

FAQS ABOUT AFFORDABLE CARE ACT IMPLEMENTATION PART 47

July 19, 2021

Set out below are Frequently Asked Questions (FAQs) regarding implementation of the Affordable Care Act. These FAQs have been prepared jointly by the Departments of Labor, Health and Human Services (HHS), and the Treasury (collectively, the Departments). Like previously issued FAQs (available at <https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs> and <http://www.cms.gov/ccio/resources/fact-sheets-and-faqs/index.html>), these FAQs answer questions from stakeholders to help people understand the law and benefit from it, as intended. Clinical stakeholders should follow the HIV Preexposure Prophylaxis (PrEP) Clinical Practice Guideline and Providers Supplement: Update 2021.

Coverage of Preventive Services

Public Health Service Act (PHS Act) section 2713 and its implementing regulations¹ require non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance coverage (referred to in this document as plans and issuers) to provide benefits for, and prohibit the imposition of cost-sharing requirements with respect to, the following:

- Evidence-based items or services that have in effect a rating of “A” or “B” in the current recommendations of the United States Preventive Services Task Force (USPSTF) with respect to the individual involved, except for the recommendations of the USPSTF regarding breast cancer screening, mammography, and prevention issued in or around November 2009, which are not considered in effect for this purpose;²
- Immunizations for routine use in children, adolescents, and adults that have in effect a recommendation from the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) with respect to the individual involved;³

¹ 26 CFR 54.9815-2713; 29 CFR 2590.715-2713; 45 CFR 147.130.

² The USPSTF published updated breast cancer screening recommendations in January 2016. However, section 223 of Division H of the Consolidated Appropriations Act, 2021 (Pub. L. 116-260) requires that for purposes of PHS Act section 2713, USPSTF recommendations relating to breast cancer screening, mammography, and prevention issued before 2009 remain in effect until January 1, 2023.

³ In addition, under section 3203 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) and its implementing regulations, plans and issuers must cover, without cost-sharing requirements, any qualifying coronavirus preventive services pursuant to section 2713(a) of the PHS Act and its implementing regulations (or any successor regulations). The term “qualifying coronavirus preventive service” means an item, service, or immunization that is intended to prevent or mitigate coronavirus diseases 2019 (COVID-19) and that is, with respect to the individual involved (1) an evidence-based item or service that has in effect a rating of “A” or “B” in the current USPSTF recommendations; or (2) an immunization that has in effect a recommendation from ACIP (regardless of whether the immunization is recommended for routine use). 85 FR 71142 (Nov. 6, 2020).

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law.

- With respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration (HRSA); and
- With respect to women, preventive care and screening provided for in comprehensive guidelines supported by HRSA, to the extent not already included in certain recommendations of the USPSTF.⁴

If a recommendation or guideline does not specify the frequency, method, treatment, or setting for the provision of a recommended preventive service, the plan or issuer may use reasonable medical management techniques to determine any coverage limitations.⁵ However, the Departments have clarified in previous guidance that plans and issuers must accommodate any individual for whom a particular medication (generic or brand name) would be medically inappropriate, as determined by the individual's health care provider, by having a mechanism for waiving the otherwise applicable cost sharing for the brand or non-preferred brand version. If utilizing reasonable medical management techniques, plans and issuers must have an easily accessible, transparent, and sufficiently expedient exceptions process that is not unduly burdensome.⁶

The clarifying guidance in Q1-Q3 explains how the Departments expect plans and issuers subject to section 2713 of the PHS Act to cover without cost sharing the recommended preventive services under the requirements of the applicable implementing regulations. In consideration of the possibility that plans and issuers may not have understood that the regulatory coverage requirements apply to all support services of the USPSTF's recommendation for pre-exposure prophylaxis (PrEP), the Departments will not take enforcement action against a plan or issuer for failing to provide coverage of such services through the period ending 60 days after publication of these FAQs, and encourage states to take a similar enforcement approach.

⁴ For accommodations and religious and moral exemptions with respect to coverage of certain recommended contraceptive services, see 26 CFR 54.9815-2713A; 29 CFR 2590.715-2713A; 45 CFR 147.131 through 147.133.

⁵ 26 CFR 54.9815-2713(a)(4); 29 CFR 2590.715-2713(a)(4); 45 CFR 147.130(a)(4).

⁶ FAQs about Affordable Care Act Implementation Part XII (Feb. 20, 2013), Q14, available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xii.pdf> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/aca_implementation_faqs12; FAQs about Affordable Care Act Implementation Part XXVI (May 11, 2015), Q2, available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf. In addition, the Departments have previously clarified that plans and issuers must cover, without cost sharing, items and services that are integral to the furnishing of the recommended preventive service, regardless of whether the item or service is billed separately. For example, the Departments clarified in subregulatory guidance that a plan or issuer may not impose cost sharing for polyp removal during a preventive screening colonoscopy, as the service is an integral part of a colonoscopy, and also stated that anesthesia provided in connection with a preventive colonoscopy must be covered without cost sharing if the attending provider determines that anesthesia would be medically appropriate for the individual. Similarly, several of the recommended preventive services involve screenings for the presence of certain health conditions, such as diabetes, or a variety of sexually transmitted infections. These recommended screenings, typically performed by laboratories, cannot be conducted without first collecting a specimen. Accordingly, the Departments have stated that plans and issuers must cover without cost sharing both the specimen collection and the recommended preventive service, regardless of how the specimen collection is billed. 85 FR 71142, 71174 (Nov. 6, 2020).

Coverage of Pre-Exposure Prophylaxis

On June 11, 2019, the USPSTF released a recommendation with an “A” rating that clinicians offer PrEP with “effective antiretroviral therapy to persons who are at high risk of human immunodeficiency virus (HIV) acquisition.” Accordingly, plans and issuers must cover PrEP consistent with the USPSTF recommendation without cost sharing for plan years (in the individual market, policy years) beginning on or after one year from the issue date of the recommendation (in this case, plan or policy years beginning on or after June 30, 2020).⁷

Q1. Are plans and issuers required to provide coverage without cost sharing for items or services that the USPSTF recommends should be received by a participant, beneficiary, or enrollee prior to being prescribed anti-retroviral medication as part of the determination of whether such medication is appropriate for the individual and for ongoing follow-up and monitoring?

Yes. As described in the USPSTF Final Recommendation Statement, the purpose of the recommendation is to decrease the risk of HIV transmission for persons who are at high risk of HIV infection.⁸ The USPSTF also notes that “the CDC provides a complete discussion of implementation considerations for PrEP, including baseline and follow-up testing and monitoring, time to achieving protection, and discontinuing PrEP.” The USPSTF recommendation cites CDC guidelines,⁹ which advise that PrEP is a comprehensive intervention comprised of antiretroviral medication and essential support services (including medication self-management/adherence counseling, risk reduction strategies, and mental health counseling, etc.) that ensure PrEP is administered safely and effectively to persons who need it. Consistent with the CDC’s advice, the USPSTF recommendation for PrEP includes a combination of baseline and monitoring services (described below), which are essential to the efficacy of PrEP. These services include certain clinical assessments necessary to ensure the medication prescribed for PrEP is given to at-risk persons who are not infected with HIV and who have no medical contraindications, and to monitor patients taking the medication to ensure its safe, ongoing use.

To this end, the USPSTF Final Recommendation Statement, in the Other Considerations, Implementation section, provides in relevant part:

“Before prescribing PrEP, clinicians should exclude persons with acute or chronic HIV infection through taking a medical history and HIV testing. The 2-drug antiretroviral regimen used in PrEP, when used alone, is not an effective treatment for HIV infection,

⁷ 26 CFR 54.9815-2713(b); 29 CFR 2590.715-2713(b); 45 CFR 147.130(b). Generally, for purposes of section 2713 of the PHS Act, USPSTF recommendations are considered to be issued on the last day of the month in which the USPSTF publishes or otherwise releases the recommendation. 75 FR 41726, 41729 (July 19, 2010).

⁸ USPSTF, Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis, JAMA. 2019, 321(22):2203-2213, available at <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis>.

⁹ The CDC guidelines on PrEP for the prevention of HIV infection are available at <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2017.pdf> and <https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-provider-supplement-2017.pdf>. Additional CDC resources on PrEP for both clinicians and consumers are available at <https://www.cdc.gov/hiv/risk/prep/index.html>, such as HIV Nexus Clinician Resources: PrEP.

and its use in persons living with HIV can lead to the emergence of, or selection for, drug-resistant HIV infection. It is also generally recommended that kidney function testing, serologic testing for hepatitis B and C virus, testing for other [sexually transmitted infections (STI)], and pregnancy testing (when appropriate) be conducted at the time of or just before initiating PrEP. Ongoing follow-up and monitoring, including HIV testing every 3 months, is also suggested ... Reduced adherence is associated with marked declines in effectiveness. Therefore, adherence support is a key component of providing PrEP. Components of adherence support include establishing trust and open communication with patients, patient education, reminder systems for taking medication, and attention to medication adverse effects and having a plan to address them.”

The USPSTF Final Recommendation Statement encompasses FDA-approved PrEP antiretroviral medications, as well as the following baseline and monitoring services:

1. *HIV testing*: Persons must be tested and confirmed to be HIV uninfected before starting PrEP and tested again for HIV every three months while taking PrEP so that, if they have become infected, the medication can be stopped promptly before it could cause a harmful drug resistance to develop.
2. *Hepatitis B and C testing*: Persons should be screened for hepatitis B virus (HBV) at baseline for the initiation of PrEP consistent with CDC guidelines, so that when the PrEP medications, which suppress HBV replication in the liver, are stopped, persons can be monitored to ensure safety and to rapidly identify any potential injury. Additionally, persons should be screened for hepatitis C virus (HCV) infection at baseline and periodically consistent with CDC guidelines. Screening for HCV infection is indicated for all people with ongoing risk of contracting HCV.
3. *Creatinine testing and calculated estimated creatine clearance (eCrCl) or glomerular filtration rate (eGFR)*: For persons taking PrEP, their estimated eCrCl or eGFR must be measured and calculated at the beginning of treatment to assess if kidney function is in the range for safe prescribing of PrEP medication. Creatinine and eCrCL or eGFR should be checked periodically consistent with CDC guidelines while on PrEP medication to assess for potential kidney injury and to ensure that it is safe to continue PrEP medication.
4. *Pregnancy testing*: Persons with childbearing potential taking PrEP must be tested for pregnancy at baseline and should be tested again periodically thereafter consistent with CDC guidelines until PrEP is stopped so that pregnant patients, together with their health care providers, can make a fully informed and individualized decision about taking PrEP.
5. *Sexually transmitted infection (STI) screening and counseling*: Persons taking PrEP must be screened for STIs at baseline and should be screened periodically thereafter consistent with CDC guidelines, which may require multiple anatomic site testing (i.e., genital, oropharyngeal, and rectal) for gonorrhea and chlamydia, and testing for syphilis, together with behavioral counseling, which are recommended to reduce the risk of STIs, the presence of which may increase the likelihood of acquiring HIV sexually.
6. *Adherence counseling*: Persons taking PrEP must be offered regular counseling for assessment of behavior and adherence consistent with CDC guidelines to ensure that PrEP is used as prescribed and to maximize PrEP’s effectiveness.

Plans and issuers are also required to cover without cost sharing office visits associated with each recommended preventive service applicable to the participant, beneficiary, or enrollee when the service is not billed separately (or is not tracked as individual encounter data separately) from an office visit, and the primary purpose of the office visit is the delivery of the recommended preventive service.¹⁰

Q2: May a plan or issuer use reasonable medical management techniques to restrict the frequency of benefits for services specified in the USPSTF recommendation for PrEP, such as HIV and STI screening, in a manner specified under other existing USPSTF recommendations, or otherwise?

No. The USPSTF PrEP recommendation specifies the frequency of certain services for individuals specified in the recommendation. Plans and issuers may use reasonable medical management techniques to determine the frequency, method, treatment, or setting for the provision of a recommended preventive service only to the extent not specified in the applicable recommendation or guideline.

In addition, when PrEP is medically appropriate for an individual specified in the USPSTF recommendation, as determined by the individual's health care provider, it would not be reasonable to restrict the number of times the individual may start PrEP.

Q3: When may a plan or issuer use reasonable medical management techniques with respect to coverage of PrEP?

Consistent with PHS Act section 2713 and its implementing regulations, plans and issuers may use reasonable medical management techniques to encourage individuals prescribed PrEP to use specific items and services, to the extent the frequency, method, treatment, or setting is not specified in the USPSTF recommendation. For example, since the branded version of PrEP is not specified in the USPSTF recommendation, plans and issuers may cover a generic version of PrEP without cost sharing and impose cost sharing on an equivalent branded version.¹¹ However, plans and issuers must accommodate any individual for whom a particular PrEP medication (generic or brand name) would be medically inappropriate, as determined by the individual's health care provider, by having a mechanism for waiving the otherwise applicable cost sharing for the brand or non-preferred brand version.¹²

If utilizing reasonable medical management techniques, plans and issuers must have an easily accessible, transparent, and sufficiently expedient exceptions process (for example, one that

¹⁰ 26 CFR 54.9815-2713(a)(2); 29 CFR 2590.715-2713(a)(2); 45 CFR 147.130(a)(2).

¹¹ Currently, there are two medications approved for daily use as PrEP. Both are combinations of two anti-HIV drugs in a single pill: (1) Emtricitabine (F) 200 mg in combination with tenofovir disoproxil fumarate (TDF) 300 mg (F-TDF; brand name Truvada®) is recommended for all adults and adolescents at risk for HIV through sex or injection drug use; and (2) Emtricitabine (F) 200 mg in combination with tenofovir alafenamide (TAF) 25 mg (F-TAF; brand name Descovy®) is recommended for adults and adolescents at risk for HIV through sex, excluding people at risk through vaginal sex.

¹² To comply with essential health benefits requirements, non-grandfathered individual and small group market insurance plans must also have an exceptions process in place that complies with 45 CFR 156.122(c).

allows prescribing and accessing PrEP medications on the same day that a participant, beneficiary, or enrollee receives a negative HIV test or decides to start taking PrEP) that is not unduly burdensome on the individual or a provider (or other individual acting as an authorized representative), as set forth in the Departments' previous guidance.¹³

¹³ FAQs about Affordable Care Act Implementation Part XXVI (May 11, 2015), available at <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/aca-part-xxvi.pdf> and https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf.