Medicare National Coverage Determinations Manual
Chapter 1, Part 2 (Sections 90 – 160.26)
Coverage Determinations

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90 - Genetics
(Rev. 1, 10-03-03)

No coverage determinations

90.1 - Pharmacogenomic Testing to Predict Warfarin Responsiveness (Effective August 3, 2009)
(Rev. 111, Issued: 12-18-09, Effective: 08-03-09, Implementation: 04-05-10)

A. General

Warfarin sodium is an orally administered anticoagulant drug that is marketed most commonly as Coumadin®. (The Food and Drug Administration (FDA) approved labeling for Coumadin® includes a Black Box Warning dating back to 2007.) Anticoagulant drugs are sometimes referred to as blood thinners by the lay public. Warfarin affects the vitamin K-dependent clotting factors II, VII, IX, and X. Warfarin is thought to interfere with clotting factor synthesis by inhibition of the C1 subunit of the vitamin K epoxide reductase (VKORC1) enzyme complex, thereby reducing the regeneration of vitamin K1 epoxide. The elimination of warfarin is almost entirely by metabolic conversion to inactive metabolites by cytochrome P450 (CYP) enzymes in liver cells. CYP2C9 is the principal cytochrome P450 enzyme that modulates the anticoagulant activity of warfarin. From results of clinical studies, genetic variation in the CYP2C9 and/or VKORC1 genes can, in concert with clinical factors, predict how each individual responds to warfarin.

Pharmacogenomics denotes the study of how an individual's genetic makeup, or genotype, affects the body's response to drugs. Pharmacogenomics as a science examines associations among variations in genes with individual responses to a drug or medication. In application, pharmacogenomic results (i.e., information on the patient's genetic variations) can contribute to predicting a patient's response to a given drug: good, bad, or none at all. Pharmacogenomic testing of CYP2C9 or VKORC1 alleles to predict a patient's response to warfarin occurs ideally prior to initiation of the drug. This would be an once-in-a-lifetime test, absent any reason to believe that the patient's personal genetic characteristics would change over time. Although such pharmacogenomic testing would be used to attempt to better approximate the best starting dose of warfarin, it would not eliminate the need for periodic PT/INR testing, a standard diagnostic test for coagulation activity and for assessing how a patient is reacting to a warfarin dose.

Nationally Covered Indications

Effective August 3, 2009, the Centers for Medicare & Medicaid Services (CMS) believes that the available evidence supports that coverage with evidence development (CED) under §1862(a)(1)(E) of the Social Security Act (the Act) is appropriate for pharmacogenomic testing of CYP2C9 or VKORC1 alleles to predict warfarin responsiveness by any method, and is therefore covered only when provided to Medicare beneficiaries who are candidates for anticoagulation therapy with warfarin who:

1. Have not been previously tested for CYP2C9 or VKORC1 alleles; and

2. Have received fewer than five days of warfarin in the anticoagulation regimen for which the testing is ordered; and

3. Are enrolled in a prospective, randomized, controlled clinical study when that study meets the following standards.

A clinical study seeking Medicare payment for pharmacogenomic testing of CYP2C9 or VKORC1 alleles to predict warfarin responsiveness provided to the Medicare beneficiary who is a candidate for anticoagulation therapy with warfarin pursuant to CED must address one or more aspects of the following question:

Prospectively, in Medicare-aged subjects whose warfarin therapy management includes pharmacogenomic testing of CYP2C9 or VKORC1 alleles to predict warfarin response, what is the frequency and severity of the following outcomes, compared to subjects whose warfarin therapy management does not include pharmacogenomic testing?

- Major hemorrhage
- Minor hemorrhage
- Thromboembolism related to the primary indication for anticoagulation
- Other thromboembolic event
- Mortality

The study must adhere to the following standards of scientific integrity and relevance to the Medicare population:

a. The principal purpose of the research study is to test whether a particular intervention potentially improves the participants' health outcomes.

b. The research study is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.

c. The research study does not unjustifiably duplicate existing studies.

d. The research study design is appropriate to answer the research question being asked in the study.

e. The research study is sponsored by an organization or individual capable of executing the proposed study successfully.

f. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found in the Code of Federal Regulations (CFR) at 45 CFR Part 46. If a study is regulated by the FDA, it also must be in compliance with 21 CFR Parts 50 and 56.

g. All aspects of the research study are conducted according to the appropriate standards of scientific integrity.

h. The research study has a written protocol that clearly addresses, or incorporates by reference, the Medicare standards.

i. The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life-threatening as defined in 21 CFR § 312.81(a) and the patient has no other viable treatment options.

j. The clinical research study is registered on the www.ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject.

k. The research study protocol specifies the method and timing of public release of all pre-specified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned to be published in a peer-reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors. However, a full report of the outcomes must be made public no later than 3 years after the end of data collection.

l. The research study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria affect enrollment of these populations, and a plan for the retention and reporting of said

populations on the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.

m. The research study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

Consistent with section 1142 of the Act, the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

B. Nationally Non-Covered Indications

The CMS believes that the available evidence does not demonstrate that pharmacogenomic testing of CYP2C9 or VKORC1 alleles to predict warfarin responsiveness improves health outcomes in Medicare beneficiaries outside the context of CED, and is therefore not reasonable and necessary under §1862(a)(1)(A) of the Act.

C. Other

This NCD does not determine coverage to identify CYP2C9 or VKORC1 alleles for other purposes, nor does it determine national coverage to identify other alleles to predict warfarin responsiveness.

(This NCD last reviewed August 2009.)

90.2 Next Generation Sequencing (NGS) for Patients with Somatic (Acquired) and Germline (Inherited) Cancer

(Rev. 10346, Issued: 09-11-20, Effective: 01-27-20, Implementation: 11-13-20)

A. General

Clinical laboratory diagnostic tests can include tests that, for example, predict the risk associated with one or more genetic variations. In addition, in vitro companion diagnostic laboratory tests provide a report of test results of genetic variations and are essential for the safe and effective use of a corresponding therapeutic product. Next Generation Sequencing (NGS) is one technique that can measure one or more genetic variations as a laboratory diagnostic test, such as when used as a companion in vitro diagnostic test.

This National Coverage Determination (NCD) is only applicable to diagnostic lab tests using NGS for somatic (acquired) and germline (inherited) cancer. Medicare Administrative Contractors (MACs) may determine coverage of diagnostic lab tests using NGS for RNA sequencing and protein analysis.

B. Nationally Covered Indications

1. Somatic (Acquired) Cancer

Effective for services performed on or after March 16, 2018, the Centers for Medicare & Medicaid Services (CMS) has determined that Next Generation Sequencing (NGS) as a diagnostic laboratory test is reasonable and necessary and covered nationally, when performed in a Clinical Laboratory Improvement Amendments (CLIA)-certified laboratory, when ordered by a treating physician, and when all of the following requirements are met:

a. Patient has:
    i. either recurrent, relapsed, refractory, metastatic, or advanced stage III or IV cancer; and

ii. not been previously tested with the same test using NGS for the same cancer genetic content, and
iii. decided to seek further cancer treatment (e.g., therapeutic chemotherapy).

b. The diagnostic laboratory test using NGS must have:
i. Food & Drug Administration (FDA) approval or clearance as a companion in vitro diagnostic; and,
ii. an FDA-approved or -cleared indication for use in that patient's cancer; and,
iii. results provided to the treating physician for management of the patient using a report template to specify treatment options.

2. Germline (Inherited) Cancer

Effective for services performed on or after January 27, 2020, CMS has determined that NGS as a diagnostic laboratory test is reasonable and necessary and covered nationally for patients with germline (inherited) cancer, when performed in a CLIA-certified laboratory, when ordered by a treating physician and when all of the following requirements are met:

a. Patient has:
i. ovarian or breast cancer; and,
ii. a clinical indication for germline (inherited) testing for hereditary breast or ovarian cancer; and,
iii. a risk factor for germline (inherited) breast or ovarian cancer; and
iv. not been previously tested with the same germline test using NGS for the same germline genetic content.

b. The diagnostic laboratory test using NGS must have all of the following:
i. FDA-approval or clearance; and,
ii. results provided to the treating physician for management of the patient using a report template to specify treatment options.

C. Nationally Non-Covered Indications

1. Somatic (Acquired) Cancer

Effective for services performed on or after March 16, 2018, NGS as a diagnostic laboratory test for patients with acquired (somatic) cancer are non-covered if the cancer patient does not meet the criteria noted in section B.1., above.

D. Other

1. Somatic (Acquired) Cancer

Effective for services performed on or after March 16, 2018, Medicare Administrative Contractors (MACs) may determine coverage of NGS as a diagnostic laboratory test for patients with advanced cancer only when the test is performed in a CLIA-certified laboratory, when ordered by a treating physician, and when the patient has:

a. either recurrent, relapsed, refractory, metastatic, or advanced stages III or IV cancer; and,
b. not been previously tested with the same test using NGS for the same cancer genetic content, and
c. decided to seek further cancer treatment (e.g., therapeutic chemotherapy).

2. Germline (Inherited) Cancer

Effective for services performed on or after January 27, 2020, MACs may determine coverage of NGS as a diagnostic laboratory test for patients with germline (inherited) cancer only when the test is performed in a CLIA-certified laboratory, when ordered by a treating physician, when results are provided to the treating physician for management of the patient and when the patient has:

a. any cancer diagnosis; and,
b. a clinical indication for germline (inherited) testing of hereditary cancers; and,
c. a risk factor for germline (inherited) cancer; and,
d. not been previously tested with the same germline test using NGS for the same germline genetic content.

(This NCD last reviewed January 2020)

100 - Gastrointestinal System
(Rev. 1, 10-03-03)

100.1 - Bariatric Surgery for Treatment of Co-Morbid Conditions Related to Morbid Obesity
(Rev. 158, Issued: 12-23-13, Effective: 09-24-13, Implementation: 12-17-13)

Please note, sections 40.5, 100.8, 100.11, and 100.14 have been removed from the National Coverage Determination (NCD) Manual and incorporated into NCD 100.1

A. General

Obesity may be caused by medical conditions such as hypothyroidism, Cushing's disease, and hypothalamic lesions, or can aggravate a number of cardiac and respiratory diseases as well as diabetes and hypertension. Non-surgical services in connection with the treatment of obesity are covered when such services are an integral and necessary part of a course of treatment for one of these medical conditions.

In addition, supplemented fasting is a type of very low calorie weight reduction regimen used to achieve rapid weight loss. The reduced calorie intake is supplemented by a mixture of protein, carbohydrates, vitamins, and minerals. Serious questions exist about the safety of prolonged adherence for 2 months or more to a very low calorie weight reduction regimen as a general treatment for obesity, because of instances of cardiopathology and sudden death, as well as possible loss of body protein.

Bariatric surgery procedures are performed to treat comorbid conditions associated with morbid obesity. Two types of surgical procedures are employed. Malabsorptive procedures divert food from the stomach to a lower part of the digestive tract where the normal mixing of digestive fluids and absorption of nutrients cannot occur. Restrictive procedures restrict the size of the stomach and decrease intake. Surgery can combine both types of procedures.

The following are descriptions of bariatric surgery procedures:

1. Roux-en-Y Gastric Bypass (RYGBP)

The RYGBP achieves weight loss by gastric restriction and malabsorption. Reduction of the stomach to a small gastric pouch (30 cc) results in feelings of satiety following even small meals. This small pouch is connected to a segment of the jejunum, bypassing the duodenum and very proximal small intestine, thereby reducing absorption. RYGBP procedures can be open or laparoscopic.

2. Biliopancreatic Diversion with Duodenal Switch (BPD/DS) or Gastric Reduction Duodenal Switch (BPD/GRDS)

The BPD achieves weight loss by gastric restriction and malabsorption. The stomach is partially resected, but the remaining capacity is generous compared to that achieved with RYGBP. As such, patients eat relatively normal-sized meals and do not need to restrict intake radically, since the most proximal areas of the small intestine (i.e., the duodenum and jejunum) are bypassed, and substantial malabsorption occurs. The partial BPD/DS or BPD/GRDS is a variant of the BPD procedure. It involves resection of the greater curvature of the stomach, preservation of the pyloric sphincter, and transection of the duodenum above the ampulla of Vater with a duodeno-ileal anastomosis and a lower ileo-ileal anastomosis. BPD/DS or BPD/GRDS procedures can be open or laparoscopic.

3. Adjustable Gastric Banding (AGB)

The AGB achieves weight loss by gastric restriction only. A band creating a gastric pouch with a capacity of approximately 15 to 30 cc's encircles the uppermost portion of the stomach. The band is an inflatable doughnut-shaped balloon, the diameter of which can be adjusted in the clinic by adding or removing saline via a port that is positioned beneath the skin. The bands are adjustable, allowing the size of the gastric outlet to be modified as needed, depending on the rate of a patient's weight loss. AGB procedures are laparoscopic only.

4. Sleeve Gastrectomy

Sleeve gastrectomy is a 70%-80% greater curvature gastrectomy (sleeve resection of the stomach) with continuity of the gastric lesser curve being maintained while simultaneously reducing stomach volume. In the past, sleeve gastrectomy was the first step in a two-stage procedure when performing RYGBP, but more recently has been offered as a stand-alone surgery. Sleeve gastrectomy procedures can be open or laparoscopic.

5. Vertical Gastric Banding (VGB)

The VGB achieves weight loss by gastric restriction only. The upper part of the stomach is stapled, creating a narrow gastric inlet or pouch that remains connected with the remainder of the stomach. In addition, a non-adjustable band is placed around this new inlet in an attempt to prevent future enlargement of the stoma (opening). As a result, patients experience a sense of fullness after eating small meals. Weight loss from this procedure results entirely from eating less. VGB procedures are essentially no longer performed.

B. Nationally Covered Indications

Effective for services performed on and after February 21, 2006, Open and laparoscopic Roux-en-Y gastric bypass (RYGBP), open and laparoscopic Biliopancreatic Diversion with Duodenal Switch (BPD/DS) or Gastric Reduction Duodenal Switch (BPD/GRDS), and laparoscopic adjustable gastric banding (LAGB) are covered for Medicare beneficiaries who have a body-mass index ≥ 35, have at least one co-morbidity related to obesity, and have been previously unsuccessful with medical treatment for obesity.

Effective for dates of service on and after February 21, 2006, these procedures are only covered when performed at facilities that are: (1) certified by the American College of Surgeons as a Level 1 Bariatric Surgery Center (program standards and requirements in effect on February 15, 2006); or (2) certified by the American Society for Bariatric Surgery as a Bariatric Surgery Center of Excellence (program standards and requirements in effect on February 15, 2006). Effective for dates of service on and after September 24, 2013, facilities are no longer required to be certified.

Effective for services performed on and after February 12, 2009, the Centers for Medicare & Medicaid Services (CMS) determines that Type 2 diabetes mellitus is a co-morbidity for purposes of this NCD.

A list of approved facilities and their approval dates are listed and maintained on the CMS Coverage Web site at http://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/Bariatric-

Surgery.html , and published in the Federal Register for services provided up to and including date of service September 23, 2013.

C. Nationally Non-Covered Indications

Treatments for obesity alone remain non-covered.

Supplemented fasting is not covered under the Medicare program as a general treatment for obesity (see section D. below for discretionary local coverage).

The following bariatric surgery procedures are non-covered for all Medicare beneficiaries:

Open adjustable gastric banding;

Open sleeve gastrectomy;

Laparoscopic sleeve gastrectomy (prior to June 27, 2012);

Open and laparoscopic vertical banded gastroplasty;

Intestinal bypass surgery; and,

Gastric balloon for treatment of obesity.

D. Other

Effective for services performed on and after June 27, 2012, A/B Medicare Administrative Contractors (A/B MACs) acting within their respective jurisdictions may determine coverage of stand-alone laparoscopic sleeve gastrectomy (LSG) for the treatment of co-morbid conditions related to obesity in Medicare beneficiaries only when all of the following conditions a.-c. are satisfied.

a. The beneficiary has a body-mass index (BMI) ≥ 35 kg/m^2,

b. The beneficiary has at least one co-morbidity related to obesity, and,

c. The beneficiary has been previously unsuccessful with medical treatment for obesity.

The determination of coverage for any bariatric surgery procedures that are not specifically identified in an NCD as covered or non-covered, for Medicare beneficiaries who have a body-mass index ≥ 35, have at least one co-morbidity related to obesity, and have been previously unsuccessful with medical treatment for obesity, is left to the local MACs.

Where weight loss is necessary before surgery in order to ameliorate the complications posed by obesity when it coexists with pathological conditions such as cardiac and respiratory diseases, diabetes, or hypertension (and other more conservative techniques to achieve this end are not regarded as appropriate), supplemented fasting with adequate monitoring of the patient is eligible for coverage on a case-by-case basis or pursuant to a local coverage determination. The risks associated with the achievement of rapid weight loss must be carefully balanced against the risk posed by the condition requiring surgical treatment.

100.2 - Endoscopy
(Rev. 1, 10-03-03)
CIM 35-59

Endoscopy is a technique in which a long flexible tube-like instrument is inserted into the body orally or rectally, permitting visual inspection of the gastrointestinal tract. Although primarily a diagnostic tool,

endoscopy includes certain therapeutic procedures such as removal of polyps, and endoscopic papillotomy, by which stones are removed from the bile duct.

Endoscopic procedures are covered when reasonable and necessary for the individual patient.

100.3 - 24-Hour Ambulatory Esophegeal pH Monitoring

(Rev. 1, 10-03-03)
CIM 35-83

Twenty-four hour ambulatory esophageal pH monitoring is a diagnostic procedure involving the placement of an indwelling electrode into the lower esophagus of a patient for the purpose of determining the presence of gastric reflux and measuring abnormal esophageal acid exposure.

Twenty-four hour ambulatory pH monitoring is covered by Medicare for patients who are suspected of having gastric reflux, but only if the patient presents diagnostic problems associated with atypical symptoms or the patient's symptoms are suggestive of reflux, but conventional tests have not confirmed the presence of reflux.

100.4 - Esophageal Manometry

(Rev. 1, 10-03-03)
CIM 50-25

Esophageal manometry is covered under Medicare where it is determined to be reasonable and necessary for the individual patient. The major use of esophageal manometry is to measure pressure within the esophagus to assist in the diagnosis of esophageal pathology including aperistalsis, spasm, achalasia, esophagitis, esophageal ulcer, esophageal congenital webs, diverticuli, scleroderma, hiatus hernia, congenital cysts, benign and malignant tumors, hypermobility, hypomobility, and extrinsic lesions. Esophageal manometry is mostly used in difficult diagnostic cases and as an adjunct to x-rays and direct visualization of the esophagus (endoscopy) through the fiberscope.

100.5 - Diagnostic Breath Analyses

(Rev. 1, 10-03-03)
CIM 50-51

Diagnostic breath analyses are tests performed to measure either the hydrogen or carbon dioxide content of the breath after the ingestion of certain compounds. The analyses are performed to diagnose certain gastrointestinal disease states.

The Following Breath Test Is Covered:

Lactose breath hydrogen to detect lactose malabsorption.

The Following Breath Tests Are Excluded From Coverage:

Lactulose breath hydrogen for diagnosing small bowel bacterial overgrowth and measuring small bowel transit time.

CO2 for diagnosing bile acid malabsorption.

CO2 for diagnosing fat malabsorption.

100.6 - Gastric Freezing

(Rev. 1, 10-03-03)
CIM 35-65

Gastric freezing for chronic peptic ulcer disease is a non-surgical treatment which was popular about 20 years ago but now is seldom done. It has been abandoned due to a high complication rate, only temporary improvement experienced by patients, and lack of effectiveness when tested by double-blind, controlled clinical trials. Since the procedure is now considered obsolete, it is not covered.

100.7 - Colonic Irrigation
CIM 35-1

Not Covered

Colonic irrigation is a procedure to wash out or lavage material on the walls of the bowel to an unlimited distance without inducing defecation. This procedure is distinguished from all types of enemas which are primarily used to induce defecation.

There are no conditions for which colonic irrigation is medically indicated and no evidence of therapeutic value. Accordingly, colonic irrigation cannot be considered reasonable and necessary within the meaning of §1862(a)(1) of the Act.

100.8 – Intestinal Bypass Surgery (RETIRED)
(Rev. 11892; Issued: 03-09-23; Effective: 04-10-23; Implementation:04-10-23)

Please note section 100.8 has been removed from the NCD Manual and incorporated into NCD 100.1 effective September 24, 2013.

100.9 - Implantation of Anti-Gastroesophageal Reflux Device (RETIRED)
(Rev. 11892; Issued: 03-09-23; Effective: 04-10-23; Implementation:04-10-23)

Effective January 1, 2021, the Centers for Medicare & Medicaid Services determined that no national coverage determination (NCD) is appropriate at this time for FDG PET for Implantation of Gastrointestinal Reflux Devices. In the absence of an NCD, coverage determinations will be made by the Medicare Administrative Contractors under 1862(a)(1)(A) of the Social Security Act.

100.10 - Injection Sclerotherapy for Esophageal Variceal Bleeding
(Rev. 1, 10-03-03)
CIM 35-73

Injection sclerotherapy is a technique involving insertion of a flexible fiberoptic endoscope into the esophagus, and the injection of a sclerosing agent or solution into the varicosities to control bleeding. This procedure is covered under Medicare.

100.11 – Gastric Balloon for Treatment of Obesity (RETIRED)
(Rev. 11892; Issued: 03-09-23; Effective: 04-10-23; Implementation:04-10-23)

Please note section 100.11 has been removed from the NCD Manual and incorporated into NCD 100.1 effective September 24, 2013.

100.12 - Gastrophotography
(Rev. 1, 10-03-03)
CIM 50-9

Gastrophotography is an accepted procedure for diagnosis and treatment of gastrointestinal disorders. The photographic record provided by this procedure is often necessary for consultation and/or follow-up

purposes and when required for such purposes, is more valuable than a conventional gastroscopic examination. Such a record facilitates the documentation and evaluation (healing or worsening) of lesions such as the gastric ulcer, facilitates consultation between physicians concerning difficult-to-interpret lesions, provides preoperative characterization for the surgeon, and permits better diagnosis of postoperative gastric bleeding to help determine whether there is a need for another operation. Therefore, program reimbursement may be made for this procedure.

100.13 - Laproscopic Cholecystectomy

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD-10, Implementation: Upon Implementation of ICD-10)

Laparoscopic cholecystectomy is a covered surgical procedure in which a diseased gall bladder is removed through the use of instruments introduced via cannulae, with vision of the operative field maintained by use of a high-resolution television camera-monitor system (video laparoscope). For inpatient claims, report the diagnosis code for laparoscopic cholecystectomy. For all other claims, report the appropriate CPT code for laparoscopy, surgical; cholecystectomy (any method), and the appropriate CPT code for laparoscopy, surgical: cholecystectomy with cholangiography.

100.14 – Surgery for Diabetes (RETIRED)

(Rev. 11892; Issued: 03-09-23; Effective: 04-10-23; Implementation:04-10-23)

Please note section 100.14 has been removed from the NCD Manual and incorporated into NCD 100.1 effective September 24, 2013.

110 - Hematology/Immunology/Oncology

(Rev. 1, 10-03-03)

110.1 - Hyperthermia for Treatment of Cancer

(Rev. 1, 10-03-03)
CIM 35-49

Local hyperthermia for treatment of cancer consists of the use of heat to make tumors more susceptible to cancer therapy measures.

Local hyperthermia is covered under Medicare when used in connection with radiation therapy for the treatment of primary or metastatic cutaneous or subcutaneous superficial malignancies. It is not covered when used alone or in connection with chemotherapy.

110.2 - Certain Drugs Distributed by the National Cancer Institute

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD-10, Implementation: Upon Implementation of ICD-10)

Under its Cancer Therapy Evaluation, the Division of Cancer Treatment of the National Cancer Institute (NCI), in cooperation with the Food and Drug Administration, approves and distributes certain drugs for use in treating terminally ill cancer patients. One group of these drugs, designated as Group C drugs, unlike other drugs distributed by the NCI, is not limited to use in clinical trials for the purpose of testing their efficacy. Drugs are classified as Group C drugs only if there is sufficient evidence demonstrating their efficacy within a tumor type and that they can be safely administered.

A physician is eligible to receive Group C drugs from the Division of Cancer Treatment only if the following requirements are met:

- A physician must be registered with the NCI as an investigator by having completed an FD-Form 1573;

- A written request for the drug, indicating the disease to be treated, must be submitted to the NCI;
- The use of the drug must be limited to indications outlined in the NCIs guidelines; and
- All adverse reactions must be reported to the Investigational Drug Branch of the Division of Cancer Treatment.

In view of these NCI controls on distribution and use of Group C drugs, A/B MACs may assume, in the absence of evidence to the contrary, that a Group C drug and the related hospital stay are covered if all other applicable coverage requirements are satisfied.

If there is reason to question coverage in a particular case, the matter should be resolved with the assistance of the Quality Improvement Organization (QIO), or if there is none, the assistance of the MAC's medical consultants.

Information regarding those drugs which are classified as Group C drugs may be obtained from:

Chief, Investigational Drug Branch
Cancer Therapy Evaluation Program
Executive Plaza North, Suite 7134
National Cancer Institute
Rockville, Maryland 20852-7426

110.3 - Anti-Inhibitor Coagulant Complex (AICC)

(Rev. 1, 10-03-03)
CIM 45-24

Anti-inhibitor coagulant complex, AICC, is a drug used to treat hemophilia in patients with factor VIII inhibitor antibodies. AICC has been shown to be safe and effective and has Medicare coverage when furnished to patients with hemophilia A and inhibitor antibodies to factor VIII who have major bleeding episodes and who fail to respond to other, less expensive therapies.

110.4 - Extracorporeal Photopheresis

(Rev. 143, Issued: 05-18-12, Effective: 04-30-12, Implementation: 10-01-12)

A. General

Extracorporeal photopheresis is a medical procedure in which a patient's white blood cells are exposed first to a drug called 8-methoxypsoralen (8-MOP) and then to ultraviolet A (UVA) light. The procedure starts with the removal of the patient's blood, which is centrifuged to isolate the white blood cells. The drug is typically administered directly to the white blood cells after they have been removed from the patient (referred to as ex vivo administration) but the drug can alternatively be administered directly to the patient before the white blood cells are withdrawn. After UVA light exposure, the treated white blood cells are then re-infused into the patient.

B. Nationally Covered Indications

The Centers for Medicare & Medicaid Services (CMS) has determined that extracorporeal photopheresis is reasonable and necessary under §1862(a)(1)(A) of the Social Security Act (the Act) under the following circumstances:

1. Effective April 8, 1988, Medicare provides coverage for:

Palliative treatment of skin manifestations of cutaneous T-cell lymphoma that has not responded to other therapy.

2. Effective December 19, 2006, Medicare also provides coverage for:

Patients with acute cardiac allograft rejection whose disease is refractory to standard immunosuppressive drug treatment; and,

Patients with chronic graft versus host disease whose disease is refractory to standard immunosuppressive drug treatment.

3. Effective April 30, 2012, Medicare also provides coverage for:

Extracorporeal photopheresis for the treatment of bronchiolitis obliterans syndrome (BOS) following lung allograft transplantation only when extracorporeal photopheresis is provided under a clinical research study that meets the following conditions:

The clinical research study meets the requirements specified below to assess the effect of extracorporeal photopheresis for the treatment of BOS following lung allograft transplantation. The clinical study must address one or more aspects of the following question:

Prospectively, do Medicare beneficiaries who have received lung allografts, developed BOS refractory to standard immunosuppressive therapy, and received extracorporeal photopheresis , experience improved patient-centered health outcomes as indicated by:

a. improved forced expiratory volume in one second (FEV1);
b. improved survival after transplant; and/or,
c. improved quality of life?

The required clinical study must adhere to the following standards of scientific integrity and relevance to the Medicare population:

a. The principal purpose of the research study is to test whether extracorporeal photopheresis potentially improves the participants' health outcomes.

b. The research study is well supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.

c. The research study does not unjustifiably duplicate existing studies.

d. The research study design is appropriate to answer the research question being asked in the study.

e. The research study is sponsored by an organization or individual capable of successfully executing the proposed study.

f. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 CFR Part 46. If a study is regulated by the Food and Drug Administration (FDA), it must also be in compliance with 21 CFR parts 50 and 56.

g. All aspects of the research study are conducted according to appropriate standards of scientific integrity (see http://www.icmje.org).

h. The research study has a written protocol that clearly addresses, or incorporates by reference, the standards listed here as Medicare requirements for coverage with evidence development.

i. The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life threatening as defined in 21 CFR § 312.81(a) and the patient has no other viable treatment options.

j. The clinical research study is registered on the ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject.

k. The research study protocol specifies the method and timing of public release of all prespecified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned to be published in a peer-reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors (http://www.icmje.org).

l. The research study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria effect enrollment of these populations, and a plan for the retention and reporting of said populations on the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.

m. The research study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

Consistent with section 1142 of the Act, the Agency for Healthcare Research and Quality supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

Any clinical study under which there is coverage of extracorporeal photopheresis for this indication pursuant to this national coverage determination (NCD) must be approved by April 30, 2014. If there are no approved clinical studies on this date, this NCD will expire and coverage of extracorporeal photopheresis for BOS will revert to the coverage policy in effect prior to the issuance of the final decision memorandum for this NCD.

C. Nationally Non-Covered Indications

All other indications for extracorporeal photopheresis not otherwise indicated above as covered remain non-covered.

D. Other

Claims processing instructions can be found in chapter 32, section 190 of the Medicare Claims Processing Manual.

(This NCD last reviewed April 2012.)

110.5 - Granulocyte Transfusions

(Rev. 1, 10-03-03)
CIM 45-18

Granulocyte transfusions to patients suffering from severe infection and granulocytopenia are a covered service under Medicare. Granulocytopenia is usually identified as fewer than 500 granulocytes/mm^3 whole blood. Accepted indications for granulocyte transfusions include:

- Granulocytopenia with evidence of gram negative sepsis; and

- Granulocytopenia in febrile patients with local progressive infections unresponsive to appropriate antibiotic therapy, thought to be due to gram negative organisms.

110.6 - Scalp Hypothermia During Chemotherapy to Prevent Hair Loss
(Rev. 1, 10-03-03)

CIM 45-21

Keeping the scalp cool during chemotherapy has been noted to reduce the risk of hair loss. The cooling may be done by packing the scalp with ice-filled bags or bandages, or by specially designed devices filled with cold-producing chemicals activated during chemotherapy.

While ice-filled bags or bandages or other devices used for scalp hypothermia during chemotherapy may be covered as supplies of the kind commonly furnished without a separate charge, no separate charge for them would be recognized.

110.7 - Blood Transfusions
(Rev. 1, 10-03-03)
CIM 45-27

Blood transfusions are used to restore blood volume after hemorrhage, to improve the oxygen carrying capacity of blood in severe anemia, and to combat shock in acute hemolytic anemia.

A. Definitions

1. Homologous Blood Transfusion

Homologous blood transfusion is the infusion of blood or blood components that have been collected from the general public.

2. Autologous Blood Transfusion

An autologous blood transfusion is the precollection and subsequent infusion of a patient's own blood.

3. Donor Directed Blood Transfusion

A donor directed blood transfusion is the infusion of blood or blood components that have been precollected from a specific individual(s) other than the patient and subsequently infused into the specific patient for whom the blood is designated. For example, patient B's brother predeposits his blood for use by patient B during upcoming surgery.

4. Perioperative Blood Salvage

Perioperative blood salvage is the collection and reinfusion of blood lost during and immediately after surgery.

B. Policy Governing Transfusions

For Medicare coverage purposes, it is important to distinguish between a transfusion itself and preoperative blood services; e.g., collection, processing, storage. Medically necessary transfusion of blood, regardless of the type, may generally be a covered service under both Part A and Part B of Medicare. Coverage does not make a distinction between the transfusion of homologous, autologous, or donor-directed blood. With respect to the coverage of the services associated with the preoperative collection, processing, and storage of autologous and donor-directed blood, the following policies apply.

1. Hospital Part A and B Coverage and Payment

Under §1862(a)(14) of the Act, nonphysician services furnished to hospital patients are covered and paid for as hospital services. As provided in §1886 of the Act, under the prospective payment system (PPS), the diagnosis related group (DRG) payment to the hospital includes all covered blood and blood processing expenses, whether or not the blood is eventually used.

In a situation where the hospital operates its own blood collection activities, rather than using an independent blood supplier, the costs incurred to collect autologous or donor-directed blood are recorded in the whole blood and packed red blood cells cost center. Because the blood has been replaced, Medicare does not recognize a charge for the blood itself. Under PPS, the DRG payment is intended to pay for all covered blood and blood services, whether or not the blood is eventually used.

Under its provider agreement, a hospital is required to furnish or arrange for all covered services furnished to hospital patients. Medicare payment is made to the hospital, under PPS or cost reimbursement, for covered inpatient and outpatient services, and it is intended to reflect payment for all costs of furnishing those services.

2. Nonhospital Part B Coverage

Under Part B, to be eligible for separate coverage, a service must fit the definition of one of the services authorized by §1832 of the Act. These services are defined in 42 CFR 410.10 and do not include a separate category for a supplier's services associated with blood donation services, either autologous or donor-directed. That is, the collection, processing, and storage of blood for later transfusion into the beneficiary is not recognized as a separate service under Part B. Therefore, there is no avenue through which a blood supplier can receive direct payment under Part B for blood donation services.

C. Perioperative Blood Salvage

When the perioperative blood salvage process is used in surgery on a hospital patient, payment made to the hospital (under PPS or through cost reimbursement) for the procedure in which that process is used is intended to encompass payment for all costs relating to that process.

110.8 - Blood Platelet Transfusions

(Rev. 1, 10-03-03)
CIM 35-30

Blood platelet transplants are safe and effective for the correction of thrombocytopenia and other blood defects. It is covered under Medicare when treatment is reasonable and necessary for the individual patient.

110.8.1 –Stem Cell Transplantation (RETIRED)

(Rev. 11892; Issued: 03-09-23; Effective: 04-10-23; Implementation:04-10-23)

Effective January 27, 2016 NCD 110.8.1 is retired and incorporated into NCD 110.23.

110.9 - Antigens Prepared for Sublingual Administration

(Rev. 1, 10-03-03)
CIM 45-28

For antigens provided to patients on or after November 17, 1996, Medicare does not cover such antigens if they are to be administered sublingually, i.e., by placing drops under the patient's tongue. This kind of allergy therapy has not been proven to be safe and effective. Antigens are covered only if they are administered by injection.

110.10 - Intravenous Iron Therapy
(Rev. 1, 10-03-03)
CIM 45-29

Iron deficiency is a common condition in end stage renal disease (ESRD) patients undergoing hemodialysis. Iron is a critical structural component of hemoglobin, a key protein found in normal red blood cells (RBCs) that transports oxygen. Without this important building block, anemic patients experience difficulty in restoring adequate, healthy RBCs that improve hematocrit levels. Clinical management of iron deficiency involves treating patients with iron replacement products while they undergo hemodialysis. Body iron stores can be supplemented with either oral or intravenous (IV) iron products. The available evidence suggests that the mode of intravenous administration is perhaps the most effective treatment for iron deficiency in hemodialysis patients. Unlike oral iron products which must be absorbed through the GI tract, IV iron products are infused directly into the bloodstream in a form that is readily available to the bone marrow for RBC synthesis, resulting in an earlier correction of iron deficiency and anemia.

Effective December 1, 2000, Medicare covers sodium ferric gluconate complex in sucrose injection as a first line treatment of iron deficiency anemia when furnished intravenously to patients undergoing chronic hemodialysis who are receiving supplemental erythropoeitin therapy.

Effective October 1, 2001, Medicare also covers iron sucrose injection as a first line treatment of iron deficiency anemia when furnished intravenously to patients undergoing chronic hemodialysis who are receiving supplemental erythropoeitin therapy.

110.11 - Food Allergy Testing and Treatment
(Rev. 1, 10-03-03)
CIM 50-53

Not Covered

Effective October 31, 1988, sublingual intracutaneous and subcutaneous provocative and neutralization testing and neutralization therapy for food allergies are excluded from Medicare coverage because available evidence does not show that these tests and therapies are effective. This exclusion was published as a Final Notice in the "Federal Register" on September 29, 1988.

110.12 - Challenge Ingestion Food Testing
(Rev. 1, 10-03-03)
CIM 50-22

Challenge ingestion food testing is a safe and effective technique in the diagnosis of food allergies. This procedure is covered when it is used on an outpatient basis if it is reasonable and necessary for the individual patient.

Challenge ingestion food testing has not been proven to be effective in the diagnosis of rheumatoid arthritis, depression, or respiratory disorders. Accordingly, its use in the diagnosis of these conditions is not reasonable and necessary within the meaning of §1862(a)(1) of the Act, and no program payment is made for this procedure when it is so used.

110.13 - Cytotoxic Food Tests
(Rev. 1, 10-03-03)

CIM 50-2

Not Covered

Prior to August 5, 1985, Medicare covered cytotoxic food tests as an adjunct to in vivo clinical allergy tests in complex food allergy problems. Effective August 5, 1985, cytotoxic leukocyte tests for food allergies are excluded from Medicare coverage because available evidence does not show that these tests are safe and effective. This exclusion was published as a CMS Ruling in the "Federal Register" on July 5, 1985.

110.14 - Apheresis (Therapeutic Pheresis)

(Rev. 1, 10-03-03)
CIM 35-60

A. General

Apheresis (also known as pheresis or therapeutic pheresis) is a medical procedure utilizing specialized equipment to remove selected blood constituents (plasma, leukocytes, plataelets, or cells) from whole blood. The remainder is retransfused into the person from whom the blood was taken.

For purposes of Medicare coverage, apheresis is defined as an autologous procedure, i.e., blood is taken from the patient, processed, and returned to the patient as part of a continuous procedure (as distinguished from the procedure in which a patient donates blood preoperatively and is transfused with the donated blood at a later date).

B. Indications

Apheresis is covered for the following indications:

- Plasma exchange for acquired myasthenia gravis;
- Leukaphersis in the treatment of leukemia;
- Plasmapheresis in the treatment of primary macroglobulinemia (Waldenstrom);
- Treatment of hyperglobulinemias, including (but not limited to) multiple myelomas, cryoglobulinemia and hyperviscosity syndromes;
- Plasmapheresis or plasma exchange as a last resort treatment of thromobotic thrombocytopenic purpura (TTP);
- Plasmapheresis or plasma exchange in the last resort treatment of life threatening rheumatoid vasculitis;
- Plasma perfusion of charcoal filters for treatment of pruritis of cholestatic liver disease;
- Plasma exchange in the treatment of Goodpasture's Syndrome;
- Plasma exchange in the treatment of glomerulonephritis associated with antiglomerular basement membrane antibodies and advancing renal failure or pulmonary hemorrhage;
- Treatment of chronic relapsing polyneuropathy for patients with severe or life threatening symptoms who have failed to respond to conventional therapy;

- Treatment of life threatening scleroderma and polymyositis when the patient is unresponsive to conventional therapy;

- Treatment of Guillain-Barre Syndrome; and

- Treatment of last resort for life threatening systemic lupus erythematosus (SLE) when conventional therapy has failed to prevent clinical deterioration.

C. Settings

Apheresis is covered only when performed in a hospital setting (either inpatient or outpatient); or in a nonhospital setting, e.g., a physician directed clinic when the following conditions are met:

- A physician (or a number of physicians) is present to perform medical services and to respond to medical emergencies at all times during patient care hours;

- Each patient is under the care of a physician; and

- All nonphysician services are furnished under the direct, personal supervision of a physician.

110.15 - Ultrafiltration, Hemoperfusion and Hemofiltration

(Rev. 1, 10-03-03)
CIM 35-38

A. Ultrafiltration

This is a process for removing excess fluid from the blood through the dialysis membrane by means of pressure. It is not a substitute for dialysis. Ultrafiltration is utilized in cases where excess fluid cannot be removed easily during the regular course of hemodialysis. When it is performed, it is commonly done during the first hour or two of each hemodialysis on patients who, e.g., have refractory edema. Ultrafiltration is a covered procedure under the Medicare program (effective for services performed on and after September 1, 1979)

Predialysis Ultrafiltration

While this procedure requires additional staff care, the facility dialysis rate is intended to cover the full range of complicated and uncomplicated nonacute dialysis treatments. Therefore, no additional facility charge is recognized for predialysis ultrafiltration. The physician's role in ultrafiltration varies with the stability of the patient's condition. In unstable patients, the physician may need to be present at the initiation of dialysis, and available either in-house or in close proximity to monitor the patient carefully. In patients who are relatively stable, but who seem to accumulate excessive weight gain, the procedure requires only a modest increase in physician involvement over routine outpatient hemodialysis.

Occasionally, medical complications may occur which require that ultrafiltration be performed separate from the dialysis treatment, and in these cases an additional charge can be recognized. However, the claim must be documented as to why the ultrafiltration could not have been performed at the same time as the dialysis.

B. Hemoperfusion

This is a process which removes substances from the blood using a charcoal or resin artificial kidney. When used in the treatment of life threatening drug overdose, hemoperfusion is a covered service for patients with or without renal failure. Hemoperfusion generally requires a physician to be present to initiate treatment and to be present in the hospital or an adjacent medical office during the entire procedure, as changes may be sudden. Special staff training and equipment are required.

Develop charges for hemoperfusion in the same manner as for any new or unusual service. One or two treatments are usually all that is necessary to remove the toxic compound; document additional treatments. Hemoperfusion may be performed concurrently with dialysis, and in those cases payment for the hemoperfusion reflects only the additional care rendered over and above the care given with dialysis.

The effects of using hemoperfusion to improve the results of chronic hemodialysis are not known. Therefore, hemoperfusion is not a covered service when used to improve the results of hemodialysis. In addition, it has not been demonstrated that the use of hemoperfusion in conjunction with deferoxamine (DFO), in treating symptomatic patients with iron overload, is efficacious. There is also a paucity of data regarding its efficacy in treating asymptomatic patients with iron overload. Therefore, hemoperfusion used in conjunction with DFO in treating patients with iron overload is not a covered service; i.e., it is not considered reasonable and necessary within the meaning of §1862(a)(1) of the Act.

However, the use of hemoperfusion in conjunction with DFO for the treatment of patients with aluminum toxicity has been demonstrated to be clinically efficacious and is therefore regarded as a covered service.

C. Hemofiltration

This is a process which removes fluid, electrolytes and other low molecular weight toxic substances from the blood by filtration through hollow artificial membranes and may be routinely performed in 3 weekly sessions. Hemofiltration (which is also known as diafiltration) is a covered procedure under Medicare and is a safe and effective technique for the treatment of ESRD patients and an alternative to peritoneal dialysis and hemodialysis. In contrast to both hemodialysis and peritoneal dialysis treatments which eliminate dissolved substances via diffusion across semipermeable membranes, hemofiltration mimics the filtration process of the normal kidney. The technique requires an arteriovenous access. Hemofiltration may be performed either in facility or at home.

The procedure is most advantageous when applied to high-risk unstable patients, such as older patients with cardiovascular diseases or diabetes, because there are fewer side effects such as hypotension, hypertension or volume overload.

110.16 - Nonselective (Random) Transfusions and Living Related Donor Specific Transfusions (DST) in Kidney Transplantation

(Rev. 1, 10-03-03)
CIM 35-71

Transplant surgeons have established a definite correlation in both cadaver and living-related kidney transplantation between pretransplant transfusions of blood into the recipient and the success of graft retention.

These pretransplant transfusions are covered under Medicare without a specific limitation on the number of transfusions, subject to the normal Medicare blood deductible provisions. Where blood is given directly to the transplant patient; e.g., in the case of donor specific transfusions, the blood is considered replaced for purposes of the blood deductible provisions. (See the Medicare General Information, Eligibility, and Entitlement Manual, Chapter 3, "Deductibles, Coinsurance Amounts, and Payment Limitations," §20.5.4.)

110.17 –*Anti-Cancer Chemotherapy for Colorectal Cancer (RETIRED)*

(Rev. 13748; Issued: 04-23-26; Effective: 02-25-26; Implementation: 10-05-26)

Effective February 25, 2026, the Centers for Medicare & Medicaid Services (CMS) removed NCD 110.17, ending coverage of the off-label use of clinical items and services, including the use of the studied drugs oxaliplatin, irinotecan, cetuximab, or bevacizumab, in specific clinical trials identified by CMS. Other coverage mechanisms remain available for these items and services under the Clinical Trial Policy NCD 310.1 and, separately, under § 1861(t)(2)(B) of the Act.

110.18 - Aprepitant for Chemotherapy-Induced Emesis

A. General

Chemotherapy-induced nausea and vomiting (CINV) can range from mild to severe, with the most severe cases resulting in dehydration, malnutrition, metabolic imbalances, and potential withdrawal from future chemotherapy treatments. The incidence and severity of CINV are influenced by the specific chemotherapeutic agent(s) used; dosage, schedule and route of administration; and drug combinations. Patient specific risk factors such as gender, age, history of motion sickness, and prior `exposure to chemotherapeutic agents can also have an effect on CINV incidence and severity. Progress has been made in reducing CINV, although it can still be hard to control symptoms that occur more than a day after chemotherapy, during repeat cycles of chemotherapy, and when chemotherapy is given on more than one day or in very high doses. No single antiemetic agent is completely effective in all patients. As noted above, many factors influence the incidence and severity of CINV, with the specific chemotherapeutic agent as the primary factor to consider when deciding which antiemetic to administer. Aprepitant (Emend®) is the first Food and Drug Administration-approved drug of its type. Aprepitant has been proposed to function in combination with other oral antiemetics for a specified population of Medicare patients receiving highly emetogenic chemotherapy and/or moderately emetogenic chemotherapy.

CMS is defining highly emetogenic chemotherapy and moderately emetogenic chemotherapy as those anticancer agents so designated in at least two of three guidelines published by the National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO), and European Society of Medical Oncology (ESMO)/Multinational Association of Supportive Care in Cancer (MASCC). The inclusive examples are: NCCN plus ASCO, NCCN plus ESMO/MASCC, or ASCO plus ESMO/MASCC.

B. Nationally Covered Indications

Effective for services performed between April 4, 2005, and May 28, 2013, the Centers for Medicare & Medicaid Services makes the following determinations regarding the use of aprepitant in the treatment of reducing chemotherapy-induced emesis:

The evidence is adequate to conclude that the use of the oral antiemetic three-drug combination of oral aprepitant (Emend®), an oral $5HT_3$ antagonist, and oral dexamethasone is reasonable and necessary for a specified patient population. CMS has defined the patient population for which the use of the oral antiemetic three-drug combination of oral aprepitant (Emend®), an oral $5HT_3$ antagonist, and oral dexamethasone is reasonable and necessary as only those patients who are receiving one or more of the following anti-cancer chemotherapeutic agents:

- Carmustine
- Cisplatin
- Cyclophosphamide
- Dacarbazine
- Mechlorethamine
- Streptozocin
- Doxorubicin
- Epirubicin
- Lomustine

Effective for services performed on or after May 29, 2013, the oral three-drug regimen of oral aprepitant, an oral $5HT_3$ antagonist and oral dexamethasone is reasonable and necessary for beneficiaries receiving, either singularly or in combination with other drugs the following anticancer chemotherapeutic agents:

- Alemtuzumab
- Azacitidine

- Bendamustine
- Carboplatin
- Carmustine
- Cisplatin
- Clofarabine
- Cyclophosphamide
- Cytarabine
- Dacarbazine
- Daunorubicin
- Doxorubicin
- Epirubicin
- Idarubicin
- Ifosfamide
- Irinotecan
- Lomustine
- Mechlorethamine
- Oxaliplatin
- Streptozocin

The oral three drug regimen must be administered immediately before and within 48 hours after the administration of these chemotherapeutic agents.

C. Nationally Noncovered Indications

The evidence is adequate to conclude that aprepitant cannot function alone as a full replacement for intravenously administered antiemetic agents for patients who are receiving highly emetogenic chemotherapy and/or moderately emetogenic chemotherapy. Medicare does not cover under Part B for oral antiemetic drugs in antiemetic drug combination regimens that are administered in part, via an oral route and in part, via an intravenous route. Medicare does not cover under Part B aprepitant when it is used alone for anticancer chemotherapy related nausea and vomiting.

D. Other

A/B MACs may determine coverage for other all-oral three-drug antiemesis regimens of aprepitant or any other FDA approved oral NK-1 antagonist in combination with an oral $5HT_3$ antagonist and oral dexamethasone with the chemotherapeutic agents listed above, or any other anticancer chemotherapeutic agents that are FDA approved and are defined as highly or moderately emetogenic.

(Last reviewed May 2013.)

110.19 – Abarelix for the Treatment of Prostate Cancer (RETIRED)

(Rev. 11892; Issued: 03-09-23; Effective: 04-10-23; Implementation:04-10-23)

Effective January 1, 2021, the Centers for Medicare & Medicaid Services determined that no national coverage determination (NCD) is appropriate at this time for Abarelix for the Treatment of Prostate Cancer. In the absence of an NCD, coverage determinations will be made by the Medicare Administrative Contractors under 1862(a)(1)(A) of the Social Security Act.

110.20 - Blood Brain Barrier Osmotic Disruption for Treatment of Brain Tumors (Effective March 20, 2007)

(Rev. 67, Issued: 04-06-07; Effective Date: 03-20-07; Implementation Date: 05-07-07)

A. General

The blood brain barrier (BBB) of the central nervous system is characterized by tight junctions between vascular endothelial cells, which prevent or impede various naturally occurring and synthetic substances (including anti-cancer drugs) from entering brain tissue. The BBB may be partly responsible for the poor efficacy of chemotherapy for malignant primary or metastatic brain tumors.

The BBBD is the disruption of the tight junctions between the endothelial cells that line the capillaries in the brain accomplished by osmotic disruption, bradykinin or irradiation. Theoretically, disruption of the BBB may, in the treatment of brain tumors, increase the concentration of chemotherapy drugs delivered to the tumor and may prolong the drug-tumor contact time.

Osmotic disruption of the BBB is the most common technique used. Chemotherapeutic agents are given in conjunction with barrier disruption. The BBBD process includes all items and services necessary to perform the procedure, including hospitalization, monitoring, and repeated imaging procedures.

B. Nationally Covered Indications

N/A

C. Nationally Non-Covered Indications

Effective for services performed on and after March 20, 2007, the Centers for Medicare & Medicaid Services determines that the use of osmotic BBBD is not reasonable and necessary when it is used as part of a treatment regimen for brain tumors.

D. Other

This NCD does not alter in any manner the coverage of anti-cancer chemotherapy.

(This NCD last reviewed March 2007.)

110.21 - Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD-10, Implementation: Upon Implementation of ICD-10)

A. General

Erythropoiesis stimulating agents (ESAs) stimulate the bone marrow to make more red blood cells and are United States Food and Drug Administration (FDA) approved for use in reducing the need for blood transfusion in patients with specific clinical indications. The FDA has issued alerts and warnings for ESAs administered for a number of clinical conditions, including cancer. Published studies report a higher risk of serious and life-threatening events associated with oncologic uses of ESAs.

B. Nationally Covered Indications

ESA treatment for the anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia is only reasonable and necessary under the following specified conditions:

- The hemoglobin level immediately prior to initiation or maintenance of ESA treatment is <10 g/dL (or the hematocrit is <30%).

- The starting dose for ESA treatment is the recommended FDA label starting dose, no more than 150 U/kg/3 times weekly for epoetin and 2.25 mcg/kg/1 time weekly for darbepoetin alpha. Equivalent doses may be given over other approved time periods.

- Maintenance of ESA therapy is the starting dose if the hemoglobin level remains below 10g/dL (or hematocrit is <30%) 4 weeks after initiation of therapy and the rise in hemoglobin is ≥1g/dL (hematocrit ≥3%);

- For patients whose hemoglobin rises <1g/dl (hematocrit rise <3%) compared to pretreatment baseline over 4 weeks of treatment and whose hemoglobin level remains <10g/dL after the 4 weeks of treatment (or the hematocrit is <30%), the recommended FDA label starting dose may be increased once by 25%. Continued use of the drug is not reasonable and necessary if the hemoglobin rises <1g/dl (hematocrit rise <3%) compared to pretreatment baseline by 8 weeks of treatment.

- Continued administration of the drug is not reasonable and necessary if there is a rapid rise in hemoglobin >1g/dl (hematocrit >3%) over 2 weeks of treatment unless the hemoglobin remains below or subsequently falls to <10g/dL (or the hematocrit is <30%). Continuation and reinstitution of ESA therapy must include a dose reduction of 25% from the previously administered dose.

- ESA treatment duration for each course of chemotherapy includes the 8 weeks following the final dose of myelosuppressive chemotherapy in a chemotherapy regimen.

C. Nationally Non-Covered Indications

ESA treatment is not reasonable and necessary for beneficiaries with certain clinical conditions, either because of a deleterious effect of the ESA on their underlying disease or because the underlying disease increases their risk of adverse effects related to ESA use. These conditions include:

- Any anemia in cancer or cancer treatment patients due to folate deficiency, B-12 deficiency, iron deficiency, hemolysis, bleeding, or bone marrow fibrosis;

- The anemia associated with the treatment of acute and chronic myelogenous leukemias (CML, AML), or erythroid cancers;

- The anemia of cancer not related to cancer treatment;

- Any anemia associated only with radiotherapy;

- Prophylactic use to prevent chemotherapy-induced anemia;

- Prophylactic use to reduce tumor hypoxia;

- Patients with erythropoietin-type resistance due to neutralizing antibodies; and

- Anemia due to cancer treatment if patients have uncontrolled hypertension.

D. Other

Local A/B MACs may continue to make reasonable and necessary determinations on all other uses of ESAs not specified in this National Coverage Determination.

See the Medicare Benefit Policy Manual, chapter 11, section 90 and chapter 15, section 50.5.2 for coverage of ESAs for end-stage renal disease-related anemia.

110.22 - Autologous Cellular Immunotherapy Treatment (Effective June 30, 2011)

(Rev. 140, Issued: 01-06-12, Effective: 06-30-11, Implementation: 08-08-11)

A. General

Prostate cancer is the most common non-cutaneous cancer in men in the United States. In 2009, an estimated 192,280 new cases of prostate cancer were diagnosed and an estimated 27,360 deaths were reported. The National Cancer Institute states that prostate cancer is predominantly a cancer of older men; the median age at diagnosis is 72 years. Once the patient has castration-resistant, metastatic prostate cancer the median survival is generally less than two years.

In 2010 the Food and Drug Administration (FDA) approved sipuleucel-T (PROVENGE®; APC8015), for patients with castration-resistant, metastatic prostate cancer. The posited mechanism of action, immunotherapy, is different from that of anti-cancer chemotherapy such as docetaxel. This is the first immunotherapy for prostate cancer to receive FDA approval.

The goal of immunotherapy is to stimulate the body's natural defenses (such as the white blood cells called dendritic cells, T-lymphocytes and mononuclear cells) in a specific manner so that they attack and destroy, or at least prevent, the proliferation of cancer cells. Specificity is attained by intentionally exposing a patient's white blood cells to a particular protein (called an antigen) associated with the prostate cancer. This exposure "trains" the white blood cells to target and attack the prostate cancer cells. Clinically, this is expected to result in a decrease in the size and/or number of cancer sites, an increase in the time to cancer progression, and/or an increase in survival of the patient.

Sipuleucel-T differs from other infused anti-cancer therapies. Most such anti-cancer therapies are manufactured and sold by a biopharmaceutical company and then purchased by and dispensed from a pharmacy. In contrast, once the decision is made to treat with sipuleucel-T, a multi-step process is used to produce sipuleucel-T. Sipuleucel-T is made individually for each patient with his own white blood cells. The patient’s white blood cells are removed via a procedure called leukapheresis. In a laboratory the white blood cells are exposed to PA2024, which is a molecule created by linking prostatic acid phosphatase (PAP) with granulocyte/macrophage-colony stimulating factor (GM-CSF). PAP is an antigen specifically associated with prostate cancer cells; GM-CSF is a protein that targets a receptor on the surface of white blood cells. Hence, PAP serves to externally manipulate the immunological functioning of the patient's white blood cells while GM-CSF serves to stimulate the white blood cells into action. As noted in the FDA's clinical review, each dose of sipuleucel-T contains a minimum of 40 million treated white blood cells, however there is "high inherent variability" in the yield of sipuleucel-T from leukapheresis to leukapheresis in the same patient as well as from patient to patient. The treated white blood cells are then infused back into the same patient. The FDA-approved dosing regimen is three doses with each dose administered two weeks apart.

Indications and Limitations of Coverage

B. Nationally Covered Indications

Effective for services performed on or after June 30, 2011, The Centers for Medicare and Medicaid Services (CMS) proposes that the evidence is adequate to conclude that the use of autologous cellular immunotherapy treatment - sipuleucel-T; PROVENGE® improves health outcomes for Medicare beneficiaries with asymptomatic or minimally symptomatic metastatic castrate-resistant (hormone refractory) prostate cancer, and thus is reasonable and necessary for this on-label indication under 1862(a)(1)(A) of the Social Security Act.

C. Nationally Non-Covered Indications

N/A

D. Other

Effective for services performed on or after June 30, 2011, coverage of all off-label uses of autologous cellular immunotherapy treatment – sipuleucel-T; PROVENGE® for the treatment of prostate cancer is left to the discretion of the local A/B MACs.

(NCD last reviewed June 2011.)

110.23 - Stem Cell Transplantation (Formerly 110.8.1) (Various Effective Dates Below)
(Rev. 193, Issued; 07-01-16, Effective: 01-27-16, Implementation: 10-03-16)

A. General

Stem cell transplantation is a process in which stem cells are harvested from either a patient's (autologous) or donor's (allogeneic) bone marrow or peripheral blood for intravenous infusion. Autologous stem cell transplantation (AuSCT) is a technique for restoring stem cells using the patient's own previously stored cells. AuSCT must be used to effect hematopoietic reconstitution following severely myelotoxic doses of chemotherapy (HDCT) and/or radiotherapy used to treat various malignancies. Allogeneic hematopoietic stem cell transplantation (HSCT) is a procedure in which a portion of a healthy donor's stem cell or bone marrow is obtained and prepared for intravenous infusion. Allogeneic HSCT may be used to restore function in recipients having an inherited or acquired deficiency or defect. Hematopoietic stem cells are multi-potent stem cells that give rise to all the blood cell types; these stem cells form blood and immune cells. A hematopoietic stem cell is a cell isolated from blood or bone marrow that can renew itself, differentiate to a variety of specialized cells, can mobilize out of the bone marrow into circulating blood, and can undergo programmed cell death, called apoptosis - a process by which cells that are unneeded or detrimental will self-destruct.

The Centers for Medicare & Medicaid Services (CMS) is clarifying that bone marrow and peripheral blood stem cell transplantation is a process which includes mobilization, harvesting, and transplant of bone marrow or peripheral blood stem cells and the administration of high dose chemotherapy or radiotherapy prior to the actual transplant. When bone marrow or peripheral blood stem cell transplantation is covered, all necessary steps are included in coverage. When bone marrow or peripheral blood stem cell transplantation is non-covered, none of the steps are covered.

B. Nationally Covered Indications

I. Allogeneic Hematopoietic Stem Cell Transplantation (HSCT)

a) Effective for services performed on or after August 1, 1978, for the treatment of leukemia, leukemia in remission, or aplastic anemia when it is reasonable and necessary,

b) Effective for services performed on or after June 3, 1985, for the treatment of severe combined immunodeficiency disease (SCID) and for the treatment of Wiskott-Aldrich syndrome.

c) Effective for services performed on or after August 4, 2010, for the treatment of Myelodysplastic Syndromes (MDS) pursuant to Coverage with Evidence Development (CED) in the context of a Medicare-approved, prospective clinical study.

   MDS refers to a group of diverse blood disorders in which the bone marrow does not produce enough healthy, functioning blood cells. These disorders are varied with regard to clinical characteristics, cytologic and pathologic features, and cytogenetics. The abnormal production of blood cells in the bone marrow leads to low blood cell counts, referred to as cytopenias, which are a hallmark feature of MDS along with a dysplastic and hypercellular-appearing bone marrow

   Medicare payment for these beneficiaries will be restricted to patients enrolled in an approved clinical study. In accordance with the Stem Cell Therapeutic and Research Act of 2005 (US Public Law 109-129) a standard dataset is collected for all allogeneic transplant patients in the United States

by the Center for International Blood and Marrow Transplant Research. The elements in this dataset, comprised of two mandatory forms plus one additional form, encompass the information we require for a study under CED.

A prospective clinical study seeking Medicare payment for treating a beneficiary with allogeneic HSCT for MDS pursuant to CED must meet one or more aspects of the following questions:

1. Prospectively, compared to Medicare beneficiaries with MDS who do not receive HSCT, do Medicare beneficiaries with MDS who receive HSCT have improved outcomes as indicated by:

    - Relapse-free mortality,
    - progression free survival,
    - relapse, and
    - overall survival?

2. Prospectively, in Medicare beneficiaries with MDS who receive HSCT, how do International Prognostic Scoring System (IPSS) scores, patient age, cytopenias, and comorbidities predict the following outcomes:

    - Relapse-free mortality,
    - progression free survival,
    - relapse, and
    - overall survival?

3. Prospectively, in Medicare beneficiaries with MDS who receive HSCT, what treatment facility characteristics predict meaningful clinical improvement in the following outcomes:

    - Relapse-free mortality,
    - progression free survival,
    - relapse, and
    - overall survival?

In addition, the clinical study must adhere to the following standards of scientific integrity and relevance to the Medicare population:

a. The principal purpose of the research study is to test whether a particular intervention potentially improves the participants' health outcomes.

b. The research study is well supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.

c. The research study does not unjustifiably duplicate existing studies.

d. The research study design is appropriate to answer the research question being asked in the study.

e. The research study is sponsored by an organization or individual capable of executing the proposed study successfully.

f. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 CFR Part 46. If a study is regulated by the Food and Drug Administration (FDA), it must be in compliance with 21 CFR parts 50 and 56.

g. All aspects of the research study are conducted according to appropriate standards of scientific integrity (see http://www.icmje.org).

h. The research study has a written protocol that clearly addresses, or incorporates by reference, the standards listed here as Medicare requirements for CED coverage.

i. The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life threatening as defined in 21 CFR §312.81(a) and the patient has no other viable treatment options.

j. The clinical research study is registered on the ClinicalTrials.gov Web site by the principal sponsor/investigator prior to the enrollment of the first study subject.

k. The research study protocol specifies the method and timing of public release of all pre-specified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned to be published in a peer-reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors (http://www.icmje.org). However a full report of the outcomes must be made public no later than 3 years after the end of data collection.

l. The research study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria effect enrollment of these populations, and a plan for the retention and reporting of said populations on the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.

m. The research study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

Consistent with section 1142 of the Social Security Act, the Agency for Health Research and Quality (AHRQ) supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

The clinical research study should also have the following features:

- It should be a prospective, longitudinal study with clinical information from the period before HSCT and short- and long-term follow-up information.

- Outcomes should be measured and compared among pre-specified subgroups within the cohort.

- The study should be powered to make inferences in subgroup analyses.

- Risk stratification methods should be used to control for selection bias. Data elements to be used in risk stratification models should include:

  Patient selection:
  - Patient Age at diagnosis of MDS and at transplantation
  - Date of onset of MDS
  - Disease classification (specific MDS subtype at diagnosis prior to preparative/conditioning regimen using World Health Organization (WHO) classifications). Include presence/absence of refractory cytopenias

- Comorbid conditions
- IPSS score (and WHO-adapted Prognostic Scoring System (WPSS) score, if applicable) at diagnosis and prior to transplantation
- Score immediately prior to transplantation and one year post-transplantation
- Disease assessment at diagnosis at start of preparative regimen and last assessment prior to preparative regimen Subtype of MDS (refractory anemia with or without blasts, degree of blasts, etc.)
- Type of preparative/conditioning regimen administered (myeloabalative, non-myeloablative, reduced–intensity conditioning)
- Donor type
- Cell Source

Facilities must submit the required transplant essential data to the Stem Cell Therapeutics Outcomes Database.

d) Effective for claims with dates of service on or after January 27, 2016, allogeneic HSCT for multiple myeloma is covered by Medicare only for beneficiaries with Durie-Salmon Stage II or III multiple myeloma, or International Staging System (ISS) Stage II or Stage III multiple myeloma, and participating in an approved prospective clinical study that meets the criteria below. There must be appropriate statistical techniques to control for selection bias and confounding by age, duration of diagnosis, disease classification, International Myeloma Working Group (IMWG) classification, ISS stage, comorbid conditions, type of preparative/conditioning regimen, graft vs. host disease (GVHD) prophylaxis, donor type and cell source.

A prospective clinical study seeking Medicare coverage for allogeneic HSCT for multiple myeloma pursuant to CED must address the following question:

Compared to patients who do not receive allogeneic HSCT, do Medicare beneficiaries with multiple myeloma who receive allogeneic HSCT have improved outcomes as indicated by:

- Graft vs. host disease (acute and chronic);
- Other transplant-related adverse events;
- Overall survival; and
- (optional) Quality of life?

All CMS-approved clinical studies and registries must adhere to the below listed standards of scientific integrity and relevance to the Medicare population as listed in section g.

e) Effective for claims with dates of service on or after January 27, 2016, allogeneic HSCT for myelofibrosis (MF) is covered by Medicare only for beneficiaries with Dynamic International Prognostic Scoring System (DIPSSplus) intermediate-2 or High primary or secondary MF and participating in an approved prospective clinical study. All Medicare approved studies must use appropriate statistical techniques in the analysis to control for selection bias and potential confounding by age, duration of diagnosis, disease classification, DIPSSplus score, comorbid conditions, type of preparative/conditioning regimen, graft vs. host disease (GVHD) prophylaxis, donor type and cell source.

A prospective clinical study seeking Medicare coverage for allogeneic HSCT for myelofibrosis pursuant to Coverage with Evidence Development (CED) must address the following question:

Compared to patients who do not receive allogeneic HSCT, do Medicare beneficiaries with MF who receive allogeneic HSCT transplantation have improved outcomes as indicated by:

- Graft vs. host disease (acute and chronic);
- Other transplant-related adverse events;

- Overall survival; and
- (optional) Quality of life?

All CMS-approved clinical studies and registries must adhere to the below listed standards of scientific integrity and relevance to the Medicare population as listed in section g.

f) Effective for claims with dates of service on or after January 27, 2016, allogeneic HSCT for sickle cell disease (SCD) is covered by Medicare only for beneficiaries with severe, symptomatic SCD who participate in an approved prospective clinical study.

A prospective clinical study seeking Medicare coverage for allogeneic HSCT for sickle cell disease pursuant to Coverage with Evidence Development (CED) must address the following question:

Compared to patients who do not receive allogeneic HSCT, do Medicare beneficiaries with SCD who receive allogeneic HSCT have improved outcomes as indicated by:

- Graft vs. host disease (acute and chronic),
- Other transplant-related adverse events;
- Overall survival; and
- (optional) Quality of life?

All CMS-approved clinical studies and registries must adhere to the below listed standards of scientific integrity and relevance to the Medicare population listed in section g:

g) All CMS-approved clinical studies and registries in sections d, e and f must adhere to the below listed standards of scientific integrity and relevance to the Medicare population:

a. The principal purpose of the study is to test whether the item or service meaningfully improves health outcomes of affected beneficiaries who are represented by the enrolled subjects.

b. The rationale for the study is well supported by available scientific and medical evidence.

c. The study results are not anticipated to unjustifiably duplicate existing knowledge.

d. The study design is methodologically appropriate and the anticipated number of enrolled subjects is sufficient to answer the research question(s) being asked in the National Coverage Determination.

e. The study is sponsored by an organization or individual capable of completing it successfully.

f. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found in the Code of Federal Regulations (CFR) at 45 CFR Part 46. If a study is regulated by the Food and Drug Administration (FDA), it is also in compliance with 21 CFR Parts 50 and 56. In addition, to further enhance the protection of human subjects in studies conducted under CED, the study must provide and obtain meaningful informed consent from patients regarding the risks associated with the study items and/or services, and the use and eventual disposition of the collected data.

g. All aspects of the study are conducted according to appropriate standards of scientific integrity.

h. The study has a written protocol that clearly demonstrates adherence to the standards listed here as Medicare requirements.

i. The study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Such studies may meet this requirement only if the disease or condition being

studied is life threatening as defined in 21 CFR §312.81(a) and the patient has no other viable treatment options.

j. The clinical research studies and registries are registered on the www.ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject. Registries are also registered in the Agency for Healthcare Quality (AHRQ) Registry of Patient Registries (RoPR).

k. The research study protocol specifies the method and timing of public release of all prespecified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 12 months of the study's primary completion date, which is the date the final subject had final data collection for the primary endpoint, even if the trial does not achieve its primary aim. The results must include number started/completed, summary results for primary and secondary outcome measures, statistical analyses, and adverse events. Final results must be reported in a publicly accessibly manner; either in a peer-reviewed scientific journal (in print or on-line), in an on-line publicly accessible registry dedicated to the dissemination of clinical trial information such as ClinicalTrials.gov, or in journals willing to publish in abbreviated format (e.g., for studies with negative or incomplete results).

l. The study protocol must explicitly discuss beneficiary subpopulations affected by the item or service under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria effect enrollment of these populations, and a plan for the retention and reporting of said populations in the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.

m. The study protocol explicitly discusses how the results are or are not expected to be generalizable to affected beneficiary subpopulations. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

Consistent with section 1142 of the Act, the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

II. **Autologous Stem Cell Transplantation (AuSCT)**

a) Effective for services performed on or after April 28, 1989, AuSCT is considered reasonable and necessary under §l862(a)(1)(A) of the Act for the following conditions and is covered under Medicare for patients with:

1. Acute leukemia in remission who have a high probability of relapse and who have no human leucocyte antigens (HLA)-matched;

2. Resistant non-Hodgkin's lymphomas or those presenting with poor prognostic features following an initial response;

3. Recurrent or refractory neuroblastoma; or,

4. Advanced Hodgkin's disease who have failed conventional therapy and have no HLA-matched donor.

b) Effective October 1, 2000, single AuSCT is only covered for Durie-Salmon Stage II or III patients that fit the following requirements:

- Newly diagnosed or responsive multiple myeloma. This includes those patients with previously untreated disease, those with at least a partial response to prior chemotherapy (defined as a 50% decrease either in measurable paraprotein [serum and/or urine] or in bone marrow infiltration, sustained for at least 1 month), and those in responsive relapse; and

- Adequate cardiac, renal, pulmonary, and hepatic function.

c) Effective for services performed on or after March 15, 2005, when recognized clinical risk factors are employed to select patients for transplantation, high dose melphalan (HDM) together with AuSCT is reasonable and necessary for Medicare beneficiaries of any age group with primary amyloid light chain (AL) amyloidosis who meet the following criteria:

- Amyloid deposition in 2 or fewer organs; and,
- Cardiac left ventricular ejection fraction (EF) greater than 45%.

C. Nationally Non-Covered Indications

I. Allogeneic Hematopoietic Stem Cell Transplantation (HSCT)

Effective for claims with dates of service on or after May 24, 1996, through January 26, 2016, allogeneic HSCT is not covered as treatment for multiple myeloma.

II. Autologous Stem Cell Transplantation (AuSCT)

Insufficient data exist to establish definite conclusions regarding the efficacy of AuSCT for the following conditions:

a) Acute leukemia not in remission;
b) Chronic granulocytic leukemia;
c) Solid tumors (other than neuroblastoma);
d) Up to October 1, 2000, multiple myeloma;
e) Tandem transplantation (multiple rounds of AuSCT) for patients with multiple myeloma;
f) Effective October 1, 2000, non primary AL amyloidosis; and,
g) Effective October 1, 2000, through March 14, 2005, primary AL amyloidosis for Medicare beneficiaries age 64 or older.

In these cases, AuSCT is not considered reasonable and necessary within the meaning of §1862(a)(1)(A) of the Act and is not covered under Medicare.

D. Other

All other indications for stem cell transplantation not otherwise noted above as covered or non-covered remain at local Medicare Administrative Contractor discretion.

(This NCD last reviewed January 2016.)

110.24 Chimeric Antigen Receptor (CAR) T-cell therapy

(Rev. 10891, Issued: 07-20-21, Effective: 08-07-19, Implementation: 09-20-21)

A. General

Cancer is a collection of related diseases of dividing cells that can start almost anywhere in or on the body, evade the immune system, and invade nearby tissues. Categories of cancer are typically organized by the location in the body and specific type of cell. These categories may include carcinoma, sarcoma, leukemia, lymphoma, multiple myeloma, melanoma, and brain and spinal cord tumors. There are also changes to these

cells that are not considered cancer. These changes include hyperplasia—when a cell divides faster than normal—and dysplasia—a buildup of extra cells with abnormal shape and disorganization.

A person's immune system contains cells to help fight substances that are foreign to the body, including cancer. These cells are called white blood cells, most of which are lymphocytes. The two main types of lymphocytes are B lymphocytes (B-cells) and T lymphocytes (T-cells). B-cells generate and release antibodies to fight infection, especially bacterial infections, while T-cells employ a number of other mechanisms to fight abnormal cells such as cancer. One type of therapy that leverages the immune system—immunotherapy—is Chimeric Antigen Receptor (CAR) T-cell therapy.

CAR T-cells have been genetically altered in order to improve the ability of the T-cells to fight cancer. The genetic modification creating a CAR can enhance the ability of the T-cell to recognize and attach to a specific protein, called an antigen, on the surface of a cancer cell.

B. Nationally Covered Indications

A. Effective for services performed on or after August 7, 2019, the Centers for Medicare & Medicaid Services (CMS) covers autologous treatment for cancer with T-cells expressing at least one chimeric antigen receptor (CAR) when administered at healthcare facilities enrolled in the FDA risk evaluation and mitigation strategies (REMS) and used for a medically accepted indication as defined at Social Security Act section 1861(t)(2) -i.e., is used for either an FDA-approved indication (according to the FDA-approved label for that product), or for other uses when the product has been FDA-approved and the use is supported in one or more CMS-approved compendia.

C. Nationally Non-Covered

Effective for services performed on or after August 7, 2019, the use of non-FDA-approved autologous T-cells expressing at least one CAR is non-covered. Autologous treatment for cancer with T-cells expressing at least one CAR is non-covered when the requirements in Section A are not met.

D. Other

Effective for services performed on or after August 7, 2019, routine costs in clinical trials that use CAR T-cell therapy as an investigational agent that meet the requirements listed in NCD 310.1 will be covered.

(This NCD last reviewed August 2019.)

120 - Infectious Diseases
(Rev. 1, 10-03-03)

No coverage determinations

130 - Mental Health
(Rev. 1, 10-03-03)

130.1 - Inpatient Hospital Stays for the Treatment of Alcoholism
(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD-10, Implementation: Upon Implementation of ICD-10)

A. Inpatient Hospital Stay for Alcohol Detoxification

Many hospitals provide detoxification services during the more acute stages of alcoholism or alcohol withdrawal. When the high probability or occurrence of medical complications (e.g., delirium, confusion,

trauma, or unconsciousness) during detoxification for acute alcoholism or alcohol withdrawal necessitates the constant availability of physicians and/or complex medical equipment found only in the hospital setting, inpatient hospital care during this period is considered reasonable and necessary and is therefore covered under the program. Generally, detoxification can be accomplished within two to three days with an occasional need for up to five days where the patient's condition dictates. This limit (five days) may be extended in an individual case where there is a need for a longer period for detoxification for a particular patient.

In such cases, however, there should be documentation by a physician which substantiates that a longer period of detoxification was reasonable and necessary. When the detoxification needs of an individual no longer require an inpatient hospital setting, coverage should be denied on the basis that inpatient hospital care is not reasonable and necessary as required by §1862(a)(l) of the Social Security Act (the Act). Following detoxification a patient may be transferred to an inpatient rehabilitation unit or discharged to a residential treatment program or outpatient treatment setting.

B. Inpatient Hospital Stay for Alcohol Rehabilitation

Hospitals may also provide structured inpatient alcohol rehabilitation programs to the chronic alcoholic. These programs are composed primarily of coordinated educational and psychotherapeutic services provided on a group basis. Depending on the subject matter, a series of lectures, discussions, films, and group therapy sessions are led by either physicians, psychologists, or alcoholism counselors from the hospital or various outside organizations. In addition, individual psychotherapy and family counseling (see §70.1) may be provided in selected cases. These programs are conducted under the supervision and direction of a physician. Patients may directly enter an inpatient hospital rehabilitation program after having undergone detoxification in the same hospital or in another hospital or may enter an inpatient hospital rehabilitation program without prior hospitalization for detoxification.

Alcohol rehabilitation can be provided in a variety of settings other than the hospital setting. In order for an inpatient hospital stay for alcohol rehabilitation to be covered under Medicare it must be medically necessary for the care to be provided in the inpatient hospital setting rather than in a less costly facility or on an outpatient basis. Inpatient hospital care for receipt of an alcohol rehabilitation program would generally be medically necessary where either (l) there is documentation by the physician that recent alcohol rehabilitation services in a less intensive setting or on an outpatient basis have proven unsuccessful and, as a consequence, the patient requires the supervision and intensity of services which can only be found in the controlled environment of the hospital, or (2) only the hospital environment can assure the medical management or control of the patient's concomitant conditions during the course of alcohol rehabilitation. (However, a patient's concomitant condition may make the use of certain alcohol treatment modalities medically inappropriate.)

In addition, the "active treatment" criteria (see the Medicare Benefit Policy Manual, Chapter 2, "Inpatient Psychiatric Hospital Services," §20) should be applied to psychiatric care in the general hospital as well as to psychiatric care in a psychiatric hospital. Since alcoholism is classifiable as a psychiatric condition the "active treatment" criteria must also be met in order for alcohol rehabilitation services to be covered under Medicare. (Thus, it is the combined need for "active treatment" and for covered care which can only be provided in the inpatient hospital setting, rather than the fact that rehabilitation immediately follows a period of detoxification which provides the basis for coverage of inpatient hospital alcohol rehabilitation programs.)

Generally 16-19 days of rehabilitation services are sufficient to bring a patient to a point where care could be continued in other than an inpatient hospital setting. An inpatient hospital stay for alcohol rehabilitation may be extended beyond this limit in an individual case where a longer period of alcohol rehabilitation is medically necessary. In such cases, however, there should be documentation by a physician which substantiates the need for such care. Where the rehabilitation needs of an individual no longer require an inpatient hospital setting, coverage should be denied on the basis that inpatient hospital care is not reasonable and necessary as required by §1862 (a)(l) of the Act.

Subsequent admissions to the inpatient hospital setting for alcohol rehabilitation follow-up, reinforcement, or "recap" treatments are considered to be readmissions (rather than an extension of the original stay) and must meet the requirements of this section for coverage under Medicare. Prior admissions to the inpatient hospital setting - either in the same hospital or in a different hospital - may be an indication that the "active treatment" requirements are not met (i.e., there is no reasonable expectation of improvement) and the stay should not be covered. Accordingly, there should be documentation to establish that "readmission" to the hospital setting for alcohol rehabilitation services can reasonably be expected to result in improvement of the patient's condition. For example, the documentation should indicate what changes in the patient's medical condition, social or emotional status, or treatment plan make improvement likely, or why the patient's initial hospital treatment was not sufficient.

C. Combined Alcohol Detoxification/Rehabilitation Programs

A/B MACs should apply the guidelines in A. and B. above to both phases of a combined inpatient hospital alcohol detoxification/rehabilitation program. Not all patients who require the inpatient hospital setting for detoxification also need the inpatient hospital setting for rehabilitation. (See §130.1 for coverage of outpatient hospital alcohol rehabilitation services.) Where the inpatient hospital setting is medically necessary for both alcohol detoxification and rehabilitation, generally a 3-week period is reasonable and necessary to bring the patient to the point where care can be continued in other than an inpatient hospital setting.

Decisions regarding reasonableness and necessity of treatment, the need for an inpatient hospital level of care, and length of treatment should be made by the A/B MAC (A) based on accepted medical practice with the advice of their medical consultant. (In hospitals under PSRO review, PSRO determinations of medical necessity of services and appropriateness of the level of care at which services are provided are binding on the A/B MAC (A) for purposes of adjudicating claims for payment.)

130.2 - Outpatient Hospital Services for Treatment of Alcoholism

(Rev. 1, 10-03-03)
CIM 35-22

Some hospitals also provide services on an outpatient basis, either individually or as part of a day hospitalization program, for treatment of alcoholism. These services may include, for example, drug therapy, psychotherapy, and patient education and may be furnished by physicians, psychologists, nurses, and alcoholism counselors to individuals who have been discharged from an inpatient hospital stay for treatment of alcoholism and require continued treatment or to individuals from the community who require treatment but do not require the inpatient hospital setting.

Coverage is available for both diagnostic and therapeutic services furnished for the treatment of alcoholism by the hospital to outpatients subject to the same rules applicable to outpatient hospital services in general (see the Medicare Benefit Policy Manual, Chapter 6, "Hospital Services Covered Under Part B," §§20). While there is no coverage for day hospitalization programs, per se, individual services which meet the requirements in the Medicare Benefit Policy Manual, Chapter 6, "Hospital Services Covered Under Part B," §§20 may be covered. (Meals, transportation, and recreational and social activities do not fall within the scope of covered outpatient hospital services under Medicare.)

All services must be reasonable and necessary for diagnosis or treatment of the patient's condition (see the Medicare Benefit Policy Manual, Chapter 16, "General Exclusions from Coverage," §20). Thus, educational services and family counseling would only be covered where they are directly related to treatment of the patient's condition. (See also §70.1.) The frequency of treatment and period of time over which it occurs must also be reasonable and necessary.

130.3 - Chemical Aversion Therapy for Treatment of Alcoholism

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD-10, Implementation: Upon Implementation of ICD-10)

Chemical aversion therapy is a behavior modification technique that is used in the treatment of alcoholism. Chemical aversion therapy facilitates alcohol abstinence through the development of conditioned aversions to the taste, smell, and sight of alcohol beverages. This is accomplished by repeatedly pairing alcohol with unpleasant symptoms (e.g., nausea) which have been induced by one of several chemical agents. While a number of drugs have been employed in chemical aversion therapy, the three most commonly used are emetine, apomorphine, and lithium. None of the drugs being used, however, have yet been approved by the Food and Drug Administration specifically for use in chemical aversion therapy for alcoholism. Accordingly, when these drugs are being employed in conjunction with this therapy, patients undergoing this treatment need to be kept under medical observation.

Available evidence indicates that chemical aversion therapy may be an effective component of certain alcoholism treatment programs, particularly as part of multi-modality treatment programs which include other behavioral techniques and therapies, such as psychotherapy. Based on this evidence, the Centers for Medicare & Medicaid Services' medical consultants have recommended that chemical aversion therapy be covered under Medicare. However, since chemical aversion therapy is a demanding therapy which may not be appropriate for all Medicare beneficiaries needing treatment for alcoholism, a physician should certify to the appropriateness of chemical aversion therapy in the individual case. Therefore, if chemical aversion therapy for treatment of alcoholism is determined to be reasonable and necessary for an individual patient, it is covered under Medicare.

When it is medically necessary for a patient to receive chemical aversion therapy as a hospital inpatient, coverage for care in that setting is available. (See §130.1 regarding coverage of multi-modality treatment programs.) Follow-up treatments for chemical aversion therapy can generally be provided on an outpatient basis. Thus, where a patient is admitted as an inpatient for receipt of chemical aversion therapy, there must be documentation by the physician of the need in the individual case for the inpatient hospital admission.

Decisions regarding reasonableness and necessity of treatment and the need for an inpatient hospital level of care should be made by the A/B MAC (A) based on accepted medical practice with the advice of their medical consultant. (In hospitals under Quality Improvement Organization (QIO) review, QIO determinations of medical necessity of services and appropriateness of the level of care at which services are provided are binding on the A/B MAC (A) for purposes of adjudicating claims for payment.)

130.4 - Electrical Aversion Therapy for Treatment of Alcoholism

(Rev. 1, 10-03-03)
CIM 35-23.1

Electroversion Therapy, Electro-shock Therapy, Noxious Faradic Stimulation.

Electrical aversion therapy is a behavior modification technique to foster abstinence from ingestion of alcoholic beverages by developing in a patient conditioned aversions to their taste, smell and sight through electric stimulation. Electrical aversion therapy has not been shown to be safe and effective and therefore is excluded from coverage. (See also §§130.1, 130.3, and 30.1).

130.5 - Treatment of Alcoholism and Drug Abuse in a Freestanding Clinic

(Rev. 1, 10-03-03)
CIM 35-22.3

Coverage is available for alcoholism or drug abuse treatment services (such as drug therapy, psychotherapy, and patient education) that are provided incident to a physicians professional service in a freestanding clinic to patients who, for example, have been discharged from an inpatient hospital stay for the treatment of alcoholism or drug abuse or to individuals who are not in the acute stages of alcoholism or drug abuse but require treatment. The coverage available for these services is subject to the same rules generally applicable

to the coverage of clinic services. (See the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §60.1; the Medicare Claims Processing Manual, Chapter 12, "Physician/Practitioners Billing," §10; the Medicare General Information, Eligibility, and Entitlement Manual, Chapter 3, "Deductibles, Coinsurance Amounts, and Payment Limitations," §30. Of course, the services also must be reasonable and necessary for the diagnosis or treatment of the individual's alcoholism or drug abuse. The Part B psychiatric limitation (see the Medicare General Information, Eligibility, and Entitlement Manual, Chapter 3, "Deductibles, Coinsurance Amounts, and Payment Limitations," §30) would apply to alcoholism or drug abuse treatment services furnished by physicians to individuals who are not hospital inpatients.

130.6 - Treatment of Drug Abuse (Chemical Dependency)

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD-10, Implementation: Upon Implementation of ICD-10)

The Centers for Medicare & Medicaid Services recognizes that there are similarities between the approach to treatment of drug abuse and alcohol detoxification and rehabilitation. However, the intensity and duration of treatment for drug abuse may vary (depending on the particular substance(s) of abuse, duration of use, and the patient's medical and emotional condition) from the duration of treatment or intensity needed to treat alcoholism. Accordingly, when it is medically necessary for a patient to receive detoxification and/or rehabilitation for drug substance abuse as a hospital inpatient, coverage for care in that setting is available. Coverage is also available for treatment services that are provided in the outpatient department of a hospital to patients who, for example, have been discharged from an inpatient stay for the treatment of drug substance abuse or who require treatment but do not require the availability and intensity of services found only in the inpatient hospital setting. The coverage available for these services is subject to the same rules generally applicable to the coverage of outpatient hospital services. (See the Medicare Benefit Policy Manual, Chapter 6, "Hospital Services Covered Under Part B," §§20.) The services must also be reasonable and necessary for treatment of the individual's condition. (See the Medicare Benefit Policy Manual, Chapter 16, "General Exclusions from Coverage," §90.) Decisions regarding reasonableness and necessity of treatment, the need for an inpatient hospital level of care and length of treatment, should be made by A/B MACs based on accepted medical practice with the advice of their medical consultant. (In hospitals under Quality Improvement Organization (QIO) review, QIO determinations of medical necessity of services and appropriateness of the level of care at which services are provided are binding on A/B MACs for purposes of adjudicating claims for payment.)

130.7 - Withdrawal Treatments for Narcotic Addictions

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD-10, Implementation: Upon Implementation of ICD-10)

Withdrawal is an accepted treatment for narcotic addiction, and Part B payment can be made for these services if they are provided by the physician directly or under his personal supervision and if they are reasonable and necessary. In reviewing claims, reasonableness and necessity are determined with the aid of the A/B MAC (B)'s medical staff.

Drugs that the physician provides in connection with this treatment are also covered if they cannot be self-administered and meet all other statutory requirements.

Cross-reference:

Medicare Benefit Policy Manual, Chapter 6, "Hospital Services Covered Under Part B," §20.4.1.

130.8 - Hemodialysis for Treatment of Schizophrenia

(Rev. 1, 10-03-03)
CIM 35-51

Not Covered

Scientific evidence supporting use of hemodialysis as a safe and effective means of treatment for schizophrenia is inconclusive at this time. Accordingly, Medicare does not cover hemodialysis for treatment of schizophrenia.

140 - Miscellaneous Surgical Procedures
(Rev. 1, 10-03-03)

140.1 - Abortion
(Rev. 48, Issued: 03-17-06; Effective/Implementation Dates: 06-19-06)
CIM 35-99

Abortions are not covered Medicare procedures except:

1. If the pregnancy is the result of an act of rape or incest; or

2. In the case where a woman suffers from a physical disorder, physical injury, or physical illness, including a life-endangering physical condition caused by or arising from the pregnancy itself, that would, as certified by a physician, place the woman in danger of death unless an abortion is performed.

140.2 - Breast Reconstruction Following Mastectomy
(Rev. 1, 10-03-03)
CIM 35-47

During recent years, there has been a considerable change in the treatment of diseases of the breast such as fibrocystic disease and cancer. While extirpation of the disease remains of primary importance, the quality of life following initial treatment is increasingly recognized as of great concern. The increased use of breast reconstruction procedures is due to several factors:

- A change in epidemiology of breast cancer, including an apparent increase in incidence;
- Improved surgical skills and techniques;
- The continuing development of better prostheses; and
- Increasing awareness by physicians of the importance of postsurgical psychological adjustment.

Reconstruction of the affected and the contralateral unaffected breast following a medically necessary mastectomy is considered a relatively safe and effective noncosmetic procedure. Accordingly, program payment may be made for breast reconstruction surgery following removal of a breast for any medical reason.

Program payment may not be made for breast reconstruction for cosmetic reasons. (Cosmetic surgery is excluded from coverage under §1862(a)(10) of the Act.)

140.4 - Plastic Surgery to Correct "Moon Face"
(Rev. 1, 10-03-03)
CIM 35-12

Not Covered

The cosmetic surgery exclusion precludes payment for any surgical procedure directed at improving appearance. The condition giving rise to the patient's preoperative appearance is generally not a consideration. The only exception to the exclusion is surgery for the prompt repair of an accidental injury or

for the improvement of a malformed body member which coincidentally serves some cosmetic purpose. Since surgery to correct a condition of "moon face" which developed as a side effect of cortisone therapy does not meet the exception to the exclusion, it is not covered under Medicare (§1862(a)(10) of the Act).

Cross reference: The Medicare Benefit Policy Manual, Chapter 16, "General Exclusions From Coverage," §120.

140.5 - Laser Procedures

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD-10, Implementation: Upon Implementation of ICD-10)

Medicare recognizes the use of lasers for many medical indications. Procedures performed with lasers are sometimes used in place of more conventional techniques. In the absence of a specific non-coverage instruction, and where a laser has been approved for marketing by the Food and Drug Administration, A/B MAC discretion may be used to determine whether a procedure performed with a laser is reasonable and necessary and, therefore, covered.

The determination of coverage for a procedure performed using a laser is made on the basis that the use of lasers to alter, revise, or destroy tissue is a surgical procedure. Therefore, coverage of laser procedures is restricted to practitioners with training in the surgical management of the disease or condition being treated.

140.6 – Wrong Surgical or Other Invasive Procedure Performed on a Patient (Effective January 15, 2009)

(Rev. 102; Issued: 07-02-09; Effective Date: 01-15-09; Implementation Date: JULY 6, 2009 FOR B MACS AND CARRIERS OCTOBER 5, 2009, FOR A MACS, FIs, AND FISS)

A. General

In 2002, the National Quality Forum (NQF) published "Serious Reportable Events in Healthcare: A Consensus Report"[1], which listed 27 adverse events that were "serious, largely preventable and of concern to both the public and health care providers." These events and subsequent revisions to the list became known as "never events." This concept and need for the proposed reporting led to NQF's "Consensus Standards Maintenance Committee on Serious Reportable Events," which maintains and updates the list which currently contains 28 items. Among surgical events on the list is "Wrong surgical procedure performed on a patient." Similar to any other patient population, Medicare beneficiaries experience serious injury and/or death if wrong surgeries are performed and may require additional healthcare in order to correct adverse outcomes resulting from such errors.

B. Nationally Covered Indications

N/A

C. Nationally Non-covered Indications

The CMS does not cover a particular surgical or other invasive procedure to treat a particular medical condition when a practitioner erroneously performs a different procedure on a Medicare beneficiary because that particular surgical or other invasive procedure is not a reasonable and necessary treatment for the Medicare beneficiary's particular medical condition.

A surgical or other invasive procedure is considered to be the wrong procedure if it is not consistent with the correctly documented informed consent for that patient. Emergent situations that occur in the course of surgery and/or whose exigency precludes obtaining informed consent are not considered erroneous under this decision. Also, the event is not intended to capture changes in the plan upon surgical entry into the

[1] http://www.qualityforum.org/pdf/reports/sre.pdf

patient due to the discovery of pathology in close proximity to the intended site when the risk of a second surgery outweighs the benefit of patient consultation; or the discovery of an unusual physical configuration (e.g., adhesions, spine level/extra vertebrae).

Surgical and other invasive procedures are defined as operative procedures in which skin or mucous membranes and connective tissue are incised or an instrument is introduced through a natural body orifice. Invasive procedures include a range of procedures from minimally invasive dermatological procedures (biopsy, excision, and deep cryotherapy for malignant lesions) to extensive multi-organ transplantation. They include all procedures described by the codes in the surgery section of the Current Procedural Terminology (CPT) and other invasive procedures such as percutaneous transluminal angioplasty and cardiac catheterization. They include minimally invasive procedures involving biopsies or placement of probes or catheters requiring the entry into a body cavity through a needle or trocar. They do not include use of instruments such as otoscopes for examinations or very minor procedures such as drawing blood.

D. Other

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(Rev. 102; Issued: 02-07-09; Effect

N/A

(NCD last reviewed January 2009.)

140.7 – Surgical or Other Invasive Procedure Performed on the Wrong Body Part (Effective January 15, 2009ive Date: 01-15-09; Implementation Date: JULY 6, 2009 FOR B MACS AND CARRIERS OCTOBER 5, 2009, FOR A MACS, FIs, AND FISS)

A. General

In 2002, the National Quality Forum (NQF) published "Serious Reportable Events in Healthcare: A Consensus Report"[2], which listed 27 adverse events that were "serious, largely preventable and of concern to both the public and health care providers." These events and subsequent revisions to the list became known as "never events." This concept and need for the proposed reporting led to NQF's "Consensus Standards Maintenance Committee on Serious Reportable Events," which maintains and updates the list which currently contains 28 items. Among surgical events on the list is "Surgery performed on the wrong body part." Similar to any other patient population, Medicare beneficiaries experience serious injury and/or death if wrong surgeries are performed and may require additional healthcare in order to correct adverse outcomes resulting from such errors.

B. Nationally Covered Indications

N/A

C. Nationally Non-covered Indications

The CMS does not cover a particular surgical or other invasive procedure to treat a particular medical condition when a practitioner erroneously performs the procedure on the wrong body part because that particular surgical or other invasive procedure is not a reasonable and necessary treatment for the Medicare beneficiary's particular medical condition.

A surgical or other invasive procedure is considered to have been performed on the wrong body part if it is not consistent with the correctly documented informed consent for that patient including surgery on the right body part, but on the wrong location of the body; for example, left versus right (appendages and/or organs), or at the wrong level (spine). Emergent situations that occur in the course of surgery and/or whose exigency

[2] http://www.qualityforum.org/pdf/reports/sre.pdf

precludes obtaining informed consent are not considered erroneous under this decision. Also, the event is not intended to capture changes in the plan upon surgical entry into the patient due to the discovery of pathology in close proximity to the intended site when the risk of a second surgery outweighs the benefit of patient consultation; or the discovery of an unusual physical configuration (e.g., adhesions, spine level/extra vertebrae).

Surgical and other invasive procedures are defined as operative procedures in which skin or mucous membranes and connective tissue are incised or an instrument is introduced through a natural body orifice. Invasive procedures include a range of procedures from minimally invasive dermatological procedures (biopsy, excision, and deep cryotherapy for malignant lesions) to extensive multi-organ transplantation. They include all procedures described by the codes in the surgery section of the Current Procedural Terminology (CPT) and other invasive procedures such as percutaneous transluminal angioplasty and cardiac catheterization. They include minimally invasive procedures involving biopsies or placement of probes or catheters requiring the entry into a body cavity through a needle or trocar. They do not include use of instruments such as otoscopes for examinations or very minor procedures such as drawing blood.

D. Other

N/A

(NCD last reviewed January 2009.)

140.8 – Surgical or Other Invasive Procedure Performed on the Wrong Patient (Effective January 15, 2009)

(Rev. 102; Issued: 07-02-09; Effective Date: 01-15-09; Implementation Date: JULY 6, 2009 FOR B MACS AND CARRIERS OCTOBER 5, 2009, FOR A MACS, FIs, AND FISS)

A. General

In 2002, the National Quality Forum (NQF) published "Serious Reportable Events in Healthcare: A Consensus Report"[3], which listed 27 adverse events that were "serious, largely preventable and of concern to both the public and health care providers." These events and subsequent revisions to the list became known as "never events." This concept and need for the proposed reporting led to NQF's "Consensus Standards Maintenance Committee on Serious Reportable Events," which maintains and updates the list which currently contains 28 items. Among surgical events on the list is "Surgical procedure performed on the wrong patient." Similar to any other patient population, Medicare beneficiaries experience serious injury and/or death if wrong surgeries are performed and may require additional healthcare in order to correct adverse outcomes resulting from such errors.

B. Nationally Covered Indications

N/A

C. Nationally Non-covered Indications

The CMS does not cover a particular surgical or other invasive procedure to treat a particular medical condition when a practitioner erroneously performs a procedure that was intended for a different patient on a Medicare beneficiary who does not need that procedure because it is not a reasonable and necessary treatment for the Medicare beneficiary's particular medical condition.

A surgical or other invasive procedure is considered to have been performed on the wrong patient if that procedure is not consistent with the correctly documented informed consent for that patient.

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[3] http://www.qualityforum.org/pdf/reports/sre.pdf

Surgical and other invasive procedures are defined as operative procedures in which skin or mucous membranes and connective tissue are incised or an instrument is introduced through a natural body orifice. Invasive procedures include a range of procedures from minimally invasive dermatological procedures (biopsy, excision, and deep cryotherapy for malignant lesions) to extensive multi-organ transplantation. They include all procedures described by the codes in the surgery section of the Current Procedural Terminology (CPT) and other invasive procedures such as percutaneous transluminal angioplasty and cardiac catheterization. They include minimally invasive procedures involving biopsies or placement of probes or catheters requiring the entry into a body cavity through a needle or trocar. They do not include use of instruments such as otoscopes for examinations or very minor procedures such as drawing blood.

D. Other

N/A

(NCD last reviewed January 2009.)

140.9 - Gender Reassignment Surgery for Gender Dysphoria
(Rev. 194, Issued: 03-03-17, Effective: 08-30-16, Implementation; 04-04-17)

A. General

Gender reassignment surgery is a general term to describe a surgery or surgeries that affirm a person's gender identity.

B. Nationally Covered Indications

N/A

C. Nationally Non-Covered Indications

N/A

D. Other

The Centers for Medicare & Medicaid Coverage (CMS) conducted a National Coverage Analysis that focused on the topic of gender reassignment surgery. Effective August 30, 2016, after examining the medical evidence, CMS determined that no national coverage determination (NCD) is appropriate at this time for gender reassignment surgery for Medicare beneficiaries with gender dysphoria. In the absence of an NCD, coverage determinations for gender reassignment surgery, under section 1862(a)(1)(A) of the Social Security Act (the Act) and any other relevant statutory requirements, will continue to be made by the local Medicare Administrative Contractors (MACs) on a case-by-case basis.

(This policy last reviewed August 2016.)

150 - Musculoskeletal System
(Rev. 1, 10-03-03)

150.1 - Manipulation
(Rev. 1, 10-03-03)
CIM 35-2

A. Manipulation of the Rib Cage

Manual manipulation of the rib cage contributes to the treatment of respiratory conditions such as bronchitis, emphysema, and asthma as part of a regimen that includes other elements of therapy, and is covered only under such circumstances.

B. Manipulation of the Head

Manipulation of the occipitocervical or temporomandibular regions of the head when indicated for conditions affecting those portions of the head and neck is a covered service.

150.2 - Osteogenic Stimulator (Various Effective Dates Below)

(Rev. 41, Issued: 06-24-05, Effective: 04-27-05, Implementation: 08-01-05)
CIM-35-48

Electrical Osteogenic Stimulators

A. General

Electrical stimulation to augment bone repair can be attained either invasively or non-invasively. Invasive devices provide electrical stimulation directly at the fracture site either through percutaneously placed cathodes or by implantation of a coiled cathode wire into the fracture site. The power pack for the latter device is implanted into soft tissue near the fracture site and subcutaneously connected to the cathode, creating a self-contained system with no external components. The power supply for the former device is externally placed and the leads connected to the inserted cathodes. With the non-invasive device, opposing pads, wired to an external power supply, are placed over the cast. An electromagnetic field is created between the pads at the fracture site.

B. Nationally Covered Indications

1. Noninvasive Stimulator

The noninvasive stimulator device is covered only for the following indications:

- Nonunion of long bone fractures;
- Failed fusion, where a minimum of 9 months has elapsed since the last surgery;
- Congenital pseudarthroses;
- Effective July 1, 1996, as an adjunct to spinal fusion surgery for patients at high risk of pseudarthrosis due to previously failed spinal fusion at the same site or for those undergoing multiple level fusion. A multiple level fusion involves 3 or more vertebrae (e.g., L3-L5, L4-S1, etc).
- Effective September 15, 1980, nonunion of long bone fractures is considered to exist only after 6 or more months have elapsed without healing of the fracture.
- Effective April 1, 2000, nonunion of long bone fractures is considered to exist only when serial radiographs have confirmed that fracture healing has ceased for **3** or more months prior to starting treatment with the electrical osteogenic stimulator. Serial radiographs must include a minimum of 2 sets of radiographs, each including multiple views of the fracture site, separated by a minimum of 90 days.

2. Invasive (Implantable) Stimulator

The invasive stimulator device is covered only for the following indications:

- Nonunion of long bone fractures;

- Effective July 1, 1996, as an adjunct to spinal fusion surgery for patients at high risk of pseudarthrosis due to previously failed spinal fusion at the same site or for those undergoing multiple level fusion. A multiple level fusion involves 3 or more vertebrae (e.g., L3-L5, L4-S1, etc).

- Effective September 15, 1980, nonunion of long bone fractures is considered to exist only after 6 or more months have elapsed without healing of the fracture.

- Effective April 1, 2000**,** nonunion of long bone fractures is considered to exist only when serial radiographs have confirmed that fracture healing has ceased for **3** or more months prior to starting treatment with the electrical osteogenic stimulator. Serial radiographs must include a minimum of **2** sets of radiographs, each including multiple views of the fracture site, separated by a minimum of 90 days.

Ultrasonic Osteogenic Stimulators

A. General

An ultrasonic osteogenic stimulator is a noninvasive device that emits low intensity, pulsed ultrasound. The device is applied to the surface of the skin at the fracture site and ultrasound waves are emitted via a conductive coupling gel to stimulate fracture healing. The ultrasonic osteogenic stimulators are not be used concurrently with other non-invasive osteogenic devices.

B. Nationally Covered Indications

Effective January 1, 2001, ultrasonic osteogenic stimulators are covered as medically reasonable and necessary for the treatment of nonunion fractures. In demonstrating non-union fractures, CMS expects:

- A minimum of **2** sets of radiographs, obtained prior to starting treatment with the osteogenic stimulator, separated by a minimum of 90 days. Each radiograph set must include multiple views of the fracture site accompanied with a written interpretation by a physician stating that there has been no clinically significant evidence of fracture healing between the **2** sets of radiographs; and,

- Indications that the patient failed at least one surgical intervention for the treatment of the fracture.

- Effective April 27, 2005, upon reconsideration of ultrasound stimulation for nonunion fracture healing, CMS determines that the evidence is adequate to conclude that noninvasive ultrasound stimulation for the treatment of nonunion bone fractures prior to surgical intervention is reasonable and necessary. In demonstrating non-union fractures, CMS expects:

- A minimum of 2 sets of radiographs, obtained prior to starting treatment with the osteogenic stimulator, separated by a minimum of 90 days. Each radiograph set must include multiple views of the fracture site accompanied with a written interpretation by a physician stating that there has been no clinically significant evidence of fracture healing between the 2 sets of radiographs.

C. Nationally Non-Covered Indications

Nonunion fractures of the skull, vertebrae and those that are tumor-related are excluded from coverage.

Ultrasonic osteogenic stimulators may not be used concurrently with other non-invasive osteogenic devices.

Ultrasonic osteogenic stimulators for fresh fractures and delayed unions remains non-covered.

(This NCD last reviewed June 2005.)

150.3 - Bone (Mineral) Density Studies (Effective January 1, 2007)

(Rev. 69, Issued: 05-11-07, Effective: 01-01-07, Implementation: 07-02-07)

Conditions for coverage of bone mass measurements are now contained in chapter 15, section 80.5 of Pub. 100-02, Medicare Benefit Policy Manual. Claims processing instructions can be found in chapter 13, section 140 of Pub. 100-04, Medicare Claims Processing Manual.

150.5 - Diathermy Treatment

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD-10, Implementation: Upon Implementation of ICD-10)

High energy pulsed wave diathermy machines have been found to produce some degree of therapeutic benefit for essentially the same conditions and to the same extent as standard diathermy. Accordingly, where the A/B MAC's medical staff has determined that the pulsed wave diathermy apparatus used is one which is considered therapeutically effective, the treatments are considered a covered service, but only for those conditions for which standard diathermy is medically indicated and only when rendered by a physician or incident to a physician's professional services.

Cross-reference: §240.3.

(This NCD last reviewed June 2006.)

150.6 - Vitamin B12 Injections to Strengthen Tendons, Ligaments, etc., of the Foot

(Rev. 1, 10-03-03)
CIM 45-4

Not Covered

Vitamin B12 injections to strengthen tendons, ligaments, etc., of the foot are not covered under Medicare because (1) there is no evidence that vitamin B12 injections are effective for the purpose of strengthening weakened tendons and ligaments, and (2) this is nonsurgical treatment under the subluxation exclusion. Accordingly, vitamin B12 injections are not considered reasonable and necessary within the meaning of §1862(a)(1) of the Act.

Cross reference:

The Medicare Benefit Policy Manual, Chapter 1, "Inpatient Hospital Services," §30.

The Medicare Benefit Policy Manual, Chapter 16, "General Exclusions from Coverage," §100.

150.7 - Prolotherapy, Joint Sclerotherapy, and Ligamentous Injections with Sclerosing Agents

(Rev. 1, 10-03-03)
CIM 35-13

Not Covered

The medical effectiveness of the above therapies has not been verified by scientifically controlled studies. Accordingly, reimbursement for these modalities should be denied on the ground that they are not reasonable and necessary as required by §1862(a)(1) of the Act.

150.8 - Fluidized Therapy Dry Heat for Certain Musculoskeletal Disorders

(Rev. 1, 10-03-03)
CIM 35-56

Fluidized therapy is a high intensity heat modality consisting of a dry whirlpool of finely divided solid particles suspended in a heated air stream, the mixture having the properties of a liquid. Use of fluidized therapy dry heat is covered as an acceptable alternative to other heat therapy modalities in the treatment of acute or subacute traumatic or nontraumatic musculoskeletal disorders of the extremities.

150.9 - Arthroscopic Lavage and Arthroscopic Debridement for the Osteoarthritic Knee (Effective June 11, 2004)

(Rev. 14, 06-10-04)

Arthroscopy is a surgical procedure that allows the direct visualization of the interior joint space. In addition to providing visualization, arthroscopy enables the process of joint cleansing through the use of lavage or irrigation. Lavage alone may involve either large or small volume saline irrigation of the knee by arthroscopy. Although generally performed to reduce pain and improve function, current practice does not recognize the benefit of lavage alone for the reduction of mechanical symptoms. Arthroscopy also permits the removal of any loose bodies from the interior joint space, a procedure termed debridement. Debridement, when used alone or not otherwise specified, may include low volume lavage or washout. Osteoarthritis is a chronic and painful joint disease caused by degeneration. The American College of Rheumatology defines a patient diagnosis of osteoarthritis of the knee as presenting with pain, and meeting at least 5 of the following criteria:

- Over 50 years of age;
- Less than 30 minutes of morning stiffness;
- Crepitus (noisy, grating sound) on active motion;
- Bony tenderness;
- Bony enlargement;
- No palpable warmth of synovium;
- ESR <40mm/hr;
- Rheumatoid Factor <1:40; or,
- Synovial fluid signs.

A. Nationally Covered Indications

Not applicable.

B. Nationally Noncovered Indications

The clinical effectiveness of arthroscopic lavage and arthroscopic debridement for the severe osteoarthritic knee has not been verified by scientifically controlled studies. After thorough discussions with clinical investigators, the orthopedic community, and other interested parties, CMS determines that the following procedures are not considered reasonable or necessary in treatment of the osteoarthritic knee and are not covered by the Medicare program:

Arthroscopic lavage used alone for the osteoarthritic knee;

- Arthroscopic debridement for osteoarthritic patients presenting with knee pain only; or,

- Arthroscopic debridement and lavage with or without debridement for patients presenting with severe osteoarthritis ((Severe osteoarthritis is defined in the Outerbridge classification scale, grades III and IV. Outerbridge is the most commonly used clinical scale that classifies the severity of joint degeneration of the knee by compartments and grades. Grade I is defined as softening or blistering of joint cartilage. Grade II is defined as fragmentation or fissuring in an area <1 cm. Grade III presents clinically with cartilage fragmentation or fissuring in an area >1 cm. Grade IV refers to cartilage erosion down to the bone. Grades III and IV are characteristic of severe osteoarthritis.)

C. Other

Apart from the noncovered indications above for arthroscopic lavage and/or arthroscopic debridement of the osteoarthritic knee, all other indications of debridement for the subpopulation of patients without severe osteoarthritis of the knee who present with symptoms other than pain alone; i.e., (1) mechanical symptoms that include, but are not limited to, locking, snapping, or popping (2) limb and knee joint alignment, and (3) less severe and/or early degenerative arthritis, remain at local A/B MAC discretion. Medicare A/B MACs may require submission of one or all of the following documents to define the patient's knee condition:

- Operative notes,
- Reports of standing x-rays, or,
- Arthroscopy results.

(This NCD last reviewed June 2004.)

150.10 - Lumbar Artificial Disc Replacement (LADR) (Effective August 14, 2007)

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD-10, Implementation: Upon Implementation of ICD-10)

A. General

The lumbar artificial disc replacement (LADR) is a surgical procedure on the lumbar spine that involves complete removal of the damaged or diseased lumbar intervertebral disc and implantation of an artificial disc. The procedure may be done as an alternative to lumbar spinal fusion and is intended to reduce pain, increase movement at the site of surgery and restore intervertebral disc height. The Food and Drug Administration has approved the use of LADR for spine arthroplasty in skeletally mature patients with degenerative or discogenic disc disease at one level for L3 to S1.

B. Nationally Covered Indications

N/A

C. Nationally Non-Covered Indications

Effective for services performed from May 16, 2006 through August 13, 2007, the Centers for Medicare and Medicaid Services (CMS) has found that LADR with the Charite™ lumbar artificial disc is not reasonable and necessary for the Medicare population over 60 years of age; therefore, LADR with the Charite™ lumbar artificial disc is non-covered for Medicare beneficiaries over 60 years of age.

Effective for services performed on or after August 14, 2007, CMS has found that LADR is not reasonable and necessary for the Medicare population over 60 years of age; therefore, LADR is non-covered for Medicare beneficiaries over 60 years of age.

D. Other

For Medicare beneficiaries 60 years of age and younger, there is no national coverage determination for LADR, leaving such determinations to continue to be made by the local A/B MACs.

For dates of service May 16, 2006 through August 13, 2007, Medicare coverage under the investigational device exemption (IDE) for LADR with a disc other than the Charite™ lumbar disc in eligible clinical trials is not impacted.

150.11 - Thermal Intradiscal Procedures (TIPs) (Effective September 29, 2008)

(Rev. 97, Issued: 12-09-08, Effective: 09-29-08, Implementation: 01-05-09)

A. General

Percutaneous thermal intradiscal procedures (TIPs) involve the insertion of a catheter(s)/probe(s) in the spinal disc under fluoroscopic guidance for the purpose of producing or applying heat and/or disruption within the disc to relieve low back pain.

The scope of this national coverage determination on TIPs includes percutaneous intradiscal techniques that employ the use of a radiofrequency energy source or electrothermal energy to apply or create heat and/or disruption within the disc for coagulation and/or decompression of disc material to treat symptomatic patients with annular disruption of a contained herniated disc, to seal annular tears or fissures, or destroy nociceptors for the purpose of relieving pain. This includes techniques that use single or multiple probe(s)/catheter(s), which utilize a resistance coil or other delivery system technology, are flexible or rigid, and are placed within the nucleus, the nuclear-annular junction, or the annulus.

Although not intended to be an all inclusive list, TIPs are commonly identified as intradiscal electrothermal therapy (IDET), intradiscal thermal annuloplasty (IDTA), percutaneous intradiscal radiofrequency thermocoagulation (PIRFT), radiofrequency annuloplasty (RA), intradiscal biacuplasty (IDB), percutaneous (or plasma) disc decompression (PDD) or coblation, or targeted disc decompression (TDD). At times, TIPs are identified or labeled based on the name of the catheter/probe that is used (e.g., SpineCath, discTRODE, SpineWand, Accutherm, or TransDiscal electrodes). Each technique or device has it own protocol for application of the therapy. Percutaneous disc decompression or nucleoplasty procedures that do not utilize a radiofrequency energy source or electrothermal energy (such as the disc decompressor procedure or laser procedure) are not within the scope of this NCD.

B. Nationally Covered Indications

N/A

C. Nationally Non-Covered Indications

Effective for services performed on or after September 29, 2008, the Centers for Medicare and Medicaid Services has determined that TIPs are not reasonable and necessary for the treatment of low back pain. Therefore, TIPs, which include procedures that employ the use of a radiofrequency energy source or electrothermal energy to apply or create heat and/or disruption within the disc for the treatment of low back pain, are **noncovered**.

D. Other

N/A

(This NCD last reviewed September 2008.)

150.12 – Collagen Meniscus Implant (Effective May 25, 2010)

(Rev. 121, Issued: 05-28-10, Effective: 05-25-10, Implementation: 07-06-10)

A. General

The knee menisci are wedge-shaped, semi-lunar discs of fibrous tissue located in the knee joint between the ends of the femur and the tibia and fibula. There is a lateral and medial meniscus in each knee. It is known now that the menisci provide mechanical support, localized pressure distribution, and lubrication of the knee joint. Initially, meniscal tears were treated with total meniscectomy; however, as knowledge of the function of the menisci and the potential long term effects of total meniscectomy on the knee joint evolved, treatment of symptomatic meniscal tears gravitated to repair of the tear, when possible, or partial meniscectomy.

The collagen meniscus implant (also referred to as collagen scaffold (CS), CMI or Menaflex™ meniscus implant throughout the published literature) is used to fill meniscal defects that result from partial meniscectomy. The collagen meniscus implant is not intended to replace the entire meniscus at it requires a meniscal rim for attachment. The literature describes the placement of the collagen meniscus implant through an arthroscopic procedure with an additional incision for capture of the repair needles and tying of the sutures. After debridement of the damaged meniscus, the implant is trimmed to the size of meniscal defect and sutured into place. The collagen meniscus implant is described as a tissue engineered scaffold to support the generation of new meniscus-like tissue. The collagen meniscus implant is manufactured from bovine collagen and should not be confused with the meniscus transplant which involves the replacement of the meniscus with a transplant meniscus from a cadaver donor. The meniscus transplant is not addressed under this national coverage determination.

B. Nationally Covered Indications

N/A

C. Nationally Non-Covered Indications

Effective for claims with dates of service performed on or after May 25, 2010, the Centers for Medicare & Medicaid Services has determined that the evidence is adequate to conclude that the collagen meniscus implant does not improve health outcomes and, therefore, is not reasonable and necessary for the treatment of meniscal injury/tear under section 1862(a)(1)(A) of the Social Security Act. Thus, the collagen meniscus implant is non-covered by Medicare.

D. Other

N/A

(This NCD last reviewed May 2010.)

150.13 – Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS) (Various Effective Dates Below)

(Rev. 200, Issued: 07-25-17, Effective: 12-07-16, Implementation: 06-27-17)

A. General

PILD is a posterior decompression of the lumbar spine performed under indirect image guidance without any direct visualization of the surgical area. This is a procedure proposed as a treatment for symptomatic LSS unresponsive to conservative therapy. This procedure is generally described as a non-invasive procedure using specially designed instruments to percutaneously remove a portion of the lamina and debulk the ligamentum flavum. The procedure is performed under x-ray guidance (e.g., fluoroscopic, CT) with the assistance of contrast media to identify and monitor the compressed area via epiduragram.

B. Nationally Covered Indications

Effective for dates of service specified below, the Centers for Medicare & Medicaid Services (CMS) has determined that PILD will be covered by Medicare when provided in a clinical study under section 1862(a)(1)(E) of the Social Security Act (the Act) through Coverage with Evidence Development (CED) for beneficiaries with LSS who are enrolled in an approved clinical study that meets the criteria in section I or II below:

I. Effective for services performed on or after January 9, 2014, PILD will be covered by Medicare through CED for beneficiaries with LSS who are enrolled in an approved clinical study that meets the following criteria. CMS has a particular interest in improved beneficiary function and quality of life, specific characteristics that identify patients who may benefit from the procedure, and the duration of benefit. A clinical study seeking Medicare payment for PILD for LSS must address one or more aspects of the following questions in a prospective, randomized, controlled design using current validated and reliable measurement instruments and clinically appropriate comparator treatments, including appropriate medical or surgical interventions or a sham controlled arm, for patients randomized to the non-PILD group.

The study protocol must specify a statistical analysis and a minimum length of patient follow up time that evaluates the effect of beneficiary characteristics on patient health outcomes as well as the duration of benefit.

i. Does PILD provide a clinically meaningful improvement of function and/or quality of life in Medicare beneficiaries with LSS compared to other treatments?

ii. Does PILD provide clinically meaningful reduction in pain in Medicare beneficiaries with LSS compared to other treatments?

iii. Does PILD affect the overall clinical management of LSS and decision making, including use of other medical treatments or services, compared to other treatments?

These studies must be designed so that the contribution of treatments in addition to the procedure under study are either controlled for or analyzed in such a way as to determine their impact.

a. The principal purpose of the research study is to test whether a particular intervention potentially improves the participants' health outcomes.
b. The research study is well supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
c. The research study does not unjustifiably duplicate existing studies.
d. The research study design is appropriate to answer the research question being asked in the study.
e. The research study is sponsored by an organization or individual capable of executing the proposed study successfully.
f. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 Code of Federal Regulations (CFR) Part 46. If a study is regulated by the Food and Drug Administration (FDA), it must be in compliance with 21 CFR parts 50 and 56.
g. All aspects of the research study are conducted according to appropriate standards of scientific integrity (see http://www.icmje.org).
h. The research study has a written protocol that clearly addresses, or incorporates by reference, the standards listed here as Medicare requirements for CED coverage.
i. The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life threatening as defined in 21 CFR§312.81(a) and the patient has no other viable treatment options.
j. The clinical research study is registered on the ClinicalTrials.gov website by

the principal sponsor/investigator prior to the enrollment of the first study subject.

k. The research study protocol specifies the method and timing of public release of all prespecified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned to be published in a peer reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors (http://www.icmje.org).

l. The research study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria effect enrollment of these populations, and a plan for the retention and reporting of said populations on the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.

m. The research study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

Consistent with section 1142 of the Act, the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

II. Effective for services performed on or after December 7, 2016, CMS will cover through a prospective, longitudinal study PILD procedures using an FDA-approved/cleared device that completed a CMS-approved randomized control trial (RCT) that met the criteria listed in section I above.

The CMS-approved prospective, longitudinal study must answer at least one of the following questions:

i. Does PILD provide a clinically meaningful improvement of function (e.g., reduced acute and post-acute hospitalizations, nursing home care or inpatient rehabilitation services) and/or quality of life in Medicare beneficiaries with LSS compared to other treatments?

ii. Does PILD provide a clinically meaningful reduction in pain (e.g., as measured by class, dose, duration of prescription pain medication use) in Medicare beneficiaries with LSS compared to other treatments?

iii. Does PILD affect the overall clinical management of LSS and decision making, including use of other medical treatments or services (e.g., repeat PILD procedures, other interventions and surgical treatments), compared to other treatments?

The prospective, longitudinal study must also meet the following criteria:

1. The protocol must specify a statistical analysis and a minimum length of patient follow-up time that evaluates the effect of beneficiary characteristics on patient health outcomes as well as the duration of the benefit.

2. The eligibility requirements, both inclusion and exclusion criteria that were specified in the CMS-approved RCT protocol, must be maintained in the new prospective, longitudinal study.

3. All study sites and study results must be listed in the ClinicalTrials.gov database.

All CMS-approved clinical research studies must adhere to the following standards of scientific integrity and relevance to the Medicare population:

a. The principal purpose of the study is to test whether the item or service meaningfully improves health outcomes of affected beneficiaries who are represented by the enrolled subjects.
b. The rationale for the study is well supported by available scientific and medical evidence.
c. The study results are not anticipated to unjustifiably duplicate existing knowledge.
d. The study design is methodologically appropriate and the anticipated number of enrolled subjects is sufficient to answer the research question(s) being asked in the National Coverage Determination.
e. The study is sponsored by an organization or individual capable of completing it successfully.
f. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found in the CFR at 45 CFR Part 46. If a study is regulated by the FDA, it is also in compliance with 21 CFR Parts 50 and 56. In addition, to further enhance the protection of human subjects in studies conducted under CED, the study must provide and obtain meaningful informed consent from patients regarding the risks associated with the study items and/or services, and the use and eventual disposition of the collected data.
g. All aspects of the study are conducted according to appropriate standards of scientific integrity.
h. The study has a written protocol that clearly demonstrates adherence to the standards listed here as Medicare requirements.

i. The study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Such studies may meet this requirement only if the disease or condition being studied is life threatening as defined in 21 CFR §312.81(a) and the patient has no other viable treatment options.
j. The clinical research studies and registries are registered on the www.ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject. Registries are also registered in the AHRQ Registry of Patient Registries (RoPR).
k. The research study protocol specifies the method and timing of public release of all prespecified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 12 months of the study's primary completion date, which is the date the final subject had final data collection for the primary endpoint, even if the trial does not achieve its primary aim. The results must include number started/completed, summary results for primary and secondary outcome measures, statistical analyses, and adverse events. Final results must be reported in a publicly accessibly manner; either in a peer-reviewed scientific journal (in print or on-line), in an on-line publicly accessible registry dedicated to the dissemination of clinical trial information such as ClinicalTrials.gov, or in journals willing to publish in abbreviated format (e.g., for studies with negative or incomplete results).
l. The study protocol must explicitly discuss beneficiary subpopulations affected by the item or service under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria effect enrollment of these populations, and a plan for the retention and reporting of said populations in the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.
m. The study protocol explicitly discusses how the results are or are not expected to be generalizable to affected beneficiary subpopulations. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

Consistent with section 1142 of the Act, tAHRQ supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

All clinical research study protocols must be reviewed and approved by CMS. The principal investigator must submit the complete study protocol, identify the relevant CMS research question(s) that will be addressed and cite the location of the detailed analysis plan for those questions in the protocol, plus provide a statement addressing how the study satisfies each of the standards of scientific integrity (a. through m. listed above), as well as the investigator's contact information, to the address below:

Director, Coverage and Analysis Group
Re: PILD CED
Centers for Medicare & Medicaid Services (CMS)
7500 Security Blvd., Mail Stop S3-02-01
Baltimore MD 21244-1850

Email address for protocol submissions: clinicalstudynotification@cms.hhs.gov
Email subject line: "CED [NCD topic (i.e. PILD)] [name of sponsor/primary investigator]"

The information will be reviewed, and approved studies will be identified on the CMS website - https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html.

C. Nationally Non-Covered Indications

Effective for services performed on or after January 9, 2014, PILD for LSS may only be covered under the context of a clinical trial as described in section B above according to section 1862(a)(1)(E) of the Social Security Act. CMS has determined that PILD for LSS is not reasonable and necessary under section 1862(a)(1)(A) of the Act.

D. Other

Endoscopically assisted laminotomy/laminectomy, which requires open and direct visualization, as well as other open lumbar decompression procedures for LSS are not within the scope of this NCD and coverage is at contractor discretion.

(This NCD last reviewed December 2016.)

150.20 – Reserved for Future Use
(Rev.)

160 - Nervous System
(Rev. 1, 10-03-03)

160.1 - Induced Lesions of Nerve Tracts
(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD-10, Implementation: Upon Implementation of ICD-10)

Surgically induced lesions of nerve tracts which involve destruction of nerve tissue are primarily indicated for controlling the chronic or acute pain arising from conditions such as terminal cancer or lumbar degenerative arthritis. Induced lesions of nerve tracts may be produced by surgical cutting of the nerve (rhizolysis), chemical destruction of the nerve, or by creation of a radio-frequency lesion (electrocautery). Accordingly, program payment may be made for these denervation procedures when used in selected cases (concurred in by the A/B MAC's medical staff) to treat chronic pain.

Note that these procedures differ from those employing implanted electrodes and associated equipment to control pain in that the nerve fibers are ablated rather than stimulated and no electronic equipment is required by the patient after the operation.

160.2 - Treatment of Motor Function Disorders with Electric Nerve Stimulation
(Rev. 1, 10-03-03)
CIM 35-20

Not Covered

While electric nerve stimulation has been employed to control chronic intractable pain for some time, its use in the treatment of motor function disorders, such as multiple sclerosis, is a recent innovation, and the medical effectiveness of such therapy has not been verified by scientifically controlled studies. Therefore, where electric nerve stimulation is employed to treat motor function disorders, no reimbursement may be made for the stimulator or for the services related to its implantation since this treatment cannot be considered reasonable and necessary. See §§30.1 and 160.7.

NOTE: For Medicare coverage of deep brain stimulation for essential tremor and Parkinson's disease, see §160.25.

160.4 - Stereotactic Cingulotomy as a Means of Psychosurgery (RETIRED)
(Rev. 11892; Issued: 03-09-23; Effective: 04-10-23; Implementation:04-10-23)

Effective December 18, 2014, NCD 160.4 is retired.

160.5 - Stereotaxic Depth Electrode Implantation
(Rev. 1, 10-03-03)
CIM 50-40

Stereotaxic depth electrode implantation prior to surgical treatment of focal epilepsy for patients who are unresponsive to anticonvulsant medications has been found both safe and effective for diagnosing resectable seizure foci that may go undetected by conventional scalp electroencephalographs (EEGs).

The procedure employs thin wire electrodes which are implanted in the brain of the focal epileptic patient for EEG monitoring. By taking several readings during seizure activity, the location of the epileptic focus may be found, so that better informed decisions can be made regarding the surgical treatment of persons with intractable seizures.

160.6 - Carotid Sinus Nerve Stimulator (RETIRED)
(Rev. 11892; Issued: 03-09-23; Effective: 04-10-23; Implementation:04-10-23)

Effective December 18, 2014, NCD 160.6 is retired.

160.7 - Electrical Nerve Stimulators
(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD-10, Implementation: Upon Implementation of ICD-10)

Two general classifications of electrical nerve stimulators are employed to treat chronic intractable pain: peripheral nerve stimulators and central nervous system stimulators.

A. Implanted Peripheral Nerve Stimulators

Payment may be made under the prosthetic device benefit for implanted peripheral nerve stimulators. Use of this stimulator involves implantation of electrodes around a selected peripheral nerve. The stimulating electrode is connected by an insulated lead to a receiver unit which is implanted under the skin at a depth not greater than 1/2 inch.

Stimulation is induced by a generator connected to an antenna unit which is attached to the skin surface over the receiver unit. Implantation of electrodes requires surgery and usually necessitates an operating room.

NOTE: Peripheral nerve stimulators may also be employed to assess a patient's suitability for continued treatment with an electric nerve stimulator. As explained in §160.7.1, such use of the stimulator is covered as part of the total diagnostic service furnished to the beneficiary rather than as a prosthesis.

B. Central Nervous System Stimulators (Dorsal Column and Depth Brain Stimulators)

The implantation of central nervous system stimulators may be covered as therapies for the relief of chronic intractable pain, subject to the following conditions:

1. Types of Implantations

There are two types of implantations covered by this instruction:

- Dorsal Column (Spinal Cord) Neurostimulation - The surgical implantation of neurostimulator electrodes within the dura mater (endodural) or the percutaneous insertion of electrodes in the epidural space is covered.

- Depth Brain Neurostimulation - The stereotactic implantation of electrodes in the deep brain (e.g., thalamus and periaqueductal gray matter) is covered.

2. Conditions for Coverage

No payment may be made for the implantation of dorsal column or depth brain stimulators or services and supplies related to such implantation, unless all of the conditions listed below have been met:

- The implantation of the stimulator is used only as a late resort (if not a last resort) for patients with chronic intractable pain;

- With respect to item a, other treatment modalities (pharmacological, surgical, physical, or psychological therapies) have been tried and did not prove satisfactory, or are judged to be unsuitable or contraindicated for the given patient;

- Patients have undergone careful screening, evaluation and diagnosis by a multidisciplinary team prior to implantation. (Such screening must include psychological, as well as physical evaluation);

- All the facilities, equipment, and professional and support personnel required for the proper diagnosis, treatment training, and follow up of the patient (including that required to satisfy item c) must be available; and

- Demonstration of pain relief with a temporarily implanted electrode precedes permanent implantation.

A/B MACs may find it helpful to work with Quality Improvement Organizations to obtain the information needed to apply these conditions to claims.

See the Medicare Benefit Policy Manual, Chapter 15, “Covered Medical and Other Health Services,” §120, and the following sections in this manual, §§160.2 and 30.1.

160.7.1 - Assessing Patients Suitability for Electrical Nerve Stimulation Therapy

(Rev. 149, Issued: 11-30-12, Effective: 06-08-12, Implementation: 01-07-13)

Electrical nerve stimulation is an accepted modality for assessing a patient's suitability for ongoing treatment with a transcutaneous or an implanted nerve stimulator.

Accordingly, program payment may be made for the following techniques when used to determine the potential therapeutic usefulness of an electrical nerve stimulator:

A. Transcutaneous Electrical Nerve Stimulation (TENS)

This technique involves attachment of a transcutaneous nerve stimulator to the surface of the skin over the peripheral nerve to be stimulated. It is used by the patient on a trial basis and its effectiveness in modulating pain is monitored by the physician, or physical therapist. Generally, the physician or physical therapist is able to determine whether the patient is likely to derive a significant therapeutic benefit from continuous use of a transcutaneous stimulator within a trial period of one month; in a few cases this determination may take longer to make. Document the medical necessity for such services which are furnished beyond the first month. (See §160.13 for an explanation of coverage of medically necessary supplies for the effective use of TENS.)

If TENS significantly alleviates pain, it may be considered as primary treatment; if it produces no relief or greater discomfort than the original pain electrical nerve stimulation therapy is ruled out. However, where TENS produces incomplete relief, further evaluation with percutaneous electrical nerve stimulation may be considered to determine whether an implanted peripheral nerve stimulator would provide significant relief from pain.

Usually, the physician or physical therapist providing the services will furnish the equipment necessary for assessment. Where the physician or physical therapist advises the patient to rent the TENS from a supplier during the trial period rather than supplying it himself/herself, program payment may be made for rental of the TENS as well as for the services of the physician or physical therapist who is evaluating its use. However, the combined program payment which is made for the physician's or physical therapist's services and the rental of the stimulator from a supplier should not exceed the amount which would be payable for the total service, including the stimulator, furnished by the physician or physical therapist alone.

B. Percutaneous Electrical Nerve Stimulation (PENS)

This diagnostic procedure which involves stimulation of peripheral nerves by a needle electrode inserted through the skin is performed only in a physician's office, clinic, or hospital outpatient department. Therefore, it is covered only when performed by a physician or incident to physician's service. If pain is effectively controlled by percutaneous stimulation, implantation of electrodes is warranted.

As in the case of TENS (described in subsection A), generally the physician should be able to determine whether the patient is likely to derive a significant therapeutic benefit from continuing use of an implanted nerve stimulator within a trial period of 1 month. In a few cases, this determination may take longer to make. The medical necessity for such diagnostic services which are furnished beyond the first month must be documented.

NOTE: Electrical nerve stimulators do not prevent pain but only alleviate pain as it occurs. A patient can be taught how to employ the stimulator, and once this is done, can use it safely and effectively without direct physician supervision. Consequently, it is inappropriate for a patient to visit his/her physician, physical therapist, or an outpatient clinic on a continuing basis for treatment of pain with electrical nerve stimulation. Once it is determined that electrical nerve stimulation should be continued as therapy and the patient has been trained to use the stimulator, it is expected that a stimulator will be implanted or the patient will employ the TENS on a continual basis in his/her home. Electrical nerve stimulation treatments furnished by a physician in his/her office, by a physical therapist or outpatient clinic are excluded from coverage by §1862(a)(1) of the Act. (See §160.7 for an explanation of coverage of the therapeutic use of implanted peripheral nerve stimulators under the prosthetic devices benefit.) See §160.27 for an explanation of coverage of the therapeutic use of TENS under the durable medical equipment benefit.

160.8 - Electroencephalographic Monitoring During Surgical Procedures Involving the Cerebral Vasculature

(Rev. 48, Issued: 03-17-06; Effective/Implementation Dates: 06-19-06)
CIM 35-57

Electroencephalographic (EEG) monitoring is a safe and reliable technique for the assessment of gross cerebral blood flow during general anesthesia and is covered under Medicare. Very characteristic changes in the EEG occur when cerebral perfusion is inadequate for cerebral function. EEG monitoring as an indirect measure of cerebral perfusion requires the expertise of an electroencephalographer, a neurologist trained in EEG, or an advanced EEG technician for its proper interpretation.

The EEG monitoring may be covered routinely in carotid endarterectomies and in other neurological procedures where cerebral perfusion could be reduced. Such other procedures might include aneurysm surgery where hypotensive anesthesia is used or other cerebral vascular procedures where cerebral blood flow may be interrupted.

160.9 – Electroencephalographic (EEG) Monitoring During Open-Heart Surgery (RETIRED)

(Rev. 11892; Issued: 03-09-23; Effective: 04-10-23; Implementation:04-10-23)

Effective December 18, 2014, NCD 160.9 is retired.

160.10 - Evoked Response Tests

(Rev. 1, 10-03-03)
CIM 50-31

Evoked response tests, including brain stem evoked response and visual evoked response tests, are generally accepted as safe and effective diagnostic tools. These tests measure brain responses to repetitive visual, click or other stimuli. Program payment may be made for these procedures.

160.12 - Neuromuscular Electrical Stimulator (NMES)
(Rev. 55, Issued: 05-05-06, Effective: 10-01-06, Implementation: 10-02-06)

Neuromuscular electrical stimulation (NMES) involves the use of a device which transmits an electrical impulse to the skin over selected muscle groups by way of electrodes. There are two broad categories of NMES. One type of device stimulates the muscle when the patient is in a resting state to treat muscle atrophy. The second type is used to enhance functional activity of neurologically impaired patients.

Treatment of Muscle Atrophy

Coverage of NMES to treat muscle atrophy is limited to the treatment of disuse atrophy where nerve supply to the muscle is intact, including brain, spinal cord and peripheral nerves, and other non-neurological reasons for disuse atrophy. Some examples would be casting or splinting of a limb, contracture due to scarring of soft tissue as in burn lesions, and hip replacement surgery (until orthotic training begins). (See §160.13 for an explanation of coverage of medically necessary supplies for the effective use of NMES.)

Use for Walking in Patients with Spinal Cord Injury (SCI)

The type of NMES that is use to enhance the ability to walk of SCI patients is commonly referred to as functional electrical stimulation (FES). These devices are surface units that use electrical impulses to activate paralyzed or weak muscles in precise sequence. Coverage for the use of NMES/FES is limited to SCI patients for walking, who have completed a training program which consists of at least 32 physical therapy sessions with the device over a period of three months. The trial period of physical therapy will enable the physician treating the patient for his or her spinal cord injury to properly evaluate the person's ability to use these devices frequently and for the long term. Physical therapy necessary to perform this training must be directly performed by the physical therapist as part of a one-on-one training program.

The goal of physical therapy must be to train SCI patients on the use of NMES/FES devices to achieve walking, not to reverse or retard muscle atrophy.

Coverage for NMES/FES for walking will be covered in SCI patients with all of the following characteristics:

1. Persons with intact lower motor unite (L1 and below) (both muscle and peripheral nerve);

2. Persons with muscle and joint stability for weight bearing at upper and lower extremities that can demonstrate balance and control to maintain an upright support posture independently;

3. Persons that demonstrate brisk muscle contraction to NMES and have sensory perception electrical stimulation sufficient for muscle contraction;

4. Persons that possess high motivation, commitment and cognitive ability to use such devices for walking;

5. Persons that can transfer independently and can demonstrate independent standing tolerance for at least 3 minutes;

6. Persons that can demonstrate hand and finger function to manipulate controls;

7. Persons with at least 6-month post recovery spinal cord injury and restorative surgery;

8. Persons with hip and knee degenerative disease and no history of long bone fracture secondary to osteoporosis; and

9. Persons who have demonstrated a willingness to use the device long-term.

The NMES/FES for walking will not be covered in SCI patient with any of the following:

1. Persons with cardiac pacemakers;

2. Severe scoliosis or severe osteoporosis;

3. Skin disease or cancer at area of stimulation;

4. Irreversible contracture; or

5. Autonomic dysflexia.

The only settings where therapists with the sufficient skills to provide these services are employed, are inpatient hospitals; outpatient hospitals; comprehensive outpatient rehabilitation facilities; and outpatient rehabilitation facilities. The physical therapy necessary to perform this training must be part of a one-on-one training program.

Additional therapy after the purchase of the DME would be limited by our general policies in converge of skilled physical therapy.

(Also reference the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §220 and 230, and the Medicare Claims Processing Manual, Chapter 5, "Part B Outpatient Rehabilitation and CORF Services," §10.1.)

160.13 - Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Electrical Stimulation (NMES)

(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD-10, Implementation: Upon Implementation of ICD-10)

Transcutaneous Electrical Nerve Stimulation (TENS) and/or Neuromuscular Electrical Stimulation (NMES) can ordinarily be delivered to patients through the use of conventional electrodes, adhesive tapes and lead wires. There may be times, however, where it might be medically necessary for certain patients receiving TENS or NMES treatment to use, as an alternative to conventional electrodes, adhesive tapes and lead wires, a form-fitting conductive garment (i.e., a garment with conductive fibers which are separated from the patients' skin by layers of fabric).

A form-fitting conductive garment (and medically necessary related supplies) may be covered under the program only when:

1. It has received permission or approval for marketing by the Food and Drug Administration;

2. It has been prescribed by a physician for use in delivering covered TENS or NMES treatment; and

3. One of the medical indications outlined below is met:

- The patient cannot manage without the conductive garment because there is such a large area or so many sites to be stimulated and the stimulation would have to be delivered so frequently that it is not feasible to use conventional electrodes, adhesive tapes and lead wires;

- The patient cannot manage without the conductive garment for the treatment of chronic intractable pain because the areas or sites to be stimulated are inaccessible with the use of conventional electrodes, adhesive tapes and lead wires;

- The patient has a documented medical condition such as skin problems that preclude the application of conventional electrodes, adhesive tapes and lead wires;

- The patient requires electrical stimulation beneath a cast either to treat disuse atrophy, where the nerve supply to the muscle is intact, or to treat chronic intractable pain; or

- The patient has a medical need for rehabilitation strengthening (pursuant to a written plan of rehabilitation) following an injury where the nerve supply to the muscle is intact.

A conductive garment is not covered for use with a TENS device during the trial period specified in §160.3 unless:

4. The patient has a documented skin problem prior to the start of the trial period; and

5. The A/B MAC (B)'s medical consultants are satisfied that use of such an item is medically necessary for the patient.

(See conditions for coverage of the use of TENS in the diagnosis and treatment of chronic intractable pain in §§160.3, 160.13, and 160.27, and the use of NMES in the treatment of disuse atrophy in §150.4.)

160.14 - Invasive Intracranial Pressure Monitoring

(Rev. 1, 10-03-03)
CIM 35-62

Invasive intracranial pressure monitoring is a safe and effective therapeutic tool used to monitor intracranial pressure. It is usually used for patients suffering from head injuries, subarachnoid hemorrhage, intracerebral hemorrhage, Reye's syndrome, or posthypoxic, metabolic, and viral encephalopathies. It is usually performed in specialized intensive care units for neurosurgical and neurologic patients. It is a covered procedure when reasonable and necessary for the individual patient.

160.15 - Electrotherapy for Treatment of Facial Nerve Palsy (Bell's Palsy)

(Rev. 1, 10-03-03)
CIM 35-72

Not Covered

Electrotherapy for the treatment of facial nerve paralysis is the application of electrical stimulation to affected facial muscles to provide muscle innervation with the intention of preventing muscle degeneration. A device that generates an electrical current with controlled frequency, intensity, wave form and type (galvanic or faradic) is used in combination with a pad electrode and a hand applicator electrode to provide electrical stimulation.

Electrotherapy for the treatment of facial nerve paralysis, commonly known as Bell's Palsy, is not covered under Medicare because its clinical effectiveness has not been established.

160.16 - Vertebral Axial Decompression (VAX-D)

(Rev. 1, 10-03-03)
CIM 35-97

Not Covered

Vertebral axial decompression is performed for symptomatic relief of pain associated with lumbar disk problems. The treatment combines pelvic and/or cervical traction connected to a special table that permits the traction application. There is insufficient scientific data to support the benefits of this technique. Therefore, VAX-D is not covered by Medicare.

160.17 - L-Dopa

(Rev. 1, 10-03-03)
CIM 45-1

A. Part A Payment for L-Dopa and Associated Inpatient Hospital Service

A hospital stay and related ancillary services for the administration of L-Dopa are covered if medically required for this purpose. Whether a drug represents an allowable inpatient hospital cost during such stay depends on whether it meets the definition of a drug in §1861(t) of the Act; i.e., on its inclusion in the compendia named in the Act or approval by the hospital's pharmacy and drug therapeutics (P&DT) or equivalent committee. (Levodopa (L-Dopa) has been favorably evaluated for the treatment of Parkinsonism by A.M.A. Drug Evaluations, First Edition 1971, the replacement compendia for "New Drugs.")

Inpatient hospital services are frequently not required in many cases when L-Dopa therapy is initiated. Therefore, determine the medical need for inpatient hospital services on the basis of medical facts in the individual case. It is not necessary to hospitalize the typical, well-functioning, ambulatory Parkinsonian patient who has no concurrent disease at the start of L-Dopa treatment. It is reasonable to provide inpatient hospital services for Parkinsonian patients with concurrent diseases, particularly of the cardiovascular, gastrointestinal, and neuropsychiatric systems. Although many patients require hospitalization for a period of under two weeks, a 4-week period of inpatient care is not unreasonable.

Laboratory tests in connection with the administration of L-Dopa - The tests medically warranted in connection with the achievement of optimal dosage and the control of the side effects of L-Dopa include a complete blood count, liver function tests such as SGOT, SGPT, and/or alkaline phosphatase, BUN or creatinine and urinalysis, blood sugar, and electrocardiogram.

Whether or not the patient is hospitalized, laboratory tests in certain cases are reasonable at weekly intervals although some physicians prefer to perform the tests much less frequently.

Physical therapy furnished in connection with administration of L-Dopa - Where, following administration of the drug, the patient experiences a reduction of rigidity which permits the reestablishment of a restorative goal for him/her, physical therapy services required to enable him/her to achieve this goal are payable provided they require the skills of a qualified physical therapist and are furnished by or under the supervision of such a therapist. However, once the individual's restoration potential has been achieved, the services required to maintain him/her at this level do not generally require the skills of a qualified physical therapist. In such situations, the role of the therapist is to evaluate the patient's needs in consultation with his/her physician and design a program of exercise appropriate to the capacity and tolerance of the patient and treatment objectives of the physician, leaving to others the actual carrying out of the program. While the evaluative services rendered by a qualified physical therapist are payable as physical therapy, services furnished by others in connection with the carrying out of the maintenance program established by the therapist are not. (See the Medicare Benefit Policy Manual, Chapter 1, "Inpatient Hospital Services," §30.)

B. Part A Reimbursement for L-Dopa Therapy in SNFs

Initiation of L-Dopa therapy can be appropriately carried out in the skilled nursing facility (SNF) setting, applying the same guidelines used for initiation of L-Dopa therapy in the hospital, including the types of patients who should be covered for inpatient services, the role of physical therapy, and the use of laboratory tests. (See subsection A.)

Where inpatient care is required and L-Dopa therapy is initiated in the SNF, limit the stay to a maximum of four weeks; but in many cases the need may be no longer than one or two weeks, depending upon the patient's condition. However, where L-Dopa therapy is begun in the hospital and the patient is transferred to a SNF for continuation of the therapy, a combined length of stay in hospital and SNF of no longer than four weeks is reasonable (i.e., 1-week hospital stay followed by three weeks SNF stay; or two weeks hospital stay followed by two weeks SNF stay; etc.). Medical need must be demonstrated in cases where the combined length of stay in hospital and SNF is longer than four weeks. The choice of hospital or SNF, and the decision regarding the relative length of time spent in each, should be left to the medical judgment of the treating physician. See the Medicare Benefit Policy Manual, Chapter 8, "Coverage of Extended Care (SNF) Services Under Hospital Insurance," §50.5.

C. L-Dopa Coverage Under Part B

Part B reimbursement may not be made for the drug L-Dopa since it is a self-administrable drug. (See the Medicare Benefit Policy Manual, Chapter 6, "Hospital Services Covered Under Part B," §20.4.1.) However, physician services rendered in connection with its administration and control of its side effects are covered if determined to be reasonable and necessary. Initiation of L-Dopa therapy on an outpatient basis is possible in most cases. Visit frequency ranging from every week to every 2 or 3 months is acceptable. However, after half a year of therapy, visits more frequent than every month would usually not be reasonable.

160.18 - Vagus Nerve Stimulation (VNS)

(Rev. 10199, Issued: 06-23-2020, Effective:-02-15- 2019, Implementation: 07-22-2020)

A. General

Vagus Nerve Stimulation (VNS) is a pulse generator, similar to a pacemaker, that is surgically implanted under the skin of the left chest and an electrical lead (wire) is connected from the generator to the left vagus nerve. Electrical signals are sent from the battery-powered generator to the vagus nerve via the lead. These signals are in turn sent to the brain. The Food and Drug Administration (FDA) approved VNS for treatment of refractory epilepsy in 1997 and for resistant depression in 2005.

B. Nationally Covered Indications

Effective for services performed on or after July 1, 1999, VNS is reasonable and necessary for patients with medically refractory partial onset seizures for whom surgery is not recommended or for whom surgery has failed.

Effective for services performed on or after February 15, 2019, the Centers for Medicare & Medicaid Services (CMS) will cover FDA-approved VNS devices for treatment resistant depression (TRD) through Coverage with Evidence Development (CED) when offered in a CMS-approved, double-blind, randomized, placebo-controlled trial with a follow-up duration of at least one year with the possibility of extending the study to a prospective longitudinal study when the CMS-approved, double-blind, randomized placebo-controlled trial has completed enrollment, and there are positive interim findings.

Each study must be approved by CMS and as a fully-described, written part of its protocol, must address whether VNS improves health outcomes for TRD patients compared to a control group, by answering all of the following research questions below. The details of the prospective longitudinal study must be described in the original protocol for the double-blind, randomized, placebo-controlled trial. Response is defined as a $\geq$ 50% improvement in depressive symptoms from baseline, as measured by a guideline recommended depression scale assessment tool. Remission is defined as being below the threshold on a guideline recommended depression scale assessment tool. The following research questions must be addressed in a separate analysis for patients with bipolar and unipolar disease.

Research Questions:

- What is the rate of response (defined as person months of response/total months of study participation)?
- What is the rate of remission (defined as person months of response/total months of study participation)?

- What is the time from treatment until response scores are first achieved?
- What is the time from treatment until remission scores are first achieved?
- What are the population distributions of the maximum months of response, both consecutive and overall, separately?
- What are the population distributions of the maximum months of remission, both consecutive and overall, separately?
- What are the patient variables associated with successful treatment of TRD with VNS?
- What are the observed harms?
- What are the changes in disability, quality of life, general psychiatric status, and suicidality?

Patient Criteria:

The following criteria must be used to identify patients demonstrating TRD:

- The patient must be in a major depressive disorder (MDD) episode for ≥ two years or have had at least four episodes of MDD, including the current episode. In order to confirm the patient has MDD, accepted diagnostic criteria from the most current edition of the Diagnostic and Statistical Manual for Mental Disorder (DSM) and a structured clinical assessment are to be used.
- The patient's depressive illness meets a minimum criterion of four prior failed treatments of adequate dose and duration as measured by a tool designed for this purpose.
- The patient is experiencing a major depressive episode (MDE) as measured by a guideline recommended depression scale assessment tool on two visits, within a 45-day span prior to implantation of the VNS device.

Patients must maintain a stable medication regimen for at least four weeks before device implantation.

If patients with bipolar disorder are included, the condition must be carefully characterized.

Patients must not have:

- Current or lifetime history of psychotic features in any MDE;
- Current or lifetime history of schizophrenia or schizoaffective disorder;
- Current or lifetime history of any other psychotic disorder;
- Current or lifetime history of rapid cycling bipolar disorder;
- Current secondary diagnosis of delirium, dementia, amnesia, or other cognitive disorder;
- Current suicidal intent; or,
- Treatment with another investigational device or investigational drugs.

Individuals who receive placebo VNS will be offered active VNS at the end of the trial.

In addition, CMS will review studies to determine if they meet the 13 criteria listed below. If CMS determines that they meet these criteria, the study will be posted on CMS' CED website (https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html).

a) The principal purpose of the study is to test whether the item or service meaningfully improves health outcomes of affected beneficiaries who are represented by the enrolled subjects.
b) The rationale for the study is well supported by available scientific and medical evidence.
c) The study results are not anticipated to unjustifiably duplicate existing knowledge.
d) The study design is methodologically appropriate and the anticipated number of enrolled subjects is sufficient to answer the research question(s) being asked in the National Coverage Determination.
e) The study is sponsored by an organization or individual capable of completing it successfully.
f) The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found in the Code of Federal Regulations (CFR) at 45 CFR Part 46. If a study is regulated by the Food and Drug Administration (FDA), it is also in compliance with 21 CFR Parts 50 and 56. In addition, to further enhance the protection of human subjects in studies conducted under CED, the study must provide and obtain meaningful informed consent from patients regarding the risks associated with the study items and/or services, and the use and eventual disposition of the collected data.
g) All aspects of the study are conducted according to appropriate standards of scientific integrity.
h) The study has a written protocol that clearly demonstrates adherence to the standards listed here as Medicare requirements.
i) The study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Such studies may meet this requirement only if the disease or condition being studied is life threatening as defined in 21 CFR §312.81(a) and the patient has no other viable treatment options.
j) The clinical research studies and registries are registered on the www.ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject. Registries are also registered in the Agency for Healthcare Quality (AHRQ) Registry of Patient Registries (RoPR).
k) The research study protocol specifies the method and timing of public release of all prespecified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 12 months of the study's primary completion date, which is the date the final subject had final data collection for the primary endpoint, even if the trial does not achieve its primary aim. The results must include number started/completed, summary results for primary and secondary outcome measures, statistical analyses, and adverse events. Final results must be reported in a publicly accessibly manner; either in a peer-reviewed scientific journal (in print or on-line), in an on-line publicly accessible

registry dedicated to the dissemination of clinical trial information such as ClinicalTrials.gov, or in journals willing to publish in abbreviated format (e.g., for studies with negative or incomplete results).

l) The study protocol must explicitly discuss beneficiary subpopulations affected by the item or service under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria effect enrollment of these populations, and a plan for the retention and reporting of said populations in the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.

m) The study protocol explicitly discusses how the results are or are not expected to be generalizable to affected beneficiary subpopulations. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

Consistent with section 1142 of the Act, the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

The principal investigator must submit the complete study protocol, identify the relevant CMS research questions that will be addressed and cite the location of the detailed analysis plan for those questions in the protocol, plus provide a statement addressing how the study satisfies each of the standards of scientific integrity (a. through m. listed above), as well as the investigator's contact information, to the address below. The information will be reviewed, and approved studies will be identified on the CMS website.

Director, Coverage and Analysis Group
Centers for Medicare & Medicaid Services (CMS)
7500 Security Blvd., Mail Stop S3-02-01
Baltimore, MD 21244-1850

C. Nationally Non-Covered Indications

Effective for services performed on or after July 1, 1999, VNS is not reasonable and necessary for all other types of seizure disorders which are medically refractory and for whom surgery is not recommended or for whom surgery has failed.

VNS is non-covered for the treatment of TRD when furnished outside of a CMS-approved CED study.

All other indications of VNS for the treatment of depression are nationally non-covered.

D. Other

Patients implanted with a VNS device for TRD may receive a VNS device replacement if it is required due to the end of battery life, or any other device-related malfunction.

(This NCD last reviewed February 2019.)

160.19 - Phrenic Nerve Stimulator
(Rev. 1, 10-03-03)
CIM 65-13

The implantation of a phrenic nerve stimulator is covered for selected patients with partial or complete respiratory insufficiency.

The phrenic nerve stimulator provides electrical stimulation of the patient's phrenic nerve to contract the diaphragm rhythmically and produce breathing in patients who have hypoventilation (a state in which an abnormally low amount of air enters the lungs). The device has been used successfully to treat hypoventilation caused by a variety of conditions, including respiratory paralysis resulting from lesions of the brain stem and cervical spinal cord and chronic pulmonary disease with ventilatory insufficiency. The phrenic nerve stimulator is intended to be an alternative to management of patients with respiratory insufficiency who are dependent upon the usual therapy of intermittent or permanent use of a mechanical ventilator as well as maintenance of a permanent tracheotomy stoma.

However, an implanted phrenic nerve stimulator can be effective only if the patient has an intact phrenic nerve and diaphragm. Moreover, nerve injury may occur during the surgical procedure and if sufficient injury is incurred, the device will not prove useful to the patient. Consequently, it is possible for such a device to be indicated for a patient but, due to injury sustained during implant, fail to assist the patient, resulting in a return to the use of mechanical ventilation.

Cross reference to §160.7, "Electrical Nerve Stimulators."

160.20 - Transfer Factor for Treatment of Multiple Sclerosis
(Rev. 1, 10-03-03)
CIM 45-17

Transfer factor is the dialysate of an extract from sensitized leukocytes which increases cellular immune activity in the recipient. It is not covered as a treatment for multiple sclerosis because its use for the purpose is still experimental.

160.21 - Telephone Transmission of EEGs
(Rev. 1, 10-03-03)
CIM - 50-39

Telephone transmission of electroencephalograms (EEGs) is covered as a physician's service, or as incident to a physician's service when reasonable and necessary for the individual patient, under appropriate circumstances. The service is safe, and may save time and cost in sending EEGs from remote areas without special competence in

neurology, neurosurgery, and electroencephalography, by avoiding the need to transport patients to large medical centers for standard EEG testing.

Telephone transmission of EEGs has been most helpful in the following clinical situations:

- Altered consciousness, such as stuporous, semicomatose, or comatose states;
- A typical seizure variants in patients experiencing bizarre, distressing symptoms as seen with "spike and wave stupor" or other forms of seizure disorders;
- Diagnosis of a suspected intracranial tumor;
- Head injury, where a subdural hematoma may be identified;
- Headaches during the acute phase where, for instance, in migraine syndrome, abnormal responses may be seen.

Telephonically transmitted EEGs should not be used for determining electrical inactivity (i.e., brain death), because of unavoidable signal interference.

160.22 - Ambulatory EEG Monitoring (Retired)

(Rev. 12299; Issued:10-12-23; Effective:01-01-23; Implementation:11-13-23)

Effective January 1, 2023, the Centers for Medicare & Medicaid Services removed the national coverage determination (NCD) for Ambulatory EEG Monitoring. In the absence of an NCD, coverage determinations will be made by the Medicare Administrative Contractors under section 1862(a)(1)(A) of the Social Security Act.

160.23 - Sensory Nerve Conduction Threshold Tests (sNCTs) (Effective April 1, 2004)

(Rev. 15, 06-18-04)

A. General

The sNCT is a psychophysical assessment of both central and peripheral nerve functions. It measures the detection threshold of accurately calibrated sensory stimuli. This procedure is intended to evaluate and quantify function in both large and small caliber fibers for the purpose of detecting neurologic disease. Sensory perception and threshold detection are dependent on the integrity of both the peripheral sensory apparatus and peripheral-central sensory pathways. In theory, an abnormality detected by this procedure may signal dysfunction anywhere in the sensory pathway from the receptors, the sensory tracts, the primary sensory cortex, to the association cortex.

This procedure is different and distinct from assessment of nerve conduction velocity, amplitude and latency. It is also different from short-latency somatosensory evoked potentials.

Effective October 1, 2002, CMS initially concluded that there was insufficient scientific or clinical evidence to consider the sNCT test and the device used in performing this test reasonable and necessary within the meaning of section 1862(a)(1)(A) of the law.

Therefore, sNCT was noncovered.

Effective April 1, 2004, based on a reconsideration of current Medicare policy for sNCT, CMS concludes that the use of any type of sNCT device (e.g., "current output" type device used to perform current perception threshold (CPT), pain perception threshold (PPT), or pain tolerance threshold (PTT) testing or "voltage input" type device used for voltage-nerve conduction threshold (v-NCT) testing) to diagnose sensory neuropathies or radiculopathies in Medicare beneficiaries is not reasonable and necessary.

B. Nationally Covered Indications

Not applicable.

C. Nationally Noncovered Indications

All uses of sNCT to diagnose sensory neuropathies or radiculopathies are noncovered.

(This NCD last reviewed June 2004.)

160.24 – Deep Brain Stimulation for Essential Tremor and Parkinson's Disease

(Rev. 1, 10-03-03)
CIM – 65-19

Effective for services furnished on or after April 1, 2003, Medicare will cover unilateral or bilateral thalamic ventralis intermedius nucleus (VIM) deep brain stimulation (DBS) for the treatment of essential tremor (ET) and/or Parkinsonian tremor and unilateral or bilateral subthalamic nucleus (STN) or globus pallidus interna (GPi) DBS for the treatment of Parkinson's disease (PD) only under the following conditions:

1. Medicare will only consider DBS devices to be reasonable and necessary if they are Food and Drug Administration (FDA) approved devices for DBS or devices used in accordance with FDA approved protocols governing Category B Investigational Device Exemption (IDE) DBS clinical trials.

2. For thalamic VIM DBS to be considered reasonable and necessary, patients must meet all of the following criteria:

a. Diagnosis of ET based on postural or kinetic tremors of hand(s) without other neurologic signs, or diagnosis of idiopathic PD (presence of at least 2 cardinal PD features (tremor, rigidity or bradykinesia)) which is of a tremor- dominant form.

b. Marked disabling tremor of at least level 3 or 4 on the Fahn-Tolosa-Marin Clinical Tremor Rating Scale (or equivalent scale) in the extremity intended for treatment, causing significant limitation in daily activities despite optimal medical therapy.

c. Willingness and ability to cooperate during conscious operative procedure, as well as during post-surgical evaluations, adjustments of medications and stimulator settings.

3. For STN or GPi DBS to be considered reasonable and necessary, patients must meet all of the following criteria:

a. Diagnosis of PD based on the presence of at least 2 cardinal PD features (tremor, rigidity or bradykinesia).

b. Advanced idiopathic PD as determined by the use of Hoehn and Yahr stage or Unified Parkinson's Disease Rating Scale (UPDRS) part III motor subscale.

c. L-dopa responsive with clearly defined "on" periods.

d. Persistent disabling Parkinson's symptoms or drug side effects (e.g., dyskinesias, motor fluctuations, or disabling "off" periods) despite optimal medical therapy.

e. Willingness and ability to cooperate during conscious operative procedure, as well as during post-surgical evaluations, adjustments of medications and stimulator settings.

The DBS is not reasonable and necessary and is not covered for ET or PD patients with any of the following:

1. Non-idiopathic Parkinson's disease or "Parkinson's Plus" syndromes.

2. Cognitive impairment, dementia or depression which would be worsened by or would interfere with the patient's ability to benefit from DBS.

3. Current psychosis, alcohol abuse or other drug abuse.

Structural lesions such as basal ganglionic stroke, tumor or vascular malformation as etiology of the movement disorder.

Previous movement disorder surgery within the affected basal ganglion.

Significant medical, surgical, neurologic or orthopedic co-morbidities contraindicating DBS surgery or stimulation.

Patients who undergo DBS implantation should not be exposed to diathermy (deep heat treatment including shortwave diathermy, microwave diathermy and ultrasound diathermy) or any type of MRI which may adversely affect the DBS system or adversely affect the brain around the implanted electrodes.

The DBS should be performed with extreme caution in patients with cardiac pacemakers or other electronically controlled implants which may adversely affect or be affected by the DBS system.

For DBS lead implantation to be considered reasonable and necessary, providers and facilities must meet all of the following criteria:

Neurosurgeons must:

a. Be properly trained in the procedure;

b. Have experience with the surgical management of movement disorders, including DBS therapy; and

c. Have experience performing stereotactic neurosurgical procedures.

Operative teams must have training and experience with DBS systems, including knowledge of anatomical and neurophysiological characteristics for localizing the targeted nucleus, surgical and/or implantation techniques for the DBS system, and operational and functional characteristics of the device.

Physicians specializing in movement disorders must be involved in both patient selection and post-procedure care.

Hospital medical centers must have:

a. Brain imaging equipment (MRI and/or CT) for pre-operative stereotactic localization and targeting of the surgical site(s);

b. Operating rooms with all necessary equipment for stereotactic surgery; and

c. Support services necessary for care of patients undergoing this procedure and any potential complications arising intraoperatively or postoperatively.

160.25 - Multiple Electroconvulsive Therapy (MECT)

(Rev. 1, 10-03-03)
CIM - 35-103

The clinical effectiveness of the multiple-seizure electroconvulsive therapy has not been verified by scientifically controlled studies. In addition, studies have demonstrated an increased risk of adverse effects with multiple seizures. Accordingly, MECT cannot be considered reasonable and necessary and is not covered by the Medicare program. Effective for services provided on or after April 1, 2003.

160.26 - Cavernous Nerves Electrical Stimulation with Penile Plethysmography - Effective August 24, 2006

(Rev.61, Issued: 11-24-06, Effective: 08-24-06, Implementation: 01-08-07)

A. General

In nerve-sparing prostatic and colorectal surgical procedures, the assessment of the function of the cavernous nerves by direct application of electrical stimulation with penile plethysmography is a diagnostic test, also referred to as cavernosal nerve mapping, which may be performed to assess the integrity of the cavernous nerves. Through an open or laparoscopic procedure, the surgeon may want to assess the function of the cavernous nerves by stimulating the most distal end of the nerve that can be located by using an electrical nerve stimulator. The presence of a response and the degree of the response may be used to provide the surgeon with a more realistic assessment of the chance of the patient regaining potency and assist in choosing appropriate therapy.

B. Nationally Covered Indications

Not applicable.

C. Nationally Non-Covered Indications

Effective August 24, 2006, Cavernous Nerves Electrical Stimulation with penile plethysmography is non-covered under Medicare. CMS reviewed the evidence and determined that this test is not reasonable and necessary for Medicare beneficiaries undergoing nerve-sparing prostatic or colorectal surgical procedures.

D. Other

Also see §20.14, Plethysmograthy.

(This NCD last reviewed September 2006.)

160.27 – Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP)

(Rev. 149, Issued: 11-30-12, Effective: 06-08-12, Implementation: 01-07-13)

The TENS is a type of electrical nerve stimulator that is employed to treat chronic intractable pain. This stimulator is attached to the surface of the patient's skin over the

peripheral nerve to be stimulated. It may be applied in a variety of settings (in the patient's home, a physician's office, or in an outpatient clinic). Payment for TENS may be made under the durable medical equipment benefit.

A. General

For the purposes of this decision chronic low back pain (CLBP) is defined as:

1. an episode of low back pain that has persisted for three months or longer; and

2. is not a manifestation of a clearly defined and generally recognizable primary disease entity. For example, there are cancers that, through metastatic spread to the spine or pelvis, may elicit pain in the lower back as a symptom; and certain systemic diseases such as rheumatoid arthritis and multiple sclerosis manifest many debilitating symptoms of which low back pain is not the primary focus.

B. Nationally Covered Indications

Effective June 8, 2012, the Centers for Medicare & Medicaid Services (CMS) will allow coverage for Transcutaneous Electrical Nerve Stimulation (TENS) for CLBP only when all of the following conditions are met.

In order to support additional research on the use of TENS for CLBP, we will cover this item under section 1862(a)(1)(E) of the Social Security Act (the Act) subject to all of the following conditions:

1. Coverage under this section expires three years after the publication of this decision on the CMS website.

2. The beneficiary is enrolled in an approved clinical study meeting all of the requirements below. The study must address one or more aspects of the following questions in a randomized, controlled design using validated and reliable instruments. This can include randomized crossover designs when the impact of prior TENS use is appropriately accounted for in the study protocol.

    i. Does the use of TENS provide clinically meaningful reduction in pain in Medicare beneficiaries with CLBP?

    ii. Does the use of TENS provide a clinically meaningful improvement of function in Medicare beneficiaries with CLBP?

    iii. Does the use of TENS impact the utilization of other medical treatments or services used in the medical management of CLBP?

These studies must be designed so that the patients in the control and comparison groups receive the same concurrent treatments and either sham (placebo) TENS or active TENS intervention.

The study must adhere to the following standards of scientific integrity and relevance to the Medicare population:

a. The principal purpose of the research study is to test whether a particular intervention potentially improves the participants' health outcomes.

b. The research study is well supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.

c. The research study does not unjustifiably duplicate existing studies.

d. The research study design is appropriate to answer the research question being asked in the study.

e. The research study is sponsored by an organization or individual capable of executing the proposed study successfully.

f. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 CFR Part 46. If a study is regulated by the Food and Drug Administration (FDA), it must be in compliance with 21 CFR parts 50 and 56.

g. All aspects of the research study are conducted according to appropriate standards of scientific integrity (see http://www.icmje.org).

h. The research study has a written protocol that clearly addresses, or incorporates by reference, the standards listed here as Medicare requirements for CED coverage.

i. The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life threatening as defined in 21 CFR §312.81(a) and the patient has no other viable treatment options.

j. The clinical research study is registered on the ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject.

k. The research study protocol specifies the method and timing of public release of all prespecified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made

public within 24 months of the end of data collection. If a report is planned to be published in a peer reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors (http://www.icmje.org).

l. The research study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria effect enrollment of these populations, and a plan for the retention and reporting of said populations on the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.

m. The research study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

C. Nationally Non-Covered Indications

TENS is not reasonable and necessary for the treatment of CLBP under section 1862(a)(1)(A) of the Act.

D. Other

See §160.13 for an explanation of coverage of medically necessary supplies for the effective use of TENS. See §160.7.1 for an explanation of coverage for assessing patients suitability for electrical nerve stimulation therapy. See §10.2 for an explanation of coverage of transcutaneous electrical nerve stimulation (TENS) for acute post-operative pain. Please note, §280.13Transcutaneous Electrical Nerve Stimulators (TENS) NCD has been removed from the NCD manual and incorporated into NCD 160.27

(This NCD last reviewed June 2012.)

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
R13748NCD	04/23/2026	National Coverage Determination (NCD) 110.17- Anti-Cancer Chemotherapy for Colorectal Cancer	10/05/2026	14433
R12299NCD	10/12/2023	An Omnibus CR to Implement Policy Updates in the CY 2023 PFS Final Rule, Including (1) Removal of Selected NCDs (NCD 160.22 Ambulatory EEG Monitoring), and, (2) Expanding Coverage of Colorectal Cancer Screening - Full Agile Pilot CR	11/13/2023	13017
R11892NCD	03/09/2023	Technical Revisions Only to the National Coverage Determination (NCD) Manual	04/10/2023	13105
R11865NCD	02/16/2023	An Omnibus CR to Implement Policy Updates in the CY 2023 PFS Final Rule, Including (1) Removal of Selected NCDs (NCD 160.22 Ambulatory EEG Monitoring), and, (2) Expanding Coverage of Colorectal Cancer Screening - Full Agile Pilot CR - Rescinded and replaced by Transmittal 12299	02/27/2023	13017
R11824NCD	01/27/2023	An Omnibus CR to Implement Policy Updates in the CY 2023 PFS Final Rule, Including (1) Removal of Selected NCDs (NCD 160.22 Ambulatory EEG Monitoring), and, (2) Expanding Coverage of Colorectal Cancer Screening - Full Agile Pilot CR- Rescinded and replaced by Transmittal 10865	02/27/2023	13017
R10891NCD	07/20/2021	National Coverage Determination (NCD 110.24): Chimeric Antigen Receptor (CAR) T-cell Therapy - This CR Rescinds and Fully Replaces CR 11783.	09/20/2021	12177
R10796NCD	05/20/2021	National Coverage Determination (NCD 110.24): Chimeric Antigen Receptor (CAR) T-cell Therapy - This CR Rescinds and Fully Replaces CR 11783. - Rescinded and replaced by Transmittal 10891	07/23/2021	12177
R10797NCD	05/20/2021	National Coverage Determination (NCD) Removal	06/22/2021	12254
R10346NCD	09/11/2020	National Coverage Determination (NCD 90.2): Next Generation Sequencing (NGS) for Medicare Beneficiaries with Germline (Inherited) Cancer	11/13/2020	10837
R10199NCD	06/23/2020	National Coverage Determination (NCD) 160.18 Vagus Nerve Stimulation (VNS)	07/22/2020	11461

R10145NCD	05/22/2020	National Coverage Determination (NCD) 160.18 Vagus Nerve Stimulation (VNS) - Rescinded and replaced by Transmittal 10199	07/22/2020	11461
R215NCD	04/10/2019	National Coverage Determination (NCD90.2): Next Generation Sequencing (NGS)	04/08/2019	10878
R214NCD	03/06/2019	National Coverage Determination (NCD90.2): Next Generation Sequencing (NGS))- Rescinded and replaced by Transmittal 215	04/08/2019	10878
R210NCD	11/30/2018	National Coverage Determination (NCD90.2): Next Generation Sequencing (NGS)- Rescinded and replaced by Transmittal 214	03/08/2019	10878
R200NCD	07/25/2017	Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS)	06/27/2017	10089
R199NCD	07/11/2017	Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS) – Rescinded and replaced by Transmittal 200	08/11/2017	10089
R196NCD	05/26/2017	Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS) – Rescinded and replaced by Transmittal 199	06/27/2017	10089
R194NCD	03/03/2017	Gender Dysphoria and Gender Reassignment Surgery	04/04/2017	9981
R193NCD	07/01/2016	Stem Cell Transplantation for Multiple Myeloma, Myelofibrosis, Sickle Cell Disease, and Myelodysplastic Syndromes	10/03/2016	9620
R191NCD	04/29/2016	Stem Cell Transplantation for Multiple Myeloma, Myelofibrosis, Sickle Cell Disease, and Myelodysplastic Syndromes – Rescinded and replaced by Transmittal 193	10/03/2016	9620
R181NCD	03/27/2015	Removal of Multiple National Coverage Determinations Using Expedited Process	04/06/2015	9095
R180NCD	03/06/2015	Removal of Multiple National Coverage Determinations Using Expedited Process – Rescinded and replaced by Transmittal 181	04/06/2015	9095
R173NCD	09/04/2014	Pub 100-03, Chapter 1, Language-only Update	Upon Implementation of ICD-10	8506
R169NCD	06/27/2014	Invalidation of National Coverage Determination 140.3 - Transsexual Surgery	06/29/2014	8825

R167NCD	05/16/2014	Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS)	10/06/2014	8757
R165NCD	04/15/2014	Aprepitant for Chemotherapy Induced Emesis	07/07/2014	8418
R163NCD	02/21/2014	Aprepitant for Chemotherapy Induced Emesis – Rescinded and replaced by Transmittal 165	07/07/2014	8418
R159NCD	02/05/2014	Pub 100-03, Chapter 1, Language-only Update – Rescinded and replaced by Transmittal 173	10/01/2014	8506
R158NCD	12/23/2013	Bariatric Surgery for Treatment of Co-Morbid Conditions Related to Morbid Obesity	12/17/2013	8484
R157NCD	11/15/2013	Bariatric Surgery for Treatment of Co-Morbid Conditions Related to Morbid Obesity – Rescinded and replaced by Transmittal 158	12/17/2013	8484
R150NCD	01/29/2013	Bariatric Surgery for the Treatment of Morbid Obesity National Coverage Determination, Addition of Laparoscopic Sleeve Gastrectomy (LSG)	02/28/2013	8028
R149NCD	11/30/2012	Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP)	01/07/2013	7836
R148NCD	11/09/2012	Bariatric Surgery for the Treatment of Morbid Obesity National Coverage Determination, Addition of Laparoscopic Sleeve Gastrectomy (LSG) – Rescinded and replaced by Transmittal 150	12/10/2012	8028
R144NCD	08/03/2012	Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP) – Rescinded and replaced by Transmittal 149	01/07/2013	7836
143NCD	05/18/2012	Extracorporeal Photopheresis (ICD-10)	10/01/2012	7806
R140NCD	01/06/2012	Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer	08/08/2011	7431
R136NCD	11/02/2011	Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer – Rescinded and replaced by Transmittal 140	08/08/2011	7431
R133NCD	07/08/2011	Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer – Rescinded and replaced by Transmittal 136	08/08/2011	7431
R127NCD	10/08/2010	Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) for Myelodysplastic Syndrome (MDS)	11/10/2010	7137
R121NCD	05/28/2010	Collagen Meniscus Implant	07/06/2010	6903

R111NCD	12/18/2009	Pharmacogenomic Testing for Warfarin Response	04/05/2010	6715
R102NCD	07/02/2009	Wrong Surgical or Other Invasive Procedure Performed on a Patient; Surgical or Other Invasive Procedure Performed on the Wrong Body Part; Surgical or Other Invasive Procedure Performed on the Wrong Patient	07/06/2009	6405
R101NCD	06/12/2009	Wrong Surgical or Other Invasive Procedure Performed on a Patient; Surgical or Other Invasive Procedure Performed on the Wrong Body Part; Surgical or Other Invasive Procedure Performed on the Wrong Patient-Rescinded and replaced by Transmittal 102	07/06/2009	6405
R100NCD	04/17/2009	Surgery for Diabetes	05/18/2009	6419
R97NCD	12/09/2008	Thermal Intradiscal Procedures (TIPs)	01/05/2009	6291
R80NCD	01/14/2008	Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions	04/07/2008	5818
R75NCD	09/11/2007	Lumbar Artificial Disc Replacement (LADR)	10/01/2007	5727
R70NCD	06/22/2007	Vagus Nerve Stimulation (VNS) for Resistant Depression	07/23/2007	5612
R69NCD	05/11/2007	Bone Mass Measurements (BMMs)	07/02/2007	5521
R67NCD	04/06/2007	Blood Brain Barrier Osmotic Disruption for Treatment of Brain Tumors	05/07/2007	5530
R66NCD	03/16/2007	Extracorporeal Photopheresis	04/02/2007	5464
R61NCD	11/24/2006	Cavernous Nerves Electrical Stimulation with Penile Plethysmography	01/08/2007	5294
R60NCD	06/23/2006	Lumbar Artificial Disc Replacement (LADR)	06/17/2006	5057
R55NCD	05/05/2006	Changes Conforming to CR 3648 Instructions for Therapy Services	10/02/2006	4014
R54NCD	04/28/2006	Bariatric Surgery for Treatment of Morbid Obesity	05/30/2006	5013
R48NCD	03/17/2006	Technical Corrections to the NCD Manual	06/19/2006	4278
R45NCD	12/06/2005	Stem Cell Transplantation	01/03/2006	4173
R43NCD	12/02/2005	Stem Cell Transplantation	01/03/2006	4173
R41NCD	06/24/2005	Osteogenic Stimulators	08/01/2005	3836
R40NCD	06/24/2005	Coverage of Aprepitant for Chemotherapy-Induced Emesis	07/05/2005	3831
R38NCD	06/17/2005	Coverage of Colorectal Anti-Cancer Drugs Included in Clinical Trials	04/18/2005	3742

R34NCD	04/25/2005	Abarelix for the Treatment of Abarelix for the Treatment of Prostate Cancer	05/25/2005	3775
R32NCD	04/15/2005	Autologous Stem Cell Transplantation (AuSCT)	05/16/2005	3797
R30NCD	03/29/2005	Coverage of Colorectal Anti-Cancer Drugs Included in Clinical Trials	04/18/2005	3742
R15NCD	06/18/2004	Sensory Nerve Conduction Threshold Tests	04/01/2004	3339
R14NCD	06/10/2004	Arthroscopic Lavage and Arthroscopic Debridement for the Osteoarthritic Knee	07/11/2004	3281
R13NCD	05/28/2004	Removal of Coding from National Coverage Determination on Stem Cell Transplantation	07/06/2004	3265
R10NCD	04/06/2004	Re-release of NCD Manual	N/A	N/A
R08NCD	03/19/2004	Sensory Nerve Conduction Threshold (sNCT) Tests	04/01/2004	2988
R01NCD	10/01/2003	Initial Release of Manual	N/A	N/A

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