements include gender dysphoria-related symptoms such as psychological distress, depression, anxiety, and acceptance of the individual's body. Additionally, the available literature also demonstrates significant benefits related to quality of life and overall well-being.

The medical necessity criteria above for pelvic and gonadal procedures are based on several sources including the WPATH SOC, published peer-reviewed studies and expert opinion. In addition to having an established gender dysphoria diagnosis, individuals seeking gender affirmation surgery must be of the age of legal majority in the country in which they are seeking care (in the United states: 18 years of age). Individuals seeking irreversible surgical procedures should have the capacity to make fully informed decisions, and any significant medical or mental health issues should be reasonably well controlled. Gender affirming surgical procedures present significant medical and psychological risks, and the results are difficult to reverse (Djordjevic, 2016).

Published peer-reviewed studies have shown that hormonal therapy and real-life experience living as the other gender, as well as social support and acceptance by peer and family groups, improve psychological outcomes in individuals undergoing gender affirming surgery (Eldh, 1997; Landen, 1998). Monstrey (2001) described the importance of close cooperation between the medical and behavioral specialties required for proper treatment of individuals with gender dysphoria who wish to undergo gender affirming surgery. Similar findings were reported earlier by Schlatterer (1996). One study of 188 subjects undergoing gender affirming surgery found that dissatisfaction with surgery was highly associated with sexual preference, psychological co-morbidity, and poor pre-operative body image and satisfaction (Smith, 2005).

While this document does not address the medical necessity of hormone therapy, when indicated, it is administered under medical supervision and begins the gender transition process by altering body hair, breast size or development, skin appearance and texture, body fat distribution, the size and function of sex organs, and other characteristics, including voice deepening. The WPATH guidelines support using hormonal therapy prior to pelvic and gonadal procedures.

For individuals undergoing gender affirming genital procedures, real-life experience living as the desired gender is important to validate the individual's desire and ability to incorporate into their desired gender role within their social network and daily environment. This generally involves gender-specific appearance (garments, hairstyle, etc.), involvement in various activities in the desired gender role including work or academic settings, legal acquisition of a gender appropriate first name, and acknowledgement by others of the new gender role. With regard to real-life experience, the WPATH states:

> The criterion noted above for some types of genital surgeries – i.e., that patients engage in 12 continuous months of living in a gender role that is congruent with their gender identity – is based on expert clinical consensus that this experience provides ample opportunity for patients to experience and socially adjust in their desired gender role, before undergoing irreversible surgery. As noted in section VII, the social aspects of changing one's gender role are usually challenging – often more so than the physical aspects. Changing gender role can have profound personal and social consequences, and the decision to do so should include an awareness of what the familial, interpersonal, educational, vocational, economic, and legal challenges are likely to be, so that people can function successfully in their gender role. Support from a qualified mental health professional and from peers can be invaluable in ensuring a successful gender role adaptation (Bockting, 2008).
>
> The duration of 12 months allows for a range of different life experiences and events that may occur throughout the year (e.g., family events, holidays, vacations, season-specific work or school experiences). During this time, patients should present consistently, on a day-to-day basis and across all settings of life, in their desired gender role. This includes coming out to partners, family, friends, and community members (e.g., at school, work, other settings).
>
> Health professionals should clearly document a patient's experience in the gender role in the medical chart, including the start date of living full time for those who are preparing for genital surgery. In some situations, if needed, health professionals may request verification that this criterion has been fulfilled: They may communicate with individuals who have related to the patient in an identity-congruent gender role, or request documentation of a legal name and/or gender marker change, if applicable.

Gender Affirming Chest Surgery:

Gender affirming chest surgery in individuals with gender dysphoria is reconstructive, in that the procedure is intended to address the significant variation from normal appearance for the experienced gender. The evidence addressing gender affirming chest surgery for the treatment of gender dysphoria supports a consistent association between surgery and satisfaction with breast appearance, psychological and sexual well-being, and body image and attractiveness; however, evidence supporting improvements in functional outcomes (for example, quality of life, gender dysphoria symptoms, or sequelae of severe illness, including crisis visits, suicide attempts, etc.) is less clear (Becker, 2018; Miller, 2019; Olson-Kennedy, 2018; Weigert, 2013). Criteria for chest surgery are generally consistent with genital/gonadal surgery including requirements related to age, capacity to consent, diagnosis of gender dysphoria, and reasonably well controlled concomitant physical and mental health conditions.

For individuals born with male anatomy and considering gender affirming breast surgery, hormone therapy results in the development of at least some breast tissue in most cases. Breast development generally occurs within the first 12 months (although development may continue through 2-3 years of therapy) (De Blok, 2020a). Published studies have reported that final breast size varies significantly, anywhere from no growth to a C-cup, although the average individual achieves an A-cup in size. WPATH notes "Although not an explicit criterion, it is recommended that patients undergo feminizing hormone therapy (minimum 12 months) prior to gender affirming breast augmentation surgery. The purpose is to maximize breast growth in order to obtain better surgical (aesthetic) results." To establish a reconstructive intent, it is important that an individual has undergone a minimum of 12 months of continuous hormonal therapy (when recommended by a mental health professional), and insufficient breast development has occurred.

Gender Affirming Chest Surgery in Individuals Under the Age of 18 (Return to Clinical Indications)

Further consideration of a gender affirming chest procedure in select individuals under 18 years of age may be appropriate; there may exist extenuating circumstances, such as the level of maturity of the individual, duration of dysphoric symptoms, medical and mental health, and other factors, that should be considered in consultation with a provider with experience treating adolescents with gender dysphoria. The WPATH SOC provides the following guidance for individuals under the age of 18:

> Genital surgery should not be carried out until (i) patients reach the legal age of majority to give consent for medical procedures in a given country, and (ii) patients have lived continuously for at least 12 months in the gender role that is congruent with their gender identity. The age threshold should be seen as a minimum criterion and not an indication in and of itself for active intervention.
>
> Chest surgery in FtM patients could be carried out earlier, preferably after ample time of living in the desired gender role and after one year of testosterone treatment. The intent of this suggested sequence is to give adolescents sufficient opportunity to experience and socially adjust in a more masculine gender role, before undergoing irreversible surgery. However, different approaches may be more suitable, depending on an adolescent's specific clinical situation and goals for gender identity expression.

Gender Affirming Facial Surgery (Return to Clinical Indations)

In some cases, an individual's facial features may be outside of what is perceived as normal for their experienced gender. Gender affirming facial surgery in individuals with gender dysphoria is considered reconstructive, in that the procedure is intended to address as a significant variation from normal appearance for the experienced gender.

The published data regarding gender affirming facial surgery generally support associations between surgery and the likelihood of being properly identified by the experienced gender by observers; however, evidence supporting improvements in functional outcomes (for example, quality of life, gender dysphoria symptoms, or sequelae of severe illness, including crisis visits, suicide attempts, etc.) is less clear (Ainsworth, 2010; Cohen, 2018; Fisher, 2020; Morrison, 2020). There is some data to demonstrate that the long-term use of hormone therapy does quantifiably femininize or masculinize facial features, thus extended use of hormone therapy prior to facial feminization may be warranted in some circumstances (Tebbens, 2019).

The WPATH does not recommend specific criteria for the use of facial feminization procedures. Instead, they note the following:

> Unfortunately, in the field of plastic and reconstructive surgery (both in general and specifically for gender-related surgeries), there is no clear distinction between what is purely reconstructive and what is purely cosmetic. Most plastic surgery procedures actually are a mixture of both reconstructive and cosmetic components.

> While most professionals agree that genital surgery and mastectomy cannot be considered purely cosmetic, opinions diverge as to what degree other surgical procedures (e.g., breast augmentation, facial feminization surgery) can be considered purely reconstructive. Although it may be much easier to see a phalloplasty or a vaginoplasty as an intervention to end lifelong suffering, for certain patients an intervention like a reduction rhinoplasty can have a radical and permanent effect on their quality of life, and therefore is much more medically necessary than for somebody without gender dysphoria.

Individuals with gender dysphoria who undergo gender affirming procedures may seek additional procedures to further alter their facial appearance when existing facial appearance demonstrates significant variation from normal appearance for the experienced gender. Such procedures may include the following:

- Facial bone reconstruction
- Facial implants
- Jaw reduction (jaw contouring)
- Lip reduction/enhancement
- Lipofilling/collagen injections
- Liposuction
- Nose implants
- Rhinoplasty
- Thyroid cartilage reduction (chondroplasty)

Gender Affirming Voice Modification Surgery

Gender affirming voice modification surgery is considered reconstructive for individuals when existing vocal presentation demonstrates significant variation from normal for the experienced gender. WPATH notes:

> Some transsexual, transgender, and gender-nonconforming people will undergo voice feminization surgery. (Voice deepening can be achieved through masculinizing hormone therapy, but feminizing hormones do not have an impact on the adult MtF (sic: male-to-female) voice.) There are varying degrees of satisfaction, safety, and long-term improvement in patients who have had such surgery. It is recommended that individuals undergoing voice feminization surgery also consult a voice and communication specialist to maximize the surgical outcome, help protect vocal health, and learn nonpitch related aspects of communication. Voice surgery procedures should include follow-up sessions with a voice and communication specialist who is licensed and/or credentialed by the board responsible for speech therapists/speech-language pathologists in that country.

WPATH notes that voice surgery to obtain a deeper voice in individuals desiring body masculinization is rare but may be recommended in some cases, such as when hormone therapy has been ineffective.

Published data evaluating gender affirming voice modification surgery is limited to postoperative satisfaction and vocal outcomes; functional outcomes (for example, quality of life, gender dysphoria symptoms, or sequelae of severe illness, including crisis visits, suicide attempts, etc.) have not been specifically assessed (Kim, 2020).

Referral Letters (Return to Clinical Indications)

An independent assessment of an individual by a qualified mental health professional is considered standard of care before an individual undergoes a gender affirming surgical procedure.

The SOC states the following regarding referral letters in support of gender affirming surgery:

> The recommended content of the referral letters for surgery is as follows:
>
> 1. The client's general identifying characteristics;
> 2. Results of the client's psychosocial assessment, including any diagnoses;
> 3. The duration of the mental health professional's relationship with the client, including the type of evaluation and therapy or counseling to date;
> 4. An explanation that the criteria for surgery have been met, and a brief description of the clinical rationale for supporting the patient's request for surgery;
> 5. A statement about the fact that informed consent has been obtained from the patient;
> 6. A statement that the mental health professional is available for coordination of care and welcomes a phone call to establish this.

While the SOC also states:

For providers working within a multidisciplinary specialty team, a letter may not be necessary, rather, the assessment and recommendation can be documented in the patient's chart.

Additionally, the SOC provides the following recommendations regarding the credentials for mental health professionals who work with adults presenting with gender dysphoria:

1. A master's degree or its equivalent in a clinical behavioral science field. This degree, or a more advanced one, should be granted by an institution accredited by the appropriate national or regional accrediting board. The mental health professional should have documented credentials from a relevant licensing board or equivalent for that country.
2. Competence in using the Diagnostic Statistical Manual of Mental Disorders and/or the International Classification of Diseases for diagnostic purposes.
3. Ability to recognize and diagnose coexisting mental health concerns and to distinguish these from gender dysphoria.
4. Documented supervised training and competence in psychotherapy or counseling.
5. Knowledgeable about gender-nonconforming identities and expressions, and the assessment and treatment of gender dysphoria.
6. Continuing education in the assessment and treatment of gender dysphoria. This may include attending relevant professional meetings, workshops, or seminars; obtaining supervision from a mental health professional with relevant experience; or participating in research related to gender nonconformity and gender dysphoria.

This statement from the SOC does not govern CG-SURG-27. A letter including all of the recommended items should be included in surgical requests.

Other Guidelines

In late 2017, the Endocrine Society released a clinical practice guideline for the endocrine treatment of gender-dysphoric/gender-incongruent persons (Hembree, 2017). This publication was co-sponsored by the American Association of Clinical Endocrinologists, the American Society of Andrology, the European Society for Pediatric Endocrinology, the European Society of Endocrinology, the Pediatric Endocrine Society, and WPATH. Among other recommendations this document includes the following:

2.1. We suggest that adolescents who meet diagnostic criteria for GD/gender incongruence, fulfill criteria for treatment, and are requesting treatment should initially undergo treatment to suppress pubertal development. (2 | ⊕⊕○○)
2.2. We suggest that clinicians begin pubertal hormone suppression after girls and boys first exhibit physical changes of puberty. (2 |⊕⊕○○)
2.3. We recommend that, where indicated, GnRH analogues are used to suppress pubertal hormones. (1 | ⊕⊕○○)
2.4. In adolescents who request sex hormone treatment (given this is a partly irreversible treatment), we recommend initiating treatment using a gradually increasing dose schedule after a multidisciplinary team of medical and MHPs has confirmed the persistence of GD/gender incongruence and sufficient mental capacity to give informed consent, which most adolescents have by age 16 years. (1 |⊕⊕○○)
2.5. We recognize that there may be compelling reasons to initiate sex hormone treatment prior to the age of 16 years in some adolescents with GD/gender incongruence, even though there are minimal published studies of gender-affirming hormone treatments administered before age 13.5 to 14 years. As with the care of adolescents ≥16 years of age, we recommend that an expert multidisciplinary team of medical and MHPs manage this treatment. (1 |⊕○○○)
5.1. We recommend that a patient pursue genital gender-affirming surgery only after the MHP and the clinician responsible for endocrine transition therapy both agree that surgery is medically necessary and would benefit the patient's overall health and/or well-being. (1 |⊕⊕○○)
5.2. We advise that clinicians approve genital gender affirming surgery only after completion of at least 1 year of consistent and compliant hormone treatment, unless hormone therapy is not desired or medically contraindicated. (Ungraded Good Practice Statement)
5.3. We advise that the clinician responsible for endocrine treatment and the primary care provider ensure appropriate medical clearance of transgender individuals for genital gender-affirming surgery and collaborate with the surgeon regarding hormone use during and after surgery. (Ungraded Good Practice Statement)
5.4. We recommend that clinicians refer hormone treated transgender individuals for genital surgery when: (1) the individual has had a satisfactory social role change, (2) the individual is satisfied about the hormonal effects, and (3) the individual desires definitive surgical changes. (1 |⊕⊕○○○)

5.5. We suggest that clinicians delay gender-affirming genital surgery involving gonadectomy and/or hysterectomy until the patient is at least 18 years old or legal age of majority in his or her country. (2 |⊕⊕○○).

Note: "MHP" is the Endocrine Society's abbreviation for "mental health professional".

Hair removal Procedures

In many instances, the creation of a neovagina or a urethra for a neopenis requires an autologous skin graft from the forearm or thigh. Such skin may be excessively hairy, which will impair the function of the newly constructed organ if not permanently removed. Pre-operative permanent hair removal treatments to these areas may be warranted to prevent post-operative complications.

Procedures to Address Postoperative Complications of Gender Affirming Surgery and Reversal Surgery (Return to Clinical Indications)

Procedures to address postoperative complications of a prior gender affirming surgery (for example, scarring, stenosis, infection, etc.) are not considered a separate gender affirming surgery procedure and are not addressed in this document.

Reversal of a prior gender affirming surgery procedure is rare and is considered gender affirming surgery. According to the literature on this issue, the predominant factor in requests for reversals are regret, which has been further associated with age greater than 30 at first surgery, personality disorders, early loss of both parents, social instability, preoperative sexual orientation for heterosexual male-to-female (MtF) individuals, degree of social support, secondary transsexualism, early decision to undergo surgery and dissatisfaction with surgical results (Blanchard, 1989; Landén, 1998; Lawrence, 2003; Lindemalm, 1986 and 1987; Olsson, 2006).

Djordjevic (2016) reported on the outcomes of surgical reversal surgery in MtF individuals wishing to transition back to male. While the main focus of this paper is related to surgical outcomes, the authors reported on characteristics of the participating subjects and contributing factors to the reversal decisions. The seven subjects had an absence of "real-life experience" prior to surgery, absence or inappropriate hormonal treatment, recommendations by inexperienced professionals, and insufficient hormonal therapy and medical follow-up. Furthermore, they failed to fulfill the complete diagnostic criteria for GID. The authors concluded that the main factor contributing to regret was absence of proper pretreatment assessment. In their reversal protocol, each subject was required to have recommendations from three well-known WPATH psychiatrists prior to reversal procedures.

The available evidence indicates the importance of thorough preoperative physical and psychological evaluation and treatment as being a critical factor in postoperative success. As noted above, these aspects of the treatment process are critical to sufficiently prepare an individual for the social, physical, and mental ramifications of the decision to undergo gender affirming surgery.

The clinical evidence addressing the satisfaction and quality of life following gender affirming surgery is limited, and the reported findings are mixed (Cardoso da Silva, 2016; Castellano, 2015). It is important that proper and thorough pre-operative work-up and preparation be conducted in individuals considering such life-altering procedures. Additionally, long-term post-operative follow-up, including availability of mental health services, may also contribute to satisfaction with surgical results.

Other Procedures

Additional surgeries have been proposed to improve the gender appropriate appearance of the individual. Such procedures may be considered cosmetic and are not reconstructive when intended to change a physical appearance that would be considered within normal human anatomic variation or are primarily intended to preserve or improve appearance irrespective of gender-defining features.

Such procedures may include the following when one or more of the medical necessary or reconstructive criteria above have not been met:

A. Abdominoplasty
B. Bilateral mastectomy
C. Blepharoplasty
D. Breast augmentation
E. Brow lift
F. Face lift
G. Facial bone reconstruction

H. Facial implants
I. Gluteal implants
J. Hair removal (for example, electrolysis or laser) and hairplasty
K. Jaw reduction (jaw contouring)
L. Lip reduction/enhancement
M. Lipofilling/collagen injections
N. Liposuction
O. Nose implants
P. Pectoral implants
Q. Rhinoplasty
R. Thyroid cartilage reduction (chondroplasty)
S. Voice modification surgery

WPATH notes that other surgeries for assisting in body feminization or masculinization may include suction-assisted lipoplasty (contour modeling) of the waist, face-lift, blepharoplasty (rejuvenation of the eyelid), gluteal augmentation (implants/lipofilling), liposuction, lipofilling, pectoral implants, and "various aesthetic procedures." Such procedures are considered cosmetic when intended to change a physical appearance that would be considered within normal human anatomic variation or are primarily intended to preserve or improve appearance.

Review Considerations:

Reconstructive procedures address features that are distinctly and directly related to gender appearance (or in the case of gender affirming voice modification surgery, vocal presentation), when documentation sufficiently demonstrates significant variation from what is considered normal for the experienced gender. When multiple procedures are requested, each procedure should be considered separately as some procedures may be cosmetic and others may be reconstructive. Procedures primarily intended to preserve or improve appearance (that is: independent of any gender-defining feature or overall gender appearance) are considered cosmetic.

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History

Status	Date	Action
Revised	05/13/2021	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated title and rest of document to replace "reassignment" with "affirming". Alphabetized procedures in MN statements. Revised gender dysphoria criteria in all MN statements. Added "or intolerance" to hormone therapy in related MN criteria. Clarified hair removal MN statement. Moved bilateral mastectomy from MN to Reconstructive section. Added breast augmentation and breast reduction procedures to Reconstructive section. Moved gender affirming facial feminization procedures and voice modification surgery from Cosmetic and NMN to Reconstructive section. Removed voice therapy from scope of document. Clarified the NMN statement and Cosmetic and NMN statement. Revised Further Considerations statement to include breast augmentation and breast

		reduction procedures. Updated Discussion and References sections. Updated Coding section with additional codes for facial and chest surgery.
Revised	02/11/2021	MPTAC review. Clarified note regarding number of letters required for mastectomy procedures. The phrase "cosmetic" was clarified to read "cosmetic and not medically necessary". Updated Description, Coding and References sections.
	12/16/2020	Updated Coding section with 01/01/2021 CPT changes, revised descriptors for codes 19318, 19325; removed deleted ICD-10-PCS codes.
Revised	08/13/2020	MPTAC review. Added penile prostheses to MN statement addressing phalloplasty procedures. Updated Description and References sections. Reformatted Coding section and added codes 54400, 54401, 54405, 55899, C1813, C2622, L8699.
Revised	05/14/2020	MPTAC review. Added text to MN statement for mastectomy referring reader to see Further Considerations section for individuals under 18 years of age. Added new Further Considerations section addressing mastectomy procedures for individuals under 18 years of age. Updated Description, Discussion, References and Index sections.
	04/01/2020	Updated Coding section; added CPT 19318 and removed deleted code 19304.
Revised	11/07/2019	MPTAC review. Updated title and document contents to replace "sex reassignment" with "gender reassignment" and "his or her" with "their". Made minor language revisions to Clinical Indications section. Clarified MN statement regarding hair removal procedures. Added text to the Background section regarding WPATH recommendations for the content of referral letters. Updated Discussion and References sections. Updated Coding section with 01/01/2020 CPT changes; noted 19304 is deleted effective 12/31/2019.
Revised	01/24/2019	MPTAC review. Revised MN criteria for bilateral mastectomy to require one referral letter. Added new notes addressing treatment of postoperative complications and reversal procedures. Updated Discussion, Coding, and References sections.
Revised	11/08/2018	MPTAC review. Added criteria for referral letters to mastectomy MN statement.
Revised	03/22/2018	MPTAC review.
Revised	02/23/2018	Behavioral Health Subcommittee review. Clarification of mastectomy criteria to remove specification that a female must be transitioning to be a male. Clarification of several Cosmetic indications.
	01/01/2018	The document header wording updated from "Current Effective Date" to "Publish Date." Updated Coding section; removed CPT 55970, 55980 (not applicable).
Revised	08/03/2017	MPTAC review.
Revised	07/21/2017	Behavioral Health Subcommittee review. Added note regarding timing of "top" and "bottom" surgical procedures. Added new statement regarding nipple reconstructions following mastectomy. Updated Coding and References sections.
Revised	02/02/2017	MPTAC review.
Revised	01/20/2017	Behavioral Health Subcommittee review. Updated criteria regarding confirmation of female gender prior to bilateral mastectomy in female-to-male transitions. Updated Reference sections.
Revised	08/04/2016	MPTAC review.
Revised	07/29/2016	Behavioral Health Subcommittee review. Updated formatting in the Clinical Indications section. Added bilateral mastectomy to MN section with criteria. Updated Reference sections. Updated Coding section to include 10/01/2016 ICD-10-CM changes.
Revised	05/05/2016	MPTAC review. Revised title from "Gender Reassignment Surgery" to "Sex Reassignment Surgery". Updated Coding, Rationale and Discussion section.
Revised	02/04/2016	MPTAC review.
Revised	01/29/2016	Behavioral Health Subcommittee review. Added new medically necessary statement addressing the use of hair removal procedures to treat tissue donor sites for a planned phalloplasty or vaginoplasty procedure. Added additional procedures to Cosmetic statement. Updated Coding and Rationale sections. Removed ICD-9 codes from Coding section.
Revised	08/06/2015	MPTAC review.
Revised	07/31/2015	Behavioral Health Subcommittee review. Revised text regarding educational and professional qualifications required for individuals submitting referral letters to include master's-level practitioners. Added text to referral letter criteria, requiring that letters need to be no more than 12 months old at time of request. Revised criteria regarding

		hormone therapy requirements. Replaced the word 'surgeries' with 'procedures' in Cosmetic statement. Added note to Cosmetic section.
Reviewed	08/14/2014	MPTAC review.
Reviewed	08/08/2014	Behavioral Health Subcommittee review.
Revised	08/08/2013	MPTAC review.
Revised	07/26/2013	Behavioral Health Subcommittee review. Revised document text to align with new DSM-5 terminology and diagnostic criteria. Updated Discussion and Reference sections.
Revised	08/09/2012	MPTAC review.
Revised	08/03/2012	Behavioral Health Subcommittee review. Created separate criteria sets for gonad and reproductive organ procedures and for external genital procedures in alignment with the WPATH SOC7. Deleted the criteria requiring 12 months of continuous living in desired gender role from the reproductive organ procedures criteria set. Deleted criteria requiring "Demonstrable knowledge of the required length of hospitalizations, likely complications, and post-surgical rehabilitation requirements of various surgical approaches". Deleted "not due to chromosomal abnormality" from medically necessary criteria. Updated Coding, Discussion and Reference sections.
Revised	02/16/2012	MPTAC review.
Revised	02/10/2012	Behavioral Health Subcommittee review. Significantly revised the medically necessary to align with new 2012 WPATH Standards of Care document. Updated Rationale and Reference sections.
Reviewed	05/19/2011	MPTAC review.
Reviewed	05/13/2010	MPTAC review. Updated Reference section.
Reviewed	11/19/2009	MPTAC review. Updated Coding section with 01/01/2010 CPT changes.
Reviewed	11/20/2008	MPTAC review. Updated Coding section.
Reviewed	11/29/2007	MPTAC review. Updated Coding section with 01/01/2008 CPT changes.
New	12/07/2006	MPTAC initial guideline development.

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