Medicare National Coverage Determinations Manual

Chapter 1, Part 1 (Sections 10 – 80.12)

Coverage Determinations

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Foreword - Purpose for National Coverage Determinations (NCD) Manual

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

A. Purpose

The statutory and policy framework within which National Coverage Determinations (NCDs) are made may be found in title XVIII of the Social Security Act (the Act), and in Medicare regulations and rulings. The NCD Manual describes whether specific medical items, services, treatment procedures, or technologies can be paid for under Medicare. NCDs have been made on the items addressed in this manual. Decisions that items/services are not covered are generally based on §1862(a)(1) of the Act (the "not reasonable and necessary" exclusion) unless otherwise specifically noted. Where another statutory authority for denial is indicated, that is the authority for denial. Where an item/service is stated to be covered, but such coverage is explicitly limited to specified indications or specified circumstances, all limitations on coverage of the items/services because they do not meet those specified indications or circumstances are based on §1862(a)(1) of the Act. Where coverage of an item/service is provided for specified indications or circumstances but is not explicitly excluded for others, or where the item/service is not mentioned at all in the Centers for Medicare & Medicaid Services (CMS) NCD Manual the Medicare Administrative Contractor (MAC) has the discretion to make the coverage decision, in consultation with its medical staff, and with CMS when appropriate, based on the law, regulations, rulings, and general program instructions

The coverage determinations in the manual will be revised based on the most recent medical and other scientific and technical evidence available to CMS.

Other manuals in this system in which coverage-related instructions may be found are:

Pub 100-02 (Benefit Policy);
Pub 100-04 (Claims Processing);
Pub 100-05 (Medicare Secondary Payer); and
Pub 100-08 (Program Integrity)

These manuals usually contain more general coverage descriptions and/or claims processing instructions. There should be no inconsistencies among the instructions in any of these manuals and the NCD Manual pertaining to coverage. If any such inconsistencies are found, bring them to the attention of CMS, Center for Clinical Standards and Quality, Coverage and Analysis Group, Division of Operations and Information Management.

B. Organization

The NCD Manual is organized by categories, e.g., medical procedures, supplies, diagnostic services. A table of contents is provided at the beginning of the manual

designating coverage determination categories. Each subject discussed within the category is listed and identified by a number.

The revision transmittal sheet identifies new material and summarizes the principal changes. When a change in policy or procedure is involved, the background and effective date for the change is provided. If, at a later date, the reader wishes to refer to the background explanation given on a transmittal sheet, the reader can identify the transmittal by its number which appears on each manual page.

C. CMS Coverage Web site

The CMS Coverage Web page http://www.cms.gov/Center/Special-Topic/Medicare-Coverage-Center.html?redirect=/center/coverage.asp contains information about pending NCDs and also provides access to a database of NCDs, National Coverage Analyses, and Local Medical review Policies.

10 - Anesthesia and Pain Management
(Rev. 1, 10-03-03)

10.1 - Use of Visual Tests Prior to and General Anesthesia During Cataract Surgery
A. Pre-Surgery Evaluations

Cataract surgery with an intraocular lens (IOL) implant is a high volume Medicare procedure. Along with the surgery, a substantial number of preoperative tests are available to the surgeon. In most cases, a comprehensive eye examination (ocular history and ocular examination) and a single scan to determine the appropriate pseudophakic power of the IOL are sufficient. In most cases involving a simple cataract, a diagnostic ultrasound A-scan is used. For patients with a dense cataract, an ultrasound B-scan may be used.

Accordingly, where the only diagnosis is cataract(s), Medicare does not routinely cover testing other than one comprehensive eye examination (or a combination of a brief/intermediate examination not to exceed the charge of a comprehensive examination) and an A-scan or, if medically justified, a B-scan. Claims for additional tests are denied as not reasonable and necessary unless there is an additional diagnosis and the medical need for the additional tests is fully documented.

Because cataract surgery is an elective procedure, the patient may decide not to have the surgery until later, or to have the surgery performed by a physician other than the diagnosing physician. In these situations, it may be medically appropriate for the operating physician to conduct another examination. To the extent the additional tests are considered reasonable and necessary by the A/B MAC's medical staff, they are covered.

B. General Anesthesia

The use of general anesthesia in cataract surgery may be considered reasonable and necessary if, for particular medical indications, it is the accepted procedure among ophthalmologists in the local community to use general anesthesia.

10.2 - Transcutaneous Electrical Nerve Stimulation (TENS) for Acute Post-Operative Pain

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

The use of transcutaneous electrical nerve stimulation (TENS) for the relief of acute post-operative pain is covered under Medicare. TENS may be covered whether used as an adjunct to the use of drugs, or as an alternative to drugs, in the treatment of acute pain resulting from surgery.

The TENS devices, whether durable or disposable, may be used in furnishing this service. When used for the purpose of treating acute post-operative pain, TENS devices are considered supplies. As such they may be hospital supplies furnished inpatients covered under Part A, or supplies incident to a physician's service when furnished in connection with surgery done on an outpatient basis, and covered under Part B.

It is expected that TENS, when used for acute post-operative pain, will be necessary for relatively short periods of time, usually 30 days or less. In cases when TENS is used for longer periods, A/B MACs should attempt to ascertain whether TENS is no longer being used for acute pain but rather for chronic pain, in which case the TENS device may be covered as durable medical equipment as described in §160.27.

Cross-references:
Medicare Benefit Policy Manual, Chapter 1, "Inpatient Hospital Services," §40; Medicare Benefit Policy Manual, Chapter 2, "Hospital Services Covered Under Part B," §§20, 20.4, and 80; Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and other Health Services, §110."

10.3 - Inpatient Hospital Pain Rehabilitation Programs

(Rev. 1, 10-03-03)
CIM 35-21

Pain rehabilitation programs are an innovative approach to the treatment of intractable pain. The goal of such programs is to give a patient the tools to manage and control his/her pain and thereby improve his/her ability to function independently.

A hospital level pain rehabilitation program is one that employs a coordinated multi-disciplinary team to deliver, in a controlled environment, a concentrated program that is designed to modify pain behavior through the treatment of the physiological, psychological, and social aspects of pain. Such programs generally include diagnostic testing, skilled nursing, psychotherapy, structured progressive withdrawal from pain medications, physical therapy, and occupational therapy to restore physical fitness

(mobility and endurance) to a maximal level within the constraints of a patient's physical disability, and the use of mechanical devices, and/or activities to relieve pain or modify a patient's reaction to it (e.g., nerve stimulator, hydrotherapy, massage, ice, systemic muscle relaxation training, and diversional activities).

The nurse's responsibility in such pain rehabilitation programs is to observe and assess, on a continuing basis, a patient's condition and response to the program as reflected by his actions while in the nursing unit, and to assure that the atmosphere within the unit is not supportive of pain behavior. The day-to-day activities involved in carrying out the program are under the general supervision and, as needed, direct supervision of a physician.

Since pain rehabilitation programs of a lesser scope than that described above would raise a question as to whether the program could be provided in a less intensive setting than on an inpatient hospital basis, carefully evaluate such programs to determine whether the program does, in fact, necessitate a hospital level of care. Some pain rehabilitation programs may utilize services and devices which are excluded from coverage, e.g., acupuncture dorsal column stimulator, and family counseling services. In determining whether the scope of a pain program does necessitate inpatient hospital care, evaluate only those services and devices which are covered. Although diagnostic tests may be an appropriate part of pain rehabilitation programs, such tests would be covered in an individual case only where they can be reasonably related to a patient's illness, complaint, symptom, or injury and where they do not represent an unnecessary duplication of tests previously performed.

An inpatient program of 4 weeks' duration is generally required to modify pain behavior. After this period, it would be expected that any additional rehabilitation services which might be required could be effectively provided on an outpatient basis under an outpatient pain rehabilitation program (see §10.4) or other outpatient program. The first 7-10 days of such an inpatient program constitute, in effect, an evaluation period. If a patient is unable to adjust to the program within this period, it is generally concluded that it is unlikely that the program will be effective and the patient is discharged from the program. On occasions, a program longer than four weeks may be required in a particular case. In such a case, there should be documentation to substantiate that inpatient care beyond a 4-week period was reasonable and necessary. Similarly, where it appears that a patient participating in a program is being granted frequent outside passes, a question would exist as to whether an inpatient program is reasonable and necessary for the treatment of the patient's condition.

An inpatient hospital stay for the purpose of participating in a pain rehabilitation program would be covered as reasonable and necessary to the treatment of a patient's condition where the pain is attributable to a physical cause, the usual methods of treatment have not been successful in alleviating it, and a significant loss of ability to function independently has resulted from the pain. Chronic pain patients often have psychological problems which accompany or stem from the physical pain, and it is appropriate to include psychological treatment in the multi-disciplinary approach. However, patients whose pain

symptoms result from a mental condition, rather than from any physical cause, generally cannot be successfully treated in a pain rehabilitation program.

10.4 - Outpatient Hospital Pain Rehabilitation Programs
(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD-10, Implementation: Upon Implementation of ICD-10)

Some hospitals also provide pain rehabilitation programs for outpatients. In such programs, services frequently are provided in group settings even though they are being furnished pursuant to each patient's individualized plan of treatment.

Coverage of services furnished under outpatient hospital pain rehabilitation programs, including services furnished in group settings under individualized plans of treatment, is available if the patient's pain is attributable to a physical cause, the usual methods of treatment have not been successful in alleviating it, and a significant loss of ability by the patient to function independently has resulted from the pain. If a patient meets these conditions and the program provides services of the types discussed in §10.3, the services provided under the program may be covered. Non-covered services (e.g., vocational counseling, meals for outpatients, or acupuncture) continue to be excluded from coverage, and A/B MACs would not be precluded from finding, in the case of particular patients, that the pain rehabilitation program is not reasonable and necessary under §1862(a)(1) of the Social Security Act for the treatment of their conditions.

10.5 - Autogenous Epidural Blood Graft
(Rev. 1, 10-03-03)
CIM 45-11

Autogenous epidural blood grafts are considered a safe and effective remedy for severe headaches that may occur after performance of spinal anesthesia, spinal taps or myelograms, and are covered. In the procedure, blood is removed from the patient's vein and injected into his epidural space, to seal the spinal fluid leak and stop the pain.

10.6 - Anesthesia in Cardiac Pacemaker Surgery
(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD-10, Implementation: Upon Implementation of ICD-10)

The use of general or monitored anesthesia during transvenous cardiac pacemaker surgery may be reasonable and necessary and therefore covered under Medicare only if adequate documentation of medical necessity is provided on a case-by-case basis. The A/B MAC obtains advice from its medical consultants or from appropriate specialty physicians or groups in its locality regarding the adequacy of documentation before deciding whether a particular claim should be covered.

A second type of pacemaker surgery that is sometimes performed involves the use of the thoracic method of implantation which requires open surgery. Where the thoracic method is employed, general anesthesia is always used and should not require special

medical documentation.

20 - Cardiovascular System
(Rev. 1, 10-03-03)

20.1 - Vertebral Artery Surgery
(Rev. 1, 10-03-03)
CIM 35-32

Obstructions which block the flow of blood through the vertebral artery can cause vertigo, visual or speech defects, ataxia, mental confusion, or stroke. These symptoms in patients result from reduction in blood flow to the brain and range from symptoms of transient basilar ischemia to mental deterioration or completed stroke.

Five types of surgical procedures are performed to relieve obstructions to vertebral artery blood flow. They are:

- Vertebral artery endarterectomy, a procedure which cleans out arteriosclerotic plaques which are inside the vertebral artery;

- Vertebral artery by-pass or resection with anastomosis or graft;

- Subclavian artery resection with or without endarterectomy;

- Removal of laterally located osteophytes anywhere in the C6 (C7)-C2 course of the vertebral artery; and

- Arteriolysis which frees the artery from surrounding tissue, with or without arteriopexy (fixation of the vessel).

These procedures can be medically reasonable and necessary, but only if each of the following conditions is met:

- Symptoms of vertebral artery obstruction exist;

- Other causes have been considered and ruled out;

- There is radiographic evidence of a valid vertebral artery obstruction; and

- Contraindications to the procedure do not exist, such as coexistent obstructions of multiple cerebral vessels.

Angiograms documenting a valid obstruction should show not only the aortic arch with the vessels off the arch, but also show the vessels in the neck and head (providing biplane views of the carotid and vertebral vascular system). In addition, serial views are needed to diagnose “subclavian steal,” the condition in which subclavian artery obstruction

causes the symptoms of vertebral artery obstruction. Because the symptoms are not specific for vertebral artery obstruction, other causes must be considered. In addition to vertebral artery obstruction, the differential diagnosis should include various degenerative disorders of the brain, orthostatic hypotension, acoustic neuroma, labyrinthitis, diabetes mellitus and hypoglycemia related disorders.

Obstructions which can cause symptoms of blocked vertebral artery blood flow and which can be documented by an angiogram include:

- Intravascular obstructions - arteriosclerotic lesions within the vertebral artery or in other arteries.

- Extravascular obstructions;

- Bony tissue or osteophytes, located laterally in the C6 (C7)-C2 cervical vertebral area course of the vertebral artery, most commonly at C5 -C6;

- Anatomical variations - Anomalous location of the origin of the vertebral artery, a congenital aberration, and tortuosity and kinks of the vertebral artery; to

- Fibrous tissue - Tissue changed as a result of manipulation of the neck for neck pain or injury associated with hematoma; external bands, tendinous slings, and fibrous bands.

The most controversial obstructions include vertebral artery tortuosity and kinks and connective tissue along the course of the vertebral artery, and variously called external bands, tendinous slings and fibrous bands. In the absence of symptoms of vertebral artery obstruction, vascular surgeons feel such abnormalities are insignificant. Vascular surgery experts, however, agree that these abnormalities in very rare cases do cause symptoms of vertebral artery obstruction and do necessitate surgical correction.

Vertebral artery construction and vertebral artery surgery are phrases which most physicians interpret to include only surgical cleaning (endarterectomy) and bypass (resection) procedures. However, some physicians who use these terms mean all operative manipulations which remove vertebral artery blood flow obstructions. Also, some physicians use general terms of vascular surgery, such as endarterectomy, when vertebral artery related surgery is performed. Use of the above terminology specifies neither the surgical procedure performed nor its relationship to the vertebral artery. Therefore, in developing claims for this type of procedure, require specific identification of the obstruction in question and the surgical procedure performed. Also, in view of the specific coverage criteria given, develop all claims for vertebral artery surgery on a case-by-case basis.

Make payment for a surgical procedure listed above if: (1) it is reasonable and necessary for the individual patient to have the surgery performed to remove or relieve an obstruction to vertebral artery flow, and (2) the four conditions noted are met.

In all other cases, these procedures cannot be considered reasonable and necessary within the meaning of §1862(a)(1) of the Act and are not reimbursable under the program.

20.2 - Extracranial - Intracranial (EC-IC) Arterial Bypass Surgery

(Rev. 1, 10-03-03)
CIM 35-37

Extracranial-Intracranial (EC-IC) arterial bypass surgery is not a covered procedure when it is performed as a treatment for ischemic cerebrovascular disease of the carotid or middle cerebral arteries which includes the treatment or prevention of strokes. The premise that this procedure which bypasses narrowed arterial segments, improves the blood supply to the brain and reduces the risk of having a stroke has not been demonstrated to be any more effective than no surgical intervention. Accordingly, EC-IC arterial bypass surgery is not considered reasonable and necessary within the meaning of §1862(a)(1) of the Act when it is performed as a treatment for ischemic cerebrovascular disease of the carotid or middle cerebral arteries.

20.3 - Thoracic Duct Drainage (TDD) in Renal Transplants

(Rev. 1, 10-03-03)
CIM 35-58

Thoracic duct drainage (TDD) is an immunosuppressive technique used in renal transplantation. This procedure which removes lymph from kidney transplant recipients as a means of achieving suppression of the immune mechanism, is currently being used both pre- and post-transplant in conjunction with more conventional immunotherapy. TDD is performed on an inpatient basis, and the inpatient stay is covered for patients admitted for treatment in advance of a kidney transplant as well as for those receiving it post-transplant.

The TDD is a covered technique when furnished to a kidney transplant recipient or an individual approved to receive kidney transplantation in a hospital approved to perform kidney transplantation.

20.4 – Implantable Cardioverter Defibrillators (ICDs)

(Rev. 12112; Issued: 06-29-23; Effective: 07- 31-23; Implementation: 07-31- 23)

A. General

An implantable cardioverter defibrillator (ICD) is an electronic device designed to diagnose and treat life-threatening ventricular tachyarrhythmias.

B. Nationally Covered Indications

Effective for services performed on or after February 15, 2018 CMS has determined that the evidence is sufficient to conclude that the use of ICDs, (also referred to as defibrillators) is reasonable and necessary:

1. Patients with a personal history of sustained ventricular tachyarrhythmia (VT) or cardiac arrest due to ventricular fibrillation (VF). Patients must have demonstrated:
    - An episode of sustained VT, either spontaneous or induced by an electrophysiology (EP) study, not associated with an acute myocardial infarction (MI) and not due to a transient or reversible cause; or
    - An episode of cardiac arrest due to VF, not due to a transient or reversible cause.

2. Patients with a prior MI and a measured left ventricular ejection fraction (LVEF) ≤ 0.30. Patients must not have:
    - New York Heart Association (NYHA) classification IV heart failure; or,
    - Had a coronary artery bypass graft (CABG), or percutaneous coronary intervention (PCI) with angioplasty and/or stenting, within the past 3 months; or,
    - Had an MI within the past 40 days; or,
    - Clinical symptoms and findings that would make them a candidate for coronary revascularization.

For these patients identified in B2, a formal shared decision making encounter must occur between the patient and a physician (as defined in Section 1861(r)(1) of the Social Security Act (the Act))or qualified non-physician practitioner (meaning a physician assistant, nurse practitioner, or clinical nurse specialist as defined in §1861(aa)(5) of the Act) using an evidence-based decision tool on ICDs prior to initial ICD implantation. The shared decision making encounter may occur at a separate visit.

3. Patients who have severe, ischemic, dilated cardiomyopathy but no personal history of sustained VT or cardiac arrest due to VF, and have NYHA Class II or III heart failure, LVEF $\leq$ 35%. Additionally, patients must not have:
    - Had a CABG, or PCI with angioplasty and/or stenting, within the past 3 months; or,
    - Had an MI within the past 40 days; or,
    - Clinical symptoms and findings that would make them a candidate for coronary revascularization.

For these patients identified in B3, a formal shared decision making encounter must occur between the patient and a physician (as defined in Section 1861(r)(1) of the Act) or qualified non-physician practitioner (meaning a physician assistant, nurse practitioner, or clinical nurse specialist as defined in §1861(aa)(5) of the Act) using an evidence-based decision tool on ICDs prior to initial ICD implantation. The shared decision making encounter may occur at a separate visit.

4. Patients who have severe, non-ischemic, dilated cardiomyopathy but no personal history of sustained VT or cardiac arrest due to VF, and have NYHA Class II or III heart failure, LVEF $\leq$ 35%, been on optimal medical therapy for at least 3 months. Additionally, patients must not have:
    - Had a CABG or PCI with angioplasty and/or stenting, within the past 3 months; or,
    - Had an MI within the past 40 days; or,
    - Clinical symptoms and findings that would make them a candidate for coronary revascularization.

For these patients identified in B4, a formal shared decision making encounter must occur between the patient and a physician (as defined in Section 1861(r)(1) of the Act) or qualified non-physician practitioner (meaning a physician assistant, nurse practitioner, or clinical nurse specialist as defined in §1861(aa)(5) of the Act) using an evidence-based decision tool on ICDs prior to initial ICD implantation. The shared decision making encounter may occur at a separate visit.

5. Patients with documented, familial or genetic disorders with a high risk of life-threatening tachyarrhythmias (sustained VT or VF), to include, but not limited to, long QT syndrome or hypertrophic cardiomyopathy.

For these patients identified in B5, a formal shared decision making encounter must occur between the patient and a physician (as defined in Section 1861(r)(1) of the Act) or qualified non-physician practitioner (meaning a physician assistant, nurse practitioner, or clinical nurse specialist as defined in §1861(aa)(5) of the Act) using an evidence-based decision tool on ICDs prior to initial ICD implantation. The shared decision making encounter may occur at a separate visit.

6. Patients with an existing ICD may receive an ICD replacement if it is required due to the end of battery life, elective replacement indicator (ERI), or device/lead malfunction.

For each of the 6 covered indications above, the following additional criteria must also be met:

1. Patients must be clinically stable (e.g., not in shock, from any etiology);
2. LVEF must be measured by echocardiography, radionuclide (nuclear medicine) imaging, cardiac magnetic resonance imaging (MRI), or catheter angiography;
3. Patients must not have:

    - Significant, irreversible brain damage; or,
    - Any disease, other than cardiac disease (e.g., cancer, renal failure, liver failure) associated with a likelihood of survival less than 1 year; or,
    - Supraventricular tachycardia such as atrial fibrillation with a poorly controlled ventricular rate.

Exceptions to waiting periods for patients that have had a CABG, or PCI with angioplasty and/or stenting, within the past 3 months, or had an MI within the past 40 days:

Cardiac Pacemakers: Patients who meet all CMS coverage requirements for cardiac pacemakers, and who meet the criteria in this national coverage determination for an ICD, may receive the combined devices in one procedure, at the time the pacemaker is clinically indicated;

Replacement of ICDs: Patients with an existing ICD may receive an ICD replacement if it is required due to the end of battery life, ERI, or device/lead malfunction.

C. Nationally Non-Covered Indications

N/A

D. Other

For patients that are candidates for heart transplantation on the United Network for Organ Sharing (UNOS) transplant list awaiting a donor heart, coverage of ICDs, as with cardiac resynchronization therapy, as a bridge-to-transplant to prolong survival until a donor becomes available, is determined by the local Medicare Administrative Contractors (MACs).

All other indications for ICDs not currently covered in accordance with this decision may be covered under Category B investigational device exemption (IDE) trials (42 CFR 405.201).

(This NCD last reviewed February 2018.)

20.5 - Extracorporeal Immunoadsorption (ECI) Using Protein A Columns (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 Extracorporeal Immunoadsorption (ECI) Using Protein A Columns. 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.

20.6 - Transmyocardial Revascularization (TMR)

(Rev. 1, 10-03-03)
CIM 35-94

Transmyocardial revascularization (TMR) is a surgical technique which uses a laser to bore holes through the myocardium of the heart in an attempt to restore perfusion to areas of the heart not being reached by diseased or clogged arteries. This technique is used as a late or last resort for relief of symptoms of severe angina in patients with ischemic heart disease not amenable to direct coronary revascularization interventions, such as angioplasty, stenting or open coronary bypass.

The precise workings of this technique are not certain. The original theory upon which the technique was based, that the open channels would result in increased perfusion of the myocardium, does not appear to be the major or only action at work. Several theories have been proposed, including partial denervation of the myocardium, or the triggering of the cascade of biological reactions which encourage increased development of blood vessels.

However, research at several facilities indicates that, despite this uncertainty, the technique does offer relief of angina symptoms for a period of time in patients for whom no other medical treatment offering relief is available. Studies indicate that both reduction in pain and reduction in hospitalizations are significant for most patients treated. Consequently, CMS has concluded that, for patients with severe angina (Class III or IV, Canadian Cardiovascular Society, or similar classification system) for whom all other medical therapies have been tried or evaluated and found insufficient, such therapy offers sufficient evidence of its medical effectiveness to treat the symptomatology. It is important to note that this technique does not provide for increased life expectancy, nor is it proven to affect the underlying cause of the angina. However, it appears effective in treating the symptoms of angina, and reducing hospitalizations and allowing patients to resume some of their normal activities of daily living.

The CMS therefore covers TMR as a late or last resort for patients with severe (Canadian Cardiovascular Society classification Classes III or IV) angina (stable or unstable) which has been found refractory to standard medical therapy, including drug therapy at the maximum tolerated or maximum safe dosages. In addition, the angina symptoms must be

caused by areas of the heart not amenable to surgical therapies such as percutaneous transluminal coronary angioplasty, stenting, coronary atherectomy or coronary bypass.

Coverage is further limited to those uses of the laser used in performing the procedure which have been approved by the Food and Drug Administration for the purpose for which they are being used.

Patients would have to meet all of the following additional selection guidelines:

- An ejection fraction of 25 percent or greater;

- Have areas of viable ischemic myocardium (as demonstrated by diagnostic study) which are not capable of being revascularized by direct coronary intervention; and

- Have been stabilized, or have had maximal efforts to stabilize acute conditions such as severe ventricular arrhythmias, decompensated congestive heart failure or acute myocardial infarction.

Coverage is limited to physicians who have been properly trained in the procedure. Providers of this service must also document that all ancillary personnel, including physicians, nurses, operating room personnel and technicians, are trained in the procedure and the proper use of the equipment involved. Coverage is further limited to providers which have dedicated cardiac care units, including the diagnostic and support services necessary for care of patients undergoing this therapy. In addition, these providers must conform to the standards for laser safety set by the American National Standards Institute, ANSIZ1363.

20.7 - Percutaneous Transluminal Angioplasty (PTA) (Various Effective Dates Below)

(Rev. 12571; Issued: 04-11-24; Effective: 10-11-23; Implementation: 05-13-24)

A. General

This procedure involves inserting a balloon catheter into a narrow or occluded blood vessel to recanalize and dilate the vessel by inflating the balloon. The objective of percutaneous transluminal angioplasty (PTA) is to improve the blood flow through the diseased segment of a vessel so that vessel patency is increased and embolization is decreased. With the development and use of balloon angioplasty for treatment of atherosclerotic and other vascular stenoses, PTA with and without the placement of a stent) is a widely used technique for dilating lesions of peripheral, renal, and coronary arteries.

B. Nationally Covered Indications

The PTA is covered when used under the following conditions:

1. Treatment of Atherosclerotic Obstructive Lesions

-In the lower extremities, i.e., the iliac, femoral, and popliteal arteries, or in the upper extremities, i.e., the innominate, subclavian, axillary, and brachial arteries. The upper extremities do not include head or neck vessels.

-Of a single coronary artery for patients for whom the likely alternative treatment is coronary bypass surgery and who exhibit the following characteristics:

- Angina refractory to optimal medical management;
- Objective evidence of myocardial ischemia; and
- Lesions amenable to angioplasty

-Of the renal arteries for patients in whom there is an inadequate response to a thorough medical management of symptoms and for whom surgery is the likely alternative. PTA for this group of patients is an alternative to surgery, not simply an addition to medical management.

-Of arteriovenous dialysis fistulas and grafts when performed through either a venous or arterial approach.

2. Concurrent with Carotid Stent Placement in Food and Drug Administration (FDA)-Approved Category B Investigational Device Exemption (IDE) Clinical Trials

Effective July 1, 2001, Medicare covers PTA of the carotid artery concurrent with carotid stent placement when furnished in accordance with the FDA-approved protocols governing Category B IDE clinical trials. PTA of the carotid artery, when provided solely for the purpose of carotid artery dilation concurrent with carotid stent placement, is considered to be a reasonable and necessary service when provided in the context of such a clinical trial.

3. Concurrent with Carotid Stent Placement in FDA-Approved Post-Approval Studies

Effective October 12, 2004, Medicare covers PTA of the carotid artery concurrent with the placement of an FDA-approved carotid stent and an FDA-approved or –cleared embolic protection device (effective December 9, 2009) for an FDA-approved indication when furnished in accordance with FDA-approved protocols governing post-approval studies. The Centers for Medicare & Medicaid Services (CMS) determines that coverage of PTA of the carotid artery is reasonable and necessary in these circumstances.

4. Concurrent with Carotid Stent Placement

Effective October 11, 2023, CMS covers PTA of the carotid artery concurrent with stenting with the placement of an FDA-approved carotid stent with an FDA-approved or cleared embolic protection device, for Medicare beneficiaries under the following conditions:

A. Patients with symptomatic carotid artery stenosis ≥50%; and,

B. Patients with asymptomatic carotid artery stenosis ≥70%.

For both A and B above:

1. Neurological assessment by a neurologist or NIH stroke scale (NIHSS) certified health professional before and after CAS must be performed.
2. First-line evaluation of carotid artery stenosis must use duplex ultrasound.
3. Computed tomography angiography or magnetic resonance angiography, if not contraindicated, must be used to confirm the degree of stenosis and provide additional information about the aortic arch, and extra- and intra-cranial circulation.
4. Intra-arterial digital subtraction (catheter) angiography may be used only when there is significant discrepancy between non-invasive imaging results, or in lieu of computed tomography angiography or magnetic resonance angiography if these are contraindicated.

Prior to furnishing CAS, the practitioner must engage in a formal shared decision-making interaction with the beneficiary. The shared decision-making interaction must include:

- Discussion of all treatment options including carotid endarterectomy (CEA), CAS (which includes transcarotid artery revascularization (TCAR), and optimal medical therapy (OMT)).
- Explanation of risks and benefits for each option specific to the beneficiary's clinical situation.
- Integration of clinical guidelines (e.g., patient comorbidities and concomitant treatments).
- Discussion and incorporation of beneficiary's personal preferences and priorities in choosing a treatment plan.

Facilities must establish and maintain institutional and physician standards to support a dedicated carotid stent program. These standards must at least include and ensure the following:

- Facilities have a clearly delineated program for granting carotid stent privileges and for monitoring patient outcomes for individual physicians and the program as a whole.
- The oversight committee for this program shall be empowered to identify the minimum case volume for a physician to maintain privileges, as well as the (risk-adjusted) threshold for complications that the institution will allow before suspending privileges or instituting measures for remediation. Committees are encouraged to apply published standards from specialty societies and widely-used, published professional society guidelines to determine appropriate physician qualifications.
- Facilities have appropriately trained staff capable of fulfilling roles and responsibilities as delineated under the dedicated carotid stent program.

- Facilities have appropriate supporting personnel and equipment for imaging, emergency management, advanced physiologic monitoring, and other ancillary care.
- Facilities must ensure continuous quality improvement by assessing procedural outcomes and making necessary programmatic adjustments to assure patient safety.

5. Concurrent with Intracranial Stent Placement in FDA-Approved Category B IDE Clinical Trials

Effective November 6, 2006, Medicare covers PTA and stenting of intracranial arteries for the treatment of cerebral artery stenosis ≥50% in patients with intracranial atherosclerotic disease when furnished in accordance with the FDA-approved protocols governing Category B IDE clinical trials. CMS determines that coverage of intracranial PTA and stenting is reasonable and necessary under these circumstances.

C. Nationally Non-Covered Indications

All other indications for PTA with or without stenting to treat obstructive lesions of the vertebral and cerebral arteries remain non-covered.

All other indications for PTA without stenting for which CMS has not specifically indicated coverage remain non-covered.

D. Other

In addition to the national coverage described above, Medicare Administrative Contractors (MACs) may make reasonable and necessary determinations under section 1862(a)(1)(A) of the Social Security Act for any other beneficiary seeking coverage for PTA of the carotid artery concurrent with stenting.

Coverage of PTA with stenting not specifically addressed or discussed in this NCD is at the discretion of the MACs.

(This NCD last reviewed October 2023)

20.8 - Cardiac Pacemakers (Various Effective Dates Below)
(Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD-10, Implementation: Upon Implementation of ICD-10)

Cardiac pacemakers are self-contained, battery-operated units that send electrical stimulation to the heart. They are generally implanted to alleviate symptoms of decreased cardiac output related to abnormal heart rate and/or rhythm. Pacemakers are generally used for persistent, symptomatic second- or third-degree atrioventricular (AV) block and symptomatic sinus bradycardia.

Cardiac pacemakers are covered as prosthetic devices under the Medicare program, subject to the following conditions and limitations. While cardiac pacemakers have been

covered under Medicare for many years, there were no specific guidelines for their use other than the general Medicare requirement that covered services be reasonable and necessary for the treatment of the condition. Services rendered for cardiac pacing on or after the effective dates of this instruction are subject to these guidelines, which are based on certain assumptions regarding the clinical goals of cardiac pacing. While some uses of pacemakers are relatively certain or unambiguous, many other uses require considerable expertise and judgment.

Consequently, the medical necessity for permanent cardiac pacing must be viewed in the context of overall patient management. The appropriateness of such pacing may be conditional on other diagnostic or therapeutic modalities having been undertaken. Although significant complications and adverse side effects of pacemaker use are relatively rare, they cannot be ignored when considering the use of pacemakers for dubious medical conditions, or marginal clinical benefit.

These guidelines represent current concepts regarding medical circumstances in which permanent cardiac pacing may be appropriate or necessary. As with other areas of medicine, advances in knowledge and techniques in cardiology are expected. Consequently, judgments about the medical necessity and acceptability of new uses for cardiac pacing in new classes of patients may change as more conclusive evidence becomes available. This instruction applies only to permanent cardiac pacemakers, and does not address the use of temporary, non-implanted pacemakers.

The two groups of conditions outlined below deal with the necessity for cardiac pacing for patients in general. These are intended as guidelines in assessing the medical necessity for pacing therapies, taking into account the particular circumstances in each case. However, as a general rule, the two groups of current medical concepts may be viewed as representing:

Group I: Single-Chamber Cardiac Pacemakers – a) conditions under which single chamber pacemaker claims may be considered covered without further claims development; and b) conditions under which single-chamber pacemaker claims would be denied unless further claims development shows that they fall into the covered category, or special medical circumstances exist of the sufficiency to convince the A/B MAC that the claim should be paid.

Group II: Dual-Chamber Cardiac Pacemakers - a) conditions under which dual-chamber pacemaker claims may be considered covered without further claims development, and b) conditions under which dual-chamber pacemaker claims would be denied unless further claims development shows that they fall into the covered categories for single- and dual-chamber pacemakers, or special medical circumstances exist sufficient to convince the A/B MAC that the claim should be paid.

The Centers for Medicare & Medicaid Services (CMS) opened the National Coverage Determination (NCD) on Cardiac Pacemakers to afford the public an opportunity to comment on the proposal to revise the language contained in the instruction. The

revisions transfer the focus of the NCD from the actual pacemaker implantation procedure itself to the reasonable and necessary medical indications that justify cardiac pacing. This is consistent with our findings that pacemaker implantation is no longer considered routinely harmful or an experimental procedure.

Group I: Single-Chamber Cardiac Pacemakers (Effective March 16, 1983)

A. Nationally Covered Indications

Conditions under which cardiac pacing is generally considered acceptable or necessary, provided that the conditions are chronic or recurrent and not due to transient causes such as acute myocardial infarction, drug toxicity, or electrolyte imbalance. (In cases where there is a rhythm disturbance, if the rhythm disturbance is chronic or recurrent, a single episode of a symptom such as syncope or seizure is adequate to establish medical necessity.)

1. Acquired complete (also referred to as third-degree) AV heart block.

2. Congenital complete heart block with severe bradycardia (in relation to age), or significant physiological deficits or significant symptoms due to the bradycardia.

3. Second-degree AV heart block of Type II (i.e., no progressive prolongation of P-R interval prior to each blocked beat. P-R interval indicates the time taken for an impulse to travel from the atria to the ventricles on an electrocardiogram).

4. Second-degree AV heart block of Type I (i.e., progressive prolongation of P-R interval prior to each blocked beat) with significant symptoms due to hemodynamic instability associated with the heart block.

5. Sinus bradycardia associated with major symptoms (e.g., syncope, seizures, congestive heart failure (CHF)); or substantial sinus bradycardia (heart rate less than 50) associated with dizziness or confusion. The correlation between symptoms and bradycardia must be documented, or the symptoms must be clearly attributable to the bradycardia rather than to some other cause.

6. In selected and few patients, sinus bradycardia of lesser severity (heart rate 50-59) with dizziness or confusion. The correlation between symptoms and bradycardia must be documented, or the symptoms must be clearly attributable to the bradycardia rather than to some other cause.

7. Sinus bradycardia is the consequence of long-term necessary drug treatment for which there is no acceptable alternative when accompanied by significant symptoms (e.g., syncope, seizures, CHF, dizziness, or confusion). The correlation between symptoms and bradycardia must be documented, or the symptoms must be clearly attributable to the bradycardia rather than to some other cause.

8. Sinus node dysfunction with or without tachyarrhythmias or AV conduction block (i.e., the bradycardia-tachycardia syndrome, sino-atrial block, sinus arrest) when accompanied by significant symptoms (e.g., syncope, seizures, CHF, dizziness, or confusion).

9. Sinus node dysfunction with or without symptoms when there are potentially life-threatening ventricular arrhythmias or tachycardia secondary to the bradycardia (e.g., numerous premature ventricular contractions, couplets, runs of premature ventricular contractions, or ventricular tachycardia).

10. Bradycardia associated with supraventricular tachycardia (e.g., atrial fibrillation, atrial flutter, or paroxysmal atrial tachycardia) with high-degree AV block which is unresponsive to appropriate pharmacological management and when the bradycardia is associated with significant symptoms (e.g., syncope, seizures, CHF, dizziness, or confusion).

11. The occasional patient with hypersensitive carotid sinus syndrome with syncope due to bradycardia and unresponsive to prophylactic medical measures.

12. Bifascicular or trifascicular block accompanied by syncope which is attributed to transient complete heart block after other plausible causes of syncope have been reasonably excluded.

13. Prophylactic pacemaker use following recovery from acute myocardial infarction (MI) during which there was temporary complete (third-degree) and/or Mobitz Type II second-degree AV block in association with bundle branch block.

14. In patients with recurrent and refractory ventricular tachycardia, "overdrive pacing" (pacing above the basal rate) to prevent ventricular tachycardia.

(Effective May 9, 1985)

15. Second-degree AV heart block of Type I with the QRS complexes prolonged.

B. Nationally Non-Covered Indications

Conditions which, although used by some physicians as a basis for permanent cardiac pacing, are considered unsupported by adequate evidence of benefit and therefore should not generally be considered appropriate uses for single-chamber pacemakers in the absence of the above indications. A/B MACs should review claims for pacemakers with these indications to determine the need for further claims development prior to denying the claim, since additional claims development may be required. The object of such further development is to establish whether the particular claim actually meets the conditions in a) above. In claims where this is not the case or where such an event appears unlikely, the A/B MAC may deny the claim:

1. Syncope of undetermined cause.

2. Sinus bradycardia without significant symptoms.

3. Sino-atrial block or sinus arrest without significant symptoms.

4. Prolonged P-R intervals with atrial fibrillation (without third-degree AV block) or with other causes of transient ventricular pause.

5. Bradycardia during sleep.

6. Right bundle branch block with left axis deviation (and other forms of fascicular or bundle branch block) without syncope or other symptoms of intermittent AV block).

7. Asymptomatic second-degree AV block of Type I unless the QRS complexes are prolonged or electrophysiological studies have demonstrated that the block is at or beyond the level of the His bundle (a component of the electrical conduction system of the heart).

Effective October 1, 2001

8. Asymptomatic bradycardia in post-MI patients about to initiate long-term beta-blocker drug therapy.

C. Other

All other indications for single-chamber cardiac pacing for which CMS has not specifically indicated coverage remain nationally non-covered, except for Category B Investigational Device Exemption (IDE) clinical trials, or as routine costs of single-chamber cardiac pacing associated with clinical trials, in accordance with section 310.1 of the NCD Manual.

Group II: Dual-Chamber Cardiac Pacemakers – (Effective May 9, 1985)

A. Nationally Covered Indications

Conditions under dual-chamber cardiac pacing are considered acceptable or necessary in the general medical community unless conditions 1 and 2 under Group II. B., are present:

1. Patients in who single-chamber (ventricular pacing) at the time of pacemaker insertion elicits a definite drop in blood pressure, retrograde conduction, or discomfort.

2. Patients in whom the pacemaker syndrome (atrial ventricular asynchrony), with significant symptoms, has already been experienced with a pacemaker that is being replaced.

3. Patients in whom even a relatively small increase in cardiac efficiency will importantly improve the quality of life, e.g., patients with CHF despite adequate other medical measures.

4. Patients in whom the pacemaker syndrome can be anticipated, e.g., in young and active people, etc.

Dual-chamber pacemakers may also be covered for the conditions as listed in Group I. A., if the medical necessity is sufficiently justified through adequate claims development. Expert physicians differ in their judgments about what constitutes appropriate criteria for dual-chamber pacemaker use. The judgment that such a pacemaker is warranted in the patient meeting accepted criteria must be based upon the individual needs and characteristics of that patient, weighing the magnitude and likelihood of anticipated benefits against the magnitude and likelihood of disadvantages to the patient.

B. Nationally Non-Covered Indications

Whenever the following conditions (which represent overriding contraindications) are present, dual-chamber pacemakers are not covered:

1. Ineffective atrial contractions (e.g., chronic atrial fibrillation or flutter, or giant left atrium.

2. Frequent or persistent supraventricular tachycardias, except where the pacemaker is specifically for the control of the tachycardia.

3. A clinical condition in which pacing takes place only intermittently and briefly, and which is not associated with a reasonable likelihood that pacing needs will become prolonged, e.g., the occasional patient with hypersensitive carotid sinus syndrome with syncope due to bradycardia and unresponsive to prophylactic medical measures.

4. Prophylactic pacemaker use following recovery from acute MI during which there was temporary complete (third-degree) and/or Type II second-degree AV block in association with bundle branch block.

C. Other

All other indications for dual-chamber cardiac pacing for which CMS has not specifically indicated coverage remain nationally non-covered, except for Category B IDE clinical trials, or as routine costs of dual-chamber cardiac pacing associated with clinical trials, in accordance with section 310.1 of the NCD Manual.

20.8.1 - Cardiac Pacemaker Evaluation Services

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

Medicare covers a variety of services for the post-implant follow-up and evaluation of implanted cardiac pacemakers. The following guidelines are designed to assist A/B MACs in identifying and processing claims for such services.

NOTE: These new guidelines are limited to lithium battery-powered pacemakers, because mercury-zinc battery-powered pacemakers are no longer being manufactured and virtually all have been replaced by lithium units. A/B MACs still receiving claims for monitoring such units should continue to apply the guidelines published in 1980 to those units until they are replaced.

There are two general types of pacemakers in current use - single-chamber pacemakers which sense and pace the ventricles of the heart, and dual-chamber pacemakers which sense and pace both the atria and the ventricles. These differences require different monitoring patterns over the expected life of the units involved. One fact of which A/B MACs should be aware is that many dual-chamber units may be programmed to pace only the ventricles; this may be done either at the time the pacemaker is implanted or at some time afterward. In such cases, a dual-chamber unit, when programmed or reprogrammed for ventricular pacing, should be treated as a single-chamber pacemaker in applying screening guidelines.

The decision as to how often any patient's pacemaker should be monitored is the responsibility of the patient's physician who is best able to take into account the condition and circumstances of the individual patient. These may vary over time, requiring modifications of the frequency with which the patient should be monitored. In cases where monitoring is done by some entity other than the patient's physician, such as a commercial monitoring service or hospital outpatient department, the physician's prescription for monitoring is required and should be periodically renewed (at least annually) to assure that the frequency of monitoring is proper for the patient. Where a patient is monitored both during clinic visits and transtelephonically, the A/B MAC should be sure to include frequency data on both types of monitoring in evaluating the reasonableness of the frequency of monitoring services received by the patient.
Since there are over 200 pacemaker models in service at any given point, and a variety of patient conditions that give rise to the need for pacemakers, the question of the appropriate frequency of monitoring is a complex one. Nevertheless, it is possible to develop guidelines within which the vast majority of pacemaker monitoring will fall and A/B MACs should do this, using their own data and experience, as well as the frequency guidelines which follow, in order to limit extensive claims development to those cases requiring special attention.

20.8.1.1 - Transtelephonic Monitoring of Cardiac Pacemakers

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

A. General

Transtelephonic monitoring of pacemakers is furnished by commercial suppliers, hospital outpatient departments, and physicians' offices.

Telephone monitoring of cardiac pacemakers as described below is medically efficacious in identifying early signs of possible pacemaker failure, thus reducing the number of sudden pacemaker failures requiring emergency replacement. All systems that monitor the pacemaker rate (bpm) in both the free-running and/or magnetic mode are effective in detecting subclinical pacemaker failure due to battery depletion. More sophisticated systems are also capable of detecting internal electronic problems within the pulse generator itself and other potential problems. In the case of dual-chamber pacemakers in particular, such monitoring may detect failure of synchronization of the atria and ventricles, and the need for adjustment and reprogramming of the device.

NOTE: The transmitting device furnished to the patient is simply one component of the diagnostic system, and is not covered as durable medical equipment. Those engaged in transtelephonic pacemaker monitoring should reflect the costs of the transmitters in setting their charges for monitoring.

B. Definition of Transtelephonic Monitoring

In order for transtelephonic monitoring services to be covered, the services must consist of the following elements:

- A minimum 30-second readable strip of the pacemaker in the free-running mode;
- Unless contraindicated, a minimum 30-second readable strip of the pacemaker in the magnetic mode; and,
- A minimum 30 seconds of readable ECG strip.

C. Frequency Guidelines for Transtelephonic Monitoring

The guidelines below constitute a system which A/B MACs should use, in conjunction with their knowledge of local medical practices, to screen claims for transtelephonic monitoring prior to payment. It is important to note that they are not recommendations with respect to a minimum frequency for such monitorings, but rather a maximum frequency (within which payment may be made without further claims development). As with previous guidelines, more frequent monitorings may be covered in cases where A/B MACs are satisfied that such monitorings are medically necessary; e.g., based on the condition of the patient, or with respect to pacemakers exhibiting unexpected defects or premature failure. A/B MACs should seek written justification for more frequent monitorings from the patient's physician and/or any monitoring service involved.

These guidelines are divided into two broad categories - Guideline I which will apply to the majority of pacemakers now in use, and Guideline II which will apply only to pacemaker systems (pacemaker and leads) for which sufficient long-term clinical

information exists to assure that they meet the standards of the Inter-Society Commission for Heart Disease Resources (ICHD) for longevity and end-of-life decay. (The ICHD standards are: (1) 90% cumulative survival at 5 years following implant; and (2) an end-of-life decay of less than a 50% drop of output voltage and less than 20% deviation of magnet rate, or a drop of 5 beats per minute or less, over a period of 3 months or more.) A/B MACs should consult with their medical advisers and other appropriate individuals and organizations (such as the North American Society of Pacing and Electrophysiology which publishes product reliability information) should questions arise over whether a pacemaker system meets the ICHD standards.

The two groups of guidelines are then further broken down into two general categories – single-chamber and dual-chamber pacemakers. A/B MACs should be aware that the frequency with which a patient is monitored may be changed from time-to-time for a number of reasons, such as a change in the patient's overall condition, a reprogramming of the patient's pacemaker, the development of better information on the pacemaker's longevity or failure mode, etc. Consequently, changes in the proper set of guidelines may be required. A/B MACs should inform physicians and monitoring services to alert A/B MACs to any changes in the patient's monitoring prescription that might necessitate changes in the screening guidelines applied to that patient. (Of particular importance is the reprogramming of a dual-chamber pacemaker to a single-chamber mode of operation. Such reprogramming would shift the patient from the appropriate dual-chamber guideline to the appropriate single-chamber guideline.)

Guideline I

1 - Single-chamber pacemakers
- 1st month - every 2 weeks.
- 2nd through 36th month - every 8 weeks.
- 37th month to failure - every 4 weeks.

2 - Dual-chamber pacemaker
- 1st month - every 2 weeks.
- 2nd through 6th month - every 4 weeks.
- 7th through 36th month - every 8 weeks.
- 37th month to failure - every 4 weeks.

Guideline II

1 - Single-chamber pacemakers
- 1st month - every 2 weeks.
- 2nd through 48th month - every 12 weeks.
- 49th through 72nd month - every 8 weeks.
- Thereafter - every 4 weeks.

2 - Dual-chamber pacemaker
- 1st month - every 2 weeks.

2nd through 30th month - every 12 weeks.
31st through 48th month - every 8 weeks.
Thereafter - every 4 weeks.

D. Pacemaker Clinic Services

1. General

Pacemaker monitoring is also covered when done by pacemaker clinics. Clinic visits may be done in conjunction with transtelephonic monitoring or as a separate service; however, the services rendered by a pacemaker clinic are more extensive than those currently possible by telephone. They include, for example, physical examination of patients and reprogramming of pacemakers. Thus, the use of one of these types of monitoring does not preclude concurrent use of the other.

2. Frequency Guidelines

As with transtelephonic pacemaker monitoring, the frequency of clinic visits is the decision of the patient's physician, taking into account, among other things, the medical condition of the patient. However, A/B MACs can develop monitoring guidelines that will prove useful in screening claims. The following are recommendations for monitoring guidelines on lithium-battery pacemakers:

- For single-chamber pacemakers - twice in the first 6 months following implant, then once every 12 months.

- For dual-chamber pacemakers - twice in the first 6 months, then once every 6 months.

20.8.2 - Self-Contained Pacemaker Monitors
(Rev. 1, 10-03-03)

CIM 60-7

Self-contained pacemaker monitors are accepted devices for monitoring cardiac pacemakers. Accordingly, program payment may be made for the rental or purchase of either of the following pacemaker monitors when a physician for a patient prescribes it with a cardiac pacemaker:

A. Digital Electronic Pacemaker Monitor

This device provides the patient with an instantaneous digital readout of his pacemaker pulse rate. Use of this device does not involve professional services until there has been a change of five pulses (or more) per minute above or below the initial rate of the pacemaker; when such change occurs, the patient contacts his physician.

B. Audible/Visible Signal Pacemaker Monitor

This device produces an audible and visible signal which indicates the pacemaker rate. Use of this device does not involve professional services until a change occurs in these signals; at such time, the patient contacts his physician.

NOTE: The design of the self-contained pacemaker monitor makes it possible for the patient to monitor his pacemaker periodically and minimizes the need for regular visits to the outpatient department of the provider.

Therefore, documentation of the medical necessity for pacemaker evaluation in the outpatient department of the provider should be obtained where such evaluation is employed in addition to the self-contained pacemaker monitor used by the patient in his home.

Cross-reference: §20.8.1

20.8.3 – Single Chamber and Dual Chamber Permanent Cardiac Pacemakers

(Rev. 187, Issued: 12-10-15, Effective: 08-13-13, Issued: 01-13-16)

A. General

Permanent cardiac pacemakers refer to a group of self-contained, battery operated, implanted devices that send electrical stimulation to the heart through one or more implanted leads. They are often classified by the number of chambers of the heart that the devices stimulate (pulse or depolarize). Single chamber pacemakers typically target either the right atrium or right ventricle. Dual chamber pacemakers stimulate both the right atrium and the right ventricle.

The implantation procedure is typically performed under local anesthesia and requires only a brief hospitalization. A catheter is inserted into the chest and the pacemaker's leads are threaded through the catheter to the appropriate chamber(s) of the heart. The surgeon then makes a small "pocket" in the pad of the flesh under the skin on the upper portion of the chest wall to hold the power source. The pocket is then closed with stitches.

The Centers for Medicare & Medicaid Services (CMS) has determined that the evidence is sufficient to conclude that implanted permanent cardiac pacemakers, single chamber or dual chamber, are reasonable and necessary for the treatment of non-reversible symptomatic bradycardia due to sinus node dysfunction and second and/or third degree atrioventricular block. Symptoms of bradycardia are symptoms that can be directly attributable to a heart rate less than 60 beats per minute (for example: syncope, seizures, congestive heart failure, dizziness, or confusion).

B. Nationally Covered Indications

The following indications are covered for implanted permanent single chamber or dual chamber cardiac pacemakers:

1. Documented non-reversible symptomatic bradycardia due to sinus node dysfunction, and
2. Documented non-reversible symptomatic bradycardia due to second degree and/or third degree atrioventricular block.

C. Nationally Non-Covered Indications

The following indications are non-covered for implanted permanent single chamber or dual chamber cardiac pacemakers:

1. Reversible causes of bradycardia such as electrolyte abnormalities, medications or drugs, and hypothermia,
2. Asymptomatic first degree atrioventricular block,
3. Asymptomatic sinus bradycardia,
4. Asymptomatic sino-atrial block or asymptomatic sinus arrest,
5. Ineffective atrial contractions (e.g., chronic atrial fibrillation or flutter, or giant left atrium) without symptomatic bradycardia,
6. Asymptomatic second degree atrioventricular block of Mobitz Type I unless the QRS complexes are prolonged or electrophysiological studies have demonstrated that the block is at or beyond the level of the His Bundle (a component of the electrical conduction system of the heart),
7. Syncope of undetermined cause,
8. Bradycardia during sleep,
9. Right bundle branch block with left axis deviation (and other forms of fascicular or bundle branch block) without syncope or other symptoms of intermittent atrioventricular block,
10. Asymptomatic bradycardia in post-myocardial infarction patients about to initiate long-term beta-blocker drug therapy,
11. Frequent or persistent supraventricular tachycardias, except where the pacemaker is specifically for the control of tachycardia, and
12. A clinical condition in which pacing takes place only intermittently and briefly, and which is not associated with a reasonable likelihood that pacing needs will become prolonged.

D. Other

A/B MACs will determine coverage under section 1862(a)(1)(A) of the Social Security Act for any other indications for the implantation and use of single chamber or dual chamber cardiac pacemakers that are not specifically addressed in this national coverage determination.

(This NCD last reviewed August 2013.)

20.8.4 – Leadless Pacemakers

(Rev. 201, Issued: 07-28-17, Effective: 01-18-18, Implementation: 08-29-17- for MAC local edits; January 2, 2018 - for MCS shared edits)

A. General

The leadless pacemaker eliminates the need for a device pocket and insertion of a pacing lead which are integral elements of traditional pacing systems. The removal of these elements eliminate an important source of complications associated with traditional pacing systems while providing similar benefits. Leadless pacemakers are delivered via catheter to the heart, and function similarly to other transvenous single-chamber ventricular pacemakers.

B. Nationally Covered Indications

Effective January 18, 2017, the Centers for Medicare & Medicaid Services (CMS) covers leadless pacemakers through Coverage with Evidence Development (CED). CMS covers leadless pacemakers when procedures are performed in Food and Drug Administration (FDA) approved studies. CMS also covers, in prospective longitudinal studies, leadless pacemakers that are used in accordance with the FDA approved label for devices that have either:

- an associated ongoing FDA approved post-approval study; or
- completed an FDA post-approval study.

Each study must be approved by CMS and as a fully-described, written part of its protocol, must address the following research questions:

- What are the peri-procedural and post-procedural complications of leadless pacemakers?
- What are the long term outcomes of leadless pacemakers?
- What are the effects of patient characteristics (age, gender, comorbidities) on the use and health effects of leadless pacemakers?

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 Research and 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.

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. The information will be reviewed, and approved studies will be identified on the CMS website.

Director, Coverage and Analysis Group
Re: Leadless Pacemakers 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. Leadless Pacemakers)] [name of sponsor/primary investigator]"

C. Nationally Non-Covered Indications

Leadless pacemakers are non-covered when furnished outside of a CMS approved CED study.

D. Other

NA

(This NCD last reviewed January 2017.)

20.9 - Artificial Hearts and Related Devices (RETIRED)

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

This section has been removed from the NCD Manual and incorporated into NCD 20.9.1 effective December 1, 2020.

20.9.1 - Ventricular Assist Devices (VADs)

(Rev.10837; Issued: 06-11-21; Effective: 12-01-20; Implementation: 07-27-21)

A. General

A ventricular assist device (VAD) is surgically attached to one or both intact ventricles and is used to assist or augment the ability of a damaged or weakened native heart to pump blood. Improvement in the performance of the native heart may allow the device to be removed.

Indications and Limitations of Coverage

B. Nationally Covered Indications

1. Post-cardiotomy (effective for services performed on or after October 18, 1993)

Post-cardiotomy is the period following open-heart surgery. VADs used for support of blood circulation post-cardiotomy are covered only if they have received approval from the Food and Drug Administration (FDA) for that purpose, and the VADs are used according to the FDA-approved labeling instructions.

2. Left ventricular assist devices (LVADs) are covered if they are FDA approved for short-term (e.g., bridge-to-recovery and bridge-to-transplant) or long-term (e.g., destination therapy) mechanical circulatory support for heart failure patients who meet the following criteria:

- Have New York Heart Association (NYHA) Class IV heart failure; and
- Have a left ventricular ejection fraction (LVEF) ≤ 25%; and
- Are inotrope dependent
  OR
  have a Cardiac Index (CI) < 2.2 L/min/m2, while not on inotropes, and also meet one of the following:
    - Are on optimal medical management (OMM), based on current heart failure practice guidelines for at least 45 out of the last 60 days and are failing to respond; or
    - Have advanced heart failure for at least 14 days and are dependent on an intra-aortic balloon pump (IABP) or similar temporary mechanical circulatory support for at least 7 days.

Beneficiaries receiving a VAD must be managed by an explicitly identified, cohesive, multidisciplinary team of medical professionals with appropriate qualifications, training, and experience. The team embodies collaboration and dedication across medical specialties to offer optimal patient-centered care. Collectively, the team must ensure that patients and caregivers have the knowledge and support necessary to participate in informed decision making. The team members must be based at the facility and must

include individuals with experience working with patients before and after placement of a VAD.

The team must include, at a minimum:

- At least one physician with cardiothoracic surgery privileges and individual experience implanting at least 10 durable, intracorporeal, left ventricular assist devices over the course of the previous 36 months with activity in the last year.
- At least one cardiologist trained in advanced heart failure with clinical competence in medical- and device-based management including VADs, and clinical competence in the management of patients before and after placement of a VAD.
- A VAD program coordinator.
- A social worker.
- A palliative care specialist.

Facilities must be credentialed by an organization approved by CMS. The process for organizations to apply for CMS approval to be designated as a credentialing organization for LVAD facilities is posted on our web site along with a list of approved credentialing organizations, approved standard versions, and credentialed facilities: http://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/VAD-Destination-Therapy-Facilities.html

C. Nationally Non-Covered Indications

All other indications for the use of VADs not otherwise listed remain non-covered, except in the context of Category B investigational device exemption clinical trials (42 CFR 405) or as a routine cost in clinical trials defined under section 310.1 of the National Coverage Determinations (NCD) Manual.

D. Other

This policy does not address coverage of VADs for right ventricular support, biventricular support, use in beneficiaries under the age of 18, use in beneficiaries with complex congenital heart disease, or use in beneficiaries with acute heart failure without a history of chronic heart failure. Coverage under section 1862(a)(1)(A) of the Act for VADs in these situations will be made by local Medicare Administrative Contractors within their respective jurisdictions.

Destination therapy (DT) is for patients that require mechanical cardiac support. The VADs used for DT are covered only if they have received approval from the FDA for that purpose.

Patient Selection (effective November 9, 2010):

The VADs are covered for patients who have chronic end-stage heart failure (New York Heart Association Class IV end-stage left ventricular failure) who are not candidates for heart transplantation at the time of VAD implant, and meet the following conditions:

- Have failed to respond to optimal medical management (including beta-blockers and ACE inhibitors if tolerated) for 45 of the last 60 days, or have been balloon pump-dependent for 7 days, or IV inotrope-dependent for 14 days; and,

- Have a left ventricular ejection fraction (LVEF) <25%; and,

- Have demonstrated functional limitation with a peak oxygen consumption of ≤14 ml/kg/min unless balloon pump- or inotrope-dependent or physically unable to perform the test.

Facility Criteria (effective October 30, 2013):

Facilities currently credentialed by the Joint Commission for placement of VADs as DT may continue as Medicare-approved facilities until October 30, 2014. At the conclusion of this transition period, these facilities must be in compliance with the following criteria as determined by a credentialing organization. As of the effective date, new facilities must meet the following criteria as a condition of coverage of this procedure as DT under section 1862(a)(1)(A) of the Social Security Act (the Act):

Beneficiaries receiving VADs for DT must be managed by an explicitly identified cohesive, multidisciplinary team of medical professionals with the appropriate qualifications, training, and experience. The team embodies collaboration and dedication across medical specialties to offer optimal patient-centered care. Collectively, the team must ensure that patients and caregivers have the knowledge and support necessary to participate in shared decision making and to provide appropriate informed consent. The team members must be based at the facility and must include individuals with experience working with patients before and after placement of a VAD.

The team must include, at a minimum:

- At least one physician with cardiothoracic surgery privileges and individual experience implanting at least 10 durable, intracorporeal, left VADs as BTT or DT over the course of the previous 36 months with activity in the last year.

- At least one cardiologist trained in advanced heart failure with clinical competence in medical and device-based management including VADs, and clinical competence in the management of patients before and after heart transplant.

- A VAD program coordinator.

- A social worker.
- A palliative care specialist.

Facilities must be credentialed by an organization approved by the Centers for Medicare & Medicaid Services.

C. Nationally Non-Covered Indications

All other indications for the use of VADs not otherwise listed remain non-covered, except in the context of Category B investigational device exemption clinical trials (42 CFR 405) or as a routine cost in clinical trials defined under section 310.1 of the National Coverage Determinations (NCD) Manual.

D. Other

This policy does not address coverage of VADs for right ventricular support, biventricular support, use in beneficiaries under the age of 18, use in beneficiaries with complex congenital heart disease, or use in beneficiaries with acute heart failure without a history of chronic heart failure. Coverage under section 1862(a)(1)(A) of the Act for VADs in these situations will be made by local A/B MACs within their respective jurisdictions.

20.10 - Cardiac Rehabilitation Programs (RETIRED)

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

This section of the NCD Manual was repealed February 22, 2010, as a result of section 144 of the Medicare Improvements for Patients and Providers Act. Instead, refer to Pub. 100-04, chapter 32, section 140.

20.10.1 – Cardiac Rehabilitation Programs for Chronic Heart Failure

(Rev. 171, Issued: 07-18-14, Effective: 02-18-14, Implementation: 08-18-14)

A. General

As per sections 1861(s)(2)(CC) and 1861(eee)(1) of the Social Security Act, items and services furnished under a Cardiac Rehabilitation (CR) program may be covered under Medicare Part B. Among other things, Medicare regulations at 42CFR410.49 define key terms, address the components of a CR program, establish the standards for physician supervision, and limit the maximum number of program sessions that may be furnished. The regulations also describe the cardiac conditions that would enable a beneficiary to obtain CR services.

Effective for dates of service on and after January 1, 2010, coverage is permitted for beneficiaries who have experienced one or more of the following:

- Acute myocardial infarction within the preceding 12 months
- Coronary artery bypasses surgery
- Current stable angina pectoris
- Heart valve repair or replacement
- Percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting
- A heart or heart-lung transplant

The Centers for Medicare & Medicaid Services (CMS) may add "other cardiac conditions as specified through a national coverage determination" (See 42 CFR §410.49(b)(1)(vii).

B. Nationally Covered Indications

Effective for dates of service on and after February 18, 2014**,** CMS has determined that the evidence is sufficient to expand coverage for cardiac rehabilitation services under 42 CFR § 410.49(b)(1)(vii) to beneficiaries with stable, chronic heart failure, defined as patients with left ventricular ejection fraction of 35% or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least six weeks. Stable patients are defined as patients who have not had recent (≤6 weeks) or planned (≤6 months) major cardiovascular hospitalizations or procedures. (See section A above for other indications covered under 42 CFR §410.49(b)(1)(vii).

C. Nationally Non-Covered Indications

Any cardiac indication not specifically identified in 42 CFR § 410.49(b)(1)(vii) or identified as covered in this NCD or any other NCD in relation to cardiac rehabilitation services is considered non-covered.

D. Other

NA

(This NCD last reviewed February 2014.)

20.11 - Intraoperative Ventricular Mapping
(Rev. 1, 10-03-03)
CIM 35-75

Intraoperative ventricular mapping is the technique of recording cardiac electrical activity directly from the heart. The recording sites are usually identified from an anatomical grid and may consist of epicardial, intramural, and endocardial sites. A probe with electrodes is used to explore these surfaces and generate a map that displays the sequence of electrical activation. This information is used by the surgeon to locate precisely the site of an operative intervention.

The intraoperative ventricular mapping procedure is covered under Medicare only for the uses and medical conditions described below:

- Localize accessory pathways associated with the Wolff-Parkinson-White (WPW) and other preexcitation syndromes;

- Map the sequence of atrial and ventricular activation for drug-resistant supraventricular tachycardias;

- Delineate the anatomical course of His bundle and/or bundle branches during corrective cardiac surgery for congenital heart diseases; and

- Direct the surgical treatment of patients with refractory ventricular tachyarrhythmias.

20.12 - Diagnostic Endocardial Electrical Stimulation (Pacing)

(Rev. 1, 10-03-03)
CIM 35-78

Diagnostic endocardial electrical stimulation (EES), also called programmed electrical stimulation of the heart, is covered under Medicare when used for patients with severe cardiac arrhythmias.

Diagnostic endocardial electrical stimulation involves the detection and stimulation of cardiac electrical activity for the purpose of studying arrhythmias and abnormalities of the heart's conduction system. Intracardiac electrode catheters, intracardiac and extracardiac recordings and a stimulator device are required. From two to six multi-polar electrode catheters are inserted percutaneously, usually through the femoral veins, and advanced to the heart under fluoroscopic control. Other venous or arterial routes may be employed as well. An intracardiac His bundle cardiogram is usually obtained during EES as are conventional electrocardiograms. No separate charge will be recognized for the His Bundle cardiogram. (See §20.16.)

The EES is used to investigate the mechanisms, site of origin and pathways of cardiac arrhythmias as well as to select therapeutic approaches for their resolution. EES is also employed to identify patients at risk of sudden arrhythmic death. The principal use for EES is in the diagnosis and treatment of sustained ventricular tachycardia. However, it has also proven to be of value in the diagnosis and management of other complex arrhythmias, conduction defects, and after cardiac arrest.

20.13 - HIS Bundle Study

(Rev. 1, 10-03-03)
CIM 50-3

The HIS Bundle Study is a specialized type of electrocardiography requiring catheterization of the right side of the heart and is a recognized diagnostic procedure.

Medicare coverage of the procedure would be limited to selected patients: those with complex ongoing acute arrhythmias, those with intermittent or permanent heart block in whom pacemaker implantation is being considered, and those patients who have recently developed heart block secondary to a myocardial infarction. When heart catheterization and the His Bundle Study are performed at the same time, the program will cover only one catheterization and a small additional charge for the study.

When a His bundle cardiogram is obtained as part of a diagnostic endocardial electrical stimulation, no separate charge will be recognized for the His bundle study. (See §20.12, "Diagnostic Endocardial Electrical Stimulation.")

20.14 - Plethysmography

(Rev. 1, 10-03-03)
CIM 50-6

Plethysmography involves the measurement and recording (by one of several methods) of changes in the size of a body part as modified by the circulation of blood in that part.

Plethysmography is of value as a noninvasive technique for diagnostic, preoperative and postoperative evaluation of peripheral artery disease in the internal medicine or vascular surgery practice. It is also a useful tool for the preoperative podiatric evaluation of the diabetic patient or one who has intermittent claudication or other signs or symptoms indicative of peripheral vascular disease which have a bearing on the patient's candidacy for foot surgery.

The oldest form of plethysmography is the venous occlusive pneumoplethysmography. This method is cumbersome, time consuming, and requires considerable training to give useful, reproducible results. Nonetheless, in the setting of the hospital vascular laboratory, this technique is considered a reasonable and necessary procedure for the diagnostic evaluation of suspected peripheral arterial disease. It is unsuitable for routine use in the physician's office.

Recently, however, a number of other plethysmographic methods have been developed which make use of phenomena such as changes in electric impedance or changes in segmental blood pressure at constant volume to assess regional perfusion. Several of these methods have reached a level of development which makes them clinically valuable.

Medicare coverage is extended to those procedures listed in Category I below when used for the accepted medical indications mentioned above. The procedures in Category II are still considered experimental and are not covered at this time. Denial of claims because a noncovered procedure was used or because there was no medical indication for plethysmographic evaluation of any type should be based on §1862(a)(1) of the Act.

Category I - Covered

Segmental Plethysmography - Included under this procedure are services performed with a regional plethysmograph, differential plethysmograph, recording oscillometer, and a pulse volume recorder.

Electrical Impedance Plethysmography

Ultrasonic Measurement of Blood Flow (Doppler) - While not strictly a plethysmographic method, this is also a useful tool in the evaluation of suspected peripheral vascular disease or preoperative screening of podiatric patients with suspected peripheral vascular compromise. (See §220.5 for the applicable coverage policy on this procedure.)

Oculoplethysmography - See §20.17, "Noninvasive Tests of Carotid Function."

Strain Gauge Plethysmography - This test is based on recording the non-pulsatile aspects of inflowing blood at various points on an extremity by a mercury-in-silastic strain gauge sensor. The instrument consists of a chart recorder, an automatic cuff inflation and deflation system, and a recording manometer.

Category II - Experimental

The following methods have not yet reached a level of development such as to allow their routine use in the evaluation of suspected peripheral vascular disease.

Inductance Plethysmography - This method is considered experimental and does not provide reproducible results.

Capacitance Plethysmography - This method is considered experimental and does not provide reproducible results.

Mechanical Oscillometry - This is a nonstandardized method which offers poor sensitivity and is not considered superior to the simple measurement of peripheral blood pressure.

Photoelectric Plethysmography - This method is considered useful only in determining whether or not a pulse is present and does not provide reproducible measurements of blood flow.

Differential plethysmography, on the other hand, is a system which uses an impedance technique to compare pulse pressures at various points along a limb, with a reference pressure at the mid-brachial or wrist level. It is not clear whether this technique, as usually performed in the physician's office, meets the definition of plethysmography because quantitative measurements of blood flow are usually not made. It has been concluded, in any event, that the differential plethysmography system is a blood pulse recorder of undetermined value which has the potential for significant overutilization. Therefore, reimbursement for studies done by techniques other than venous occlusive

pneumoplethysmography should be denied, at least until additional data on these devices, including controlled clinical studies, become available.

20.15 – Electrocardiographic Services

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

A. General

1. An electrocardiogram (EKG) is a graphic representation of electrical activity within the heart. Electrodes placed on the body in predetermined locations sense this electrical activity, which is then recorded by various means for review and interpretation. EKG recordings are used to diagnose a wide range of heart disease and other conditions that manifest themselves by abnormal cardiac electrical activity.

EKG services are covered diagnostic tests when there are documented signs and symptoms or other clinical indications for providing the service. Coverage includes the review and interpretation of EKGs only by a physician. There is no coverage for EKG services when rendered as a screening test or as part of a routine examination unless performed as part of the one-time, "Welcome to Medicare" preventive physical examination under section 611 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

2. Ambulatory electrocardiography (AECG) refers to services rendered in an outpatient setting over a specified period of time, generally while a patient is engaged in daily activities, including sleep. AECG devices are intended to provide the physician with documented episodes of arrhythmia, which may not be detected using a standard 12-lead EKG. AECG is most typically used to evaluate symptoms that may correlate with intermittent cardiac arrhythmias and/or myocardial ischemia. Such symptoms include syncope, dizziness, chest pain, palpitations, or shortness of breath. Additionally, AECG is used to evaluate patient response to initiation, revision, or discontinuation of arrhythmic drug therapy.

3. The Centers for Medicare & Medicaid Services (CMS), through the national coverage determination (NCD) process, may create new ambulatory EKG monitoring device categories if published, peer-reviewed clinical studies demonstrate evidence of improved clinical utility, or equal utility with additional advantage to the patient, as indicated by improved patient management and/or improved health outcomes in the Medicare population (such as superior ability to detect serious or life-threatening arrhythmias) as compared to devices or services in the currently described categories below.

Descriptions of Ambulatory EKG Monitoring Technologies

1. Dynamic electrocardiography devices that continuously record a real-time EKG, commonly known as Holter™ monitors, typically record over a 24-hour period. The

recording is captured either on a magnetic tape or other digital medium. The data is then computer-analyzed at a later time, and a physician interprets the computer-generated report. A 24-hour recording is generally adequate to detect most transient arrhythmias. Documentation of medical necessity is required for monitoring longer than 24 hours. The recording device itself is not covered as durable medical equipment (DME) separate from the total diagnostic service.

2. An event monitor, or event recorder, is a patient-activated or event-activated EKG device that intermittently records cardiac arrhythmic events as they occur. The EKG is recorded on magnetic tape or other digital medium.

Cardiac event monitor technology varies among different devices. For patient-activated event monitors, the patient initiates recording when symptoms appear or when instructed to do so by a physician (e.g., following exercise). For self-sensing, automatically triggered monitors, an EKG is automatically recorded when the device detects an arrhythmia, without patient intervention. Some devices permit a patient to transmit EKG data transtelephonically (i.e., via telephone) to a receiving center where the data is reviewed. A technician may be available at these centers to review transmitted data 24 hours per day. In some instances, when the EKG is determined to be outside certain pre-set criteria by a technician or other non-physician, a physician is available 24 hours per day to review the transmitted data and to make clinical decisions regarding the patient. These services are known as “24-hour attended monitoring”. In other instances, transmitted EKG data is reviewed at a later time and are, therefore, considered “non-attended.”

Cardiac event monitors without transtelephonic capability must be removed from the patient and taken to a location for review of the stored EKG data. Some devices also permit a "time sampling" mode of operation. The "time sampling" mode is not covered under ambulatory EKG monitoring technology. Some cardiac event monitoring devices with trans-telephonic capabilities require the patient to dial the phone number of a central EKG data reception center and initiate transmission of EKG data. Other devices use Internet-based in-home computers to capture and store EKG data. When such devices detect pre-programmed arrhythmias, data is automatically sent via modem and standard telephone lines to a central receiving center, or independent diagnostic testing facility (IDTF), where the data is reviewed. Internet-based in-home computer systems may also provide the receiving center with a daily computer-generated report that summarizes 24 hours of EKG data.

Certain cardiac event monitors capture electrical activity with a single electrode attached to the skin. Other devices may employ multiple electrodes in order to record more complex EKG tracings. Additionally, devices may be individually programmed to detect patient-specific factors, electrode malfunction, or other factors. Cardiac event monitors can be further categorized as either “pre-event” or “post-event” recorders, based on their memory capabilities:

a. Pre-symptom Memory Loop Recorder (MLR)

Upon detecting symptoms, the wearer presses a button, which activates the recorder to save (i.e., memorize) an interval of pre-symptom EKG data along with data during and subsequent to the symptomatic event. Self-sensing recorders (also known as event-activated or automatic trigger) do not require patient input to capture these data. Single or multiple events may be recorded. The device is worn at all times, usually for up to 30 days.

- Implantable (or Insertable Loop) Recorder (ILR)

Another type of pre-symptom MLR, it is implanted subcutaneously in a patient's upper left chest and may remain implanted for many months. An ILR is used when syncope is thought to be cardiac-related, but is too infrequent to be detected by either a Holter™ monitor or a traditional pre-symptom MLR.

b. Post-symptom Recorder

The patient temporarily places this device against the chest when symptoms occur and activates it by pressing a button. These recorders represent old technology, as they do not include a memory loop. The device transmits EKG data telephonically in real-time and is usually used for up to 30 days.

B. Nationally Covered Indications

The following indications are covered nationally unless otherwise indicated:

1. Computer analysis of EKGs when furnished in a setting and under the circumstances required for coverage of other EKG services.

2. EKG services rendered by an IDTF, including physician review and interpretation. Separate physician services are not covered unless he/she is the patient's attending or consulting physician.

3. Emergency EKGs (i.e., when the patient is or may be experiencing a life-threatening event) performed as a laboratory or diagnostic service by a portable x-ray supplier only when a physician is in attendance at the time the service is performed or immediately thereafter.

4 Home EKG services with documentation of medical necessity.

5. Transtelephonic EKG transmissions (effective March 1, 1980) as a diagnostic service for the indications described below, when performed with equipment meeting the standards described below, subject to the limitations and conditions specified below. Coverage is further limited to the amounts payable with respect to the physician's service in interpreting the results of such transmissions, including charges for rental of the

equipment. The device used by the beneficiary is part of a total diagnostic system and is not considered DME separately. Covered uses are to:

a. Detect, characterize, and document symptomatic transient arrhythmias;

b. Initiate, revise, or discontinue arrhythmic drug therapy; or,

c. Carry-out early post-hospital monitoring of patients discharged after myocardial infarction (MI); (only if 24-hour coverage is provided, see C.5. below).

Certain uses other than those specified above may be covered if, in the judgment of the local A/B MAC, such use is medically necessary.

Additionally, the transmitting devices must meet at least the following criteria:

a. They must be capable of transmitting EKG Leads, I, II, or III; and,

b. The tracing must be sufficiently comparable to a conventional EKG.

24-hour attended coverage used as early post-hospital monitoring of patients discharged after MI is only covered if provision is made for such 24-hour attended coverage in the manner described below:

24-hour attended coverage means there must be, at a monitoring site or central data center, an EKG technician or other non-physician, receiving calls and/or EKG data; tape recording devices do not meet this requirement. Further, such technicians should have immediate, 24-hour access to a physician to review transmitted data and make clinical decisions regarding the patient. The technician should also be instructed as to when and how to contact available facilities to assist the patient in case of emergencies.

C. Nationally Non-Covered Indications

The following indications are non-covered nationally unless otherwise specified below:

1. The time-sampling mode of operation of ambulatory EKG cardiac event monitoring/recording.

2. Separate physician services other than those rendered by an IDTF unless rendered by the patient's attending or consulting physician.

3. Home EKG services without documentation of medical necessity.

4. Emergency EKG services by a portable x-ray supplier without a physician in attendance at the time of service or immediately thereafter.

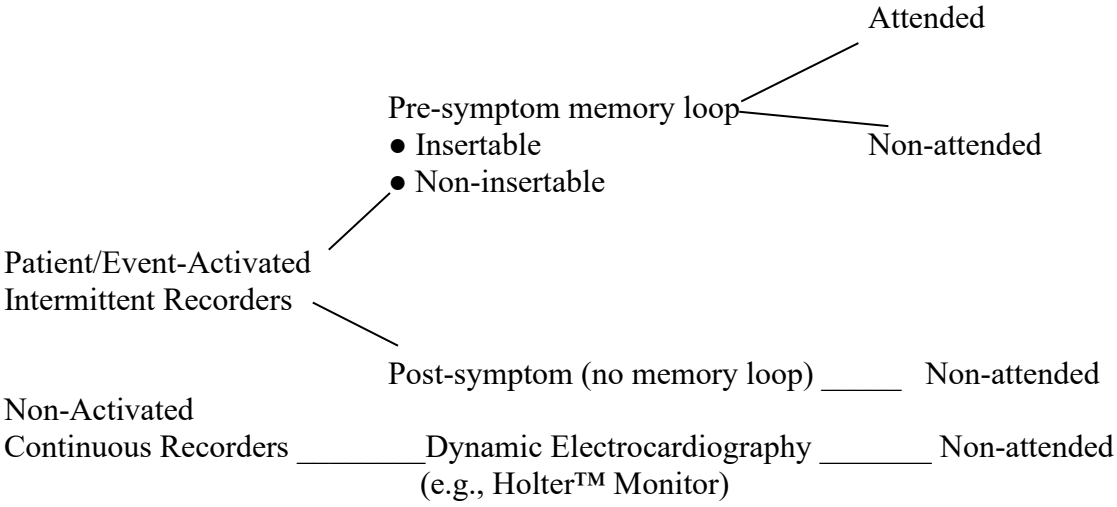
5. 24-hour attended coverage used as early post-hospital monitoring of patients discharged after MI unless provision is made for such 24-hour attended coverage in the manner described in section B.5. above.

6. Any marketed Food and Drug Administration (FDA)-approved ambulatory cardiac monitoring device or service that cannot be categorized according to the framework below.

D. Other

Ambulatory cardiac monitoring performed with a marketed, FDA-approved device, is eligible for coverage if it can be categorized according to the framework below. Unless there is a specific NCD for that device or service, determination as to whether a device or service that fits into the framework is reasonable and necessary is according to local A/B MAC discretion.

Electrocardiographic Services Framework



20.16 - Cardiac Output Monitoring By Thoracic Electrical Bioimpedance (TEB) – Various Effective Dates Below

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

A. General

Thoracic electrical bioimpedance (TEB) devices, a form of plethysmography, monitor cardiac output by non-invasively measuring hemodynamic parameters, including: stroke volume, systemic vascular resistance, and thoracic fluid status. Under a previous coverage determination, effective for services performed on and after July 1, 1999, use of TEB was covered for the "noninvasive diagnosis or monitoring of hemodynamics in patients with suspected or known cardiovascular disease." In reconsidering this policy, the Centers for Medicare & Medicaid Services (CMS) concluded that this use was neither

sufficiently defined nor supported by available clinical literature to offer the guidance necessary for practitioners to determine when TEB would be covered for patient management. Therefore, CMS revised its coverage policy language in response to a request for reconsideration to offer more explicit guidance and clarity for coverage of TEB based on a complete and updated literature review.

B. Nationally Covered Indications

Effective for services performed on and after January 23, 2004, TEB is covered for the following uses:

1. Differentiation of cardiogenic from pulmonary causes of acute dyspnea when medical history, physical examination, and standard assessment tools provide insufficient information, and the treating physician has determined that TEB hemodynamic data are necessary for appropriate management of the patient.

2. Optimization of atrioventricular (A/V) interval for patients with A/V sequential cardiac pacemakers when medical history, physical examination, and standard assessment tools provide insufficient information, and the treating physician has determined that TEB hemodynamic data are necessary for appropriate management of the patient.

3. Monitoring of continuous inotropic therapy for patients with terminal congestive heart failure, when those patients have chosen to die with comfort at home, or for patients waiting at home for a heart transplant.

4. Evaluation for rejection in patients with a heart transplant as a predetermined alternative to a myocardial biopsy. Medical necessity must be documented should a biopsy be performed after TEB.

5. Optimization of fluid management in patients with congestive heart failure when medical history, physical examination, and standard assessment tools provide insufficient information, and the treating physician has determined that TEB hemodynamic data are necessary for appropriate management of the patient.

C. Nationally Non-Covered Indications

1. TEB is non-covered when used for patients:

   a) With proven or suspected disease involving severe regurgitation of the aorta;
   b) With minute ventilation (MV) sensor function pacemakers, since the device may adversely affect the functioning of that type of pacemaker;
   c) During cardiac bypass surgery; or,
   d) In the management of all forms of hypertension (with the exception of drug-resistant hypertension as outlined below).

2. All other uses of TEB not otherwise specified remain non-covered.

D. Other

A/B MACs have discretion to determine whether the use of TEB for the management of drug-resistant hypertension is reasonable and necessary. Drug resistant hypertension is defined as failure to achieve goal blood pressure in patients who are adhering to full doses of an appropriate 3-drug regimen that includes a diuretic. Effective November 24, 2006, after reconsideration of Medicare policy, CMS will continue current Medicare policy for TEB.

20.17 - Noninvasive Tests of Carotid Function

(Rev. 1, 10-03-03)
CIM 50-37

Noninvasive tests of carotid function aid physicians in studying and diagnosing carotid disease. There are varieties of these tests which measure various anatomical and physiological aspects of carotid function, including pressure (systolic, diastolic, and pulse), flow, collateral circulation, and turbulence.

For operational purposes, it is useful to classify noninvasive tests of carotid function into direct and indirect tests. The direct tests examine the anatomy and physiology of the carotid artery, while the indirect tests examine hemodynamic changes in the distal beds of the carotid artery (the orbital and cerebral circulations).

It is important to note that the names of these tests are not standardized. Following are some of the acceptable tests, recognizing that this list is not inclusive and that local medical consultants should make determinations:

Direct Tests

- Carotid Phonoangiography
- Direct Bruit Analysis
- Spectral Bruit Analysis
- Doppler Flow Velocity
- Ultrasound Imaging including Real Time
- B-Scan and Doppler Devices

Indirect Tests

- Periorbital Directional Doppler Ultrasonography
- Oculoplethysmography
- Ophthalmodynamometry

20.18 - Carotid Body Resection/Carotid Body Denervation

(Rev. 1, 10-03-03)

Carotid body resection is occasionally used to relieve pulmonary symptoms, including asthma, but has been shown to lack general acceptance of the professional medical community. In addition, controlled clinical studies establishing the safety and effectiveness of this procedure are needed. Therefore, all carotid body resections to relieve pulmonary symptoms must be considered investigational and cannot be considered reasonable and necessary within the meaning of §1862(a)(l) of the Act. No program reimbursement may be made in such cases.

However, there is one instance where carotid body resection has been accepted by the medical community as effective. That instance is when evidence of a mass in the carotid body, with or without symptoms, indicates the need for surgery to remove the carotid body tumor.

Denervation of a carotid sinus to treat hypersensitive carotid sinus reflex is another procedure performed in the area of the carotid body. In the case of hypersensitive carotid sinus, light pressure on the upper part of the neck (such as might be experienced when turning or raising one's head) results in symptoms such as dizziness or syncope due to hypotension and slowed heart rate. Failure of medical therapy and continued deterioration in the condition of the patient in such cases may indicate need for surgery.

Denervation of the carotid sinus is rarely performed, but when elected as the therapy of choice with the above indications, this procedure may be considered reasonable and necessary.

20.19 - Ambulatory Blood Pressure Monitoring

(Rev. 10073, Issued: 05-01-20, Effective: 07-02-19 Implementation: 06- 16-20, 10-05-20)

A. General

Ambulatory Blood Pressure Monitoring (ABPM) is a diagnostic test that allows for the identification of various types of high blood pressure (BP). ABPM devices are small portable machines that are connected to a blood pressure cuff worn by patients that record blood pressure at regular periods over 24 to 48 hours while the patient goes about their normal activities, including sleep. The recording is interpreted by a physician or non-physician practitioner, and appropriate action is taken based on the findings. Diagnosis and treatment of high BP is important for the management of various conditions including cardiovascular disease and kidney disease.

B. Nationally Covered Indications

For dates of service on and after July 2, 2019, the Centers for Medicare & Medicaid Services (CMS) believes that the evidence is sufficient to determine that ABPM is reasonable and necessary for the diagnosis of hypertension in Medicare beneficiaries under the following circumstances:

1. For beneficiaries with suspected white coat hypertension, which is defined as average office BP of systolic BP >130 mm Hg but <160 mm Hg, or diastolic BP >80 mm Hg but <100 mm Hg on two separate clinic/office visits with at least two separate measurements made at each visit, and with at least two BP measurements taken outside the office which are <130/80 mm Hg.

2. For beneficiaries with suspected masked hypertension, which is defined as average office BP between 120 mm Hg and 129 mm Hg for systolic BP, or between 75 mm HG and 79 mm Hg for diastolic BP on two separate clinic/office visits with at least two separate measurements made at each visit, and at least two BP measurements taken outside the office which are ≥130/80 mm Hg.

ABPM devices must be:

- capable of producing standardized plots of BP measurements for 24 hours with daytime and night-time windows and normal BP bands demarcated; and,
- provided to patients with oral and written instructions and a test run in the physician's office must be performed; and,
- interpreted by the treating physician or treating non-physician practitioner.

For eligible patients, ABPM is covered once per year.

C. Nationally Non-Covered Indications

N/A

D. Other

Coverage of other indications for ABPM not indicated above are at the discretion of the Medicare Administrative Contractors.
(Last reviewed July 2019.)

20.20 - External Counterpulsation (ECP) Therapy for Severe Angina (Effective March 20, 2006)

(Rev. 50, Issued: 03-31-06; Effective: 03-20-06; Implementation: 04-03-06)

A. General

External counterpulsation (ECP), commonly referred to as enhanced external counterpulsation, is a noninvasive outpatient treatment for coronary artery disease refractory to medical and/or surgical therapy. Although ECP devices are cleared by the Food and Drug Administration (FDA) for use in treating a variety of cardiac conditions, including stable or unstable angina pectoris, acute myocardial infarction and cardiogenic shock, the use of this device to treat cardiac conditions other than stable angina pectoris is not covered, since only that use has developed sufficient evidence to demonstrate its medical effectiveness. Non-coverage of hydraulic versions of these types of devices remains in force.

B. Nationally Covered Indications

Effective for services performed on or after July 1, 1999, coverage is provided for the use of ECP for patients who have been diagnosed with disabling angina (Class III or Class IV, Canadian Cardiovascular Society Classification or equivalent classification) who, in the opinion of a cardiologist or cardiothoracic surgeon, are not readily amenable to surgical intervention, such as PTCA or cardiac bypass, because:

1. Their condition is inoperable, or at high risk of operative complications or post-operative failure;

2. Their coronary anatomy is not readily amenable to such procedures; or

3. They have co-morbid states that create excessive risk.

A full course of therapy usually consists of 35 one-hour treatments which may be offered once or twice daily, usually 5 days per week. The patient is placed on a treatment table where their lower trunk and lower extremities are wrapped in a series of three compressive air cuffs which inflate and deflate in synchronization with the patient's cardiac cycle.

During diastole, the three sets of air cuffs are inflated sequentially (distal to proximal) compressing the vascular beds within the muscles of the calves, lower thighs and upper thighs. This action results in an increase in diastolic pressure, generation of retrograde arterial blood flow and an increase in venous return. The cuffs are deflated simultaneously just prior to systole which produces a rapid drop in vascular impedance, a decrease in ventricular workload and an increase in cardiac output.

The augmented diastolic pressure and retrograde aortic flow appear to improve myocardial perfusion, while systolic unloading appears to reduce cardiac workload and oxygen requirements. The increased venous return coupled with enhanced systolic flow appears to increase cardiac output. As a result of this treatment, most patients experience increased time until onset of ischemia, increased exercise tolerance, and a reduction in the number and severity of anginal episodes. Evidence was presented that this effect lasted well beyond the immediate post-treatment phase, with patients symptom-free for several months to 2 years. This procedure must be done under direct supervision of a physician.

C. Nationally Non-Covered Indications

All other cardiac conditions not otherwise specified as nationally covered for the use of ECP remain nationally non-covered.

(This NCD last reviewed March 2006.)

20.21 - Chelation Therapy for Treatment of Atherosclerosis

(Rev. 1, 10-03-03)
CIM 35-64

Chelation therapy is the application of chelation techniques for the therapeutic or preventive effects of removing unwanted metal ions from the body. The application of chelation therapy using ethylenediamine-tetra-acetic acid (EDTA) for the treatment and prevention of atherosclerosis is controversial. There is no widely accepted rationale to explain the beneficial effects attributed to this therapy. Its safety is questioned and its clinical effectiveness has never been established by well-designed, controlled clinical trials. It is not widely accepted and practiced by American physicians. EDTA chelation therapy for atherosclerosis is considered experimental. For these reasons, EDTA chelation therapy for the treatment or prevention of atherosclerosis is not covered. Some practitioners refer to this therapy as chemoendarterectomy and may also show a diagnosis other than atherosclerosis, such as arteriosclerosis or calcinosis. Claims employing such variant terms should also be denied under this section.

Cross-reference: §20.22.

20.22 - Ethylenediamine-Tetra-Acetic (EDTA) Chelation Therapy for Treatment of Atherosclerosis

(Rev. 1, 10-03-03)
CIM 45-20

The use of EDTA as a chelating agent to treat atherosclerosis, arteriosclerosis, calcinosis, or similar generalized condition not listed by the FDA as an approved use is not covered. Any such use of EDTA is considered experimental. See §20.21 for an explanation of this conclusion.

20.23 - Fabric Wrapping of Abdominal Aneurysms

(Rev. 1, 10-03-03)

Not Covered
CIM 35-34

Fabric wrapping of abdominal aneurysms is not a covered Medicare procedure. This is a treatment for abdominal aneurysms which involves wrapping aneurysms with cellophane or fascia lata. This procedure has not been shown to prevent eventual rupture. In extremely rare instances, external wall reinforcement may be indicated when the current accepted treatment (excision of the aneurysm and reconstruction with synthetic materials) is not a viable alternative, but external wall reinforcement is not fabric wrapping. Accordingly, fabric wrapping of abdominal aneurysms is not considered reasonable and necessary within the meaning of §1862(a)(1) of the Act.

20.24 - Displacement Cardiography

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

Displacement cardiography, including cardiokymography and photokymography, is a noninvasive diagnostic test used in evaluating coronary artery disease.

A. Cardiokymography

Cardiokymography is covered for services rendered on or after October 12, 1988.

Cardiokymography is a covered service only when it is used as an adjunct to electrocardiographic stress testing in evaluating coronary artery disease and only when the following clinical indications are present:

- For male patients, atypical angina pectoris or nonischemic chest pain; or
- For female patients, angina, either typical or atypical.

B. Photokymography - Not Covered

Photokymography remains excluded from coverage.

20.25 - Cardiac Catheterization Performed in Other Than a Hospital Setting (RETIRED)

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

This section of the NCD Manual was repealed January 12, 2006.

20.26 - Partial Ventriculectomy

(Rev. 1, 10-03-03)
CIM 35-95

(Also Known as Ventricular Reduction, Ventricular Remodeling, or Heart Volume Reduction Surgery)

Not Covered

Partial ventriculectomy, also known as ventricular reduction, ventricular remodeling, or heart volume reduction surgery, was developed by a Brazilian surgeon and has been performed only on a limited basis in the United States. This procedure is performed on patients with enlarged hearts due to end-stage congestive heart failure. Partial ventriculectomy involves reducing the size of an enlarged heart by excising a portion of the left ventricular wall followed by repair of the defect. It is asserted that this procedure makes the failing heart pump better by improving the efficiency of the remaining left ventricle.

Since the mortality rate is high and there are no published scientific articles or clinical studies regarding partial ventriculectomy, this procedure cannot be considered reasonable and necessary within the meaning of §1862(a)(1) of the Act. Therefore, partial

ventriculectomy is not covered by Medicare.

20.27 - Cardiointegram (CIG) as an Alternative to Stress Test or Thallium Stress Test

(Rev. 1, 10-03-03)
CIM 50-47

Not Covered

A cardiointegram device consists of a microcomputer which receives output from a standard electrocardiogram (EKG) and transforms it to produce a graphic representation of heart electrophysiologic signals. This procedure is used primarily as a substitute for Exercise Tolerance Testing with Thallium Imaging in patients for whom a resting EKG may be inadequate to identify changes compatible with coronary artery disease. Because this device is still considered investigational pending additional data on its clinical efficacy/sensitivity and value as a diagnostic tool, program payment may not be made for its use at this time.

20.28 – Therapeutic Embolization

(Rev. 1, 10-03-03)

CIM 35-35

Therapeutic embolization is covered when done for hemorrhage, and for other conditions amenable to treatment by the procedure, when reasonable and necessary for the individual patient. Renal embolization for the treatment of renal adenocarcinoma continues to be covered, effective December 15, 1978, as one type of therapeutic embolization, to:

- Reduce tumor vascularity preoperatively;
- Reduce tumor bulk in inoperable cases; or
- Palliate specific symptoms.

20.29 – Hyperbaric Oxygen Therapy

(Rev.203, Issued:11-17-17, Effective:04- 03-17, Implementation: 12-18-17)

For purposes of coverage under Medicare, hyperbaric oxygen (HBO) therapy is a modality in which the entire body is exposed to oxygen under increased atmospheric pressure.

A. Covered Conditions

Program reimbursement for HBO therapy will be limited to that which is administered in a chamber (including the one man unit) and is limited to the following conditions:

1. Acute carbon monoxide intoxication,
2. Decompression illness,

3. Gas embolism,
4. Gas gangrene,
5. Acute traumatic peripheral ischemia. HBO therapy is a valuable adjunctive treatment to be used in combination with accepted standard therapeutic measures when loss of function, limb, or life is threatened.
6. Crush injuries and suturing of severed limbs. As in the previous conditions, HBO therapy would be an adjunctive treatment when loss of function, limb, or life is threatened.
7. Progressive necrotizing infections (necrotizing fasciitis),
8. Acute peripheral arterial insufficiency,
9. Preparation and preservation of compromised skin grafts (not for primary management of wounds),
10. Chronic refractory osteomyelitis, unresponsive to conventional medical and surgical management,
11. Osteoradionecrosis as an adjunct to conventional treatment,
12. Soft tissue radionecrosis as an adjunct to conventional treatment,
13. Cyanide poisoning,
14. Actinomycosis, only as an adjunct to conventional therapy when the disease process is refractory to antibiotics and surgical treatment,
15. Diabetic wounds of the lower extremities in patients who meet the following three criteria:

a. Patient has type I or type II diabetes and has a lower extremity wound that is due to diabetes;
b. Patient has a wound classified as Wagner grade III or higher; and
c. Patient has failed an adequate course of standard wound therapy.

The use of HBO therapy is covered as adjunctive therapy only after there are no measurable signs of healing for at least 30 days of treatment with standard wound therapy and must be used in addition to standard wound care. Standard wound care in patients with diabetic wounds includes: assessment of a patient's vascular status and correction of any vascular problems in the affected limb if possible, optimization of nutritional status, optimization of glucose control, debridement by any means to remove devitalized tissue, maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings, appropriate off-loading, and necessary treatment to resolve any infection that might be present. Failure to respond to standard wound care occurs when there are no measurable signs of healing for at least 30 consecutive days. Wounds must be evaluated at least every 30 days during administration of HBO therapy. Continued treatment with HBO therapy is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment.

B. Non-covered Conditions

All other indications not specified under §270.4(A) are not covered under the Medicare program. No program payment may be made for any conditions other than those listed in §270.4(A).

No program payment may be made for HBO in the treatment of the following conditions:

1. Cutaneous, decubitus, and stasis ulcers.
2. Chronic peripheral vascular insufficiency.
3. Anaerobic septicemia and infection other than clostridial.
4. Skin burns (thermal).
5. Senility.
6. Myocardial infarction.
7. Cardiogenic shock.
8. Sickle cell anemia.
9. Acute thermal and chemical pulmonary damage, i.e., smoke inhalation with pulmonary.
10. Acute or chronic cerebral vascular insufficiency.
11. Hepatic necrosis.
12. Aerobic septicemia.
13. Nonvascular causes of chronic brain syndrome (Pick's disease, Alzheimer's disease, Korsakoff's disease).
14. Tetanus.
15. Systemic aerobic infection.
16. Organ transplantation.
17. Organ storage.
18. Pulmonary emphysema.
19. Exceptional blood loss anemia.
20. Multiple Sclerosis.
21. Arthritic Diseases.
22. Acute cerebral edema.

C. Topical Application of Oxygen

Section C-Topical Application of Oxygen has been removed from NCD 20.29. Effective for dates of service on and after (DATE), Medicare Administrative Contractors (MACs) acting within their respective jurisdictions may determine coverage of topical application of oxygen for chronic non-healing wounds.
Cross reference: §270.5 of this manual.

(This NCD was last reviewed April 2017)

20.30 - Microvolt T-Wave Alternans (MTWA)

(Rev. 182, Issued: 05-22-15, Effective: 01-13-15, Implementation: 06-23-15)

A. General

Microvolt T-wave Alternans (MTWA) testing is a non-invasive diagnostic test that detects minute electrical activity in a portion of the electrocardiogram (ECG) known as the T-wave. MTWA testing has a role in the stratification of patients who may be at risk for sudden cardiac death (SCD) from ventricular arrhythmias.

Within patient groups that may be considered candidates for implantable cardioverter defibrillator (ICD) therapy, a negative MTWA test may be useful in identifying low-risk

patients who are unlikely to benefit from, and who may experience worse outcomes from, ICD placement.

Spectral analysis (SA) is a sensitive mathematical method of measuring and comparing time and the ECG signals. It requires specialized propriety electrodes to calculate minute T-wave voltage changes. Software then analyzes these microvolt changes and produces a report to be interpreted by a physician. The Modified Moving Average (MMA) method uses a temporal domain in which T-wave alternans are assessed as a continuous variable along the complete ECG. The MMA method of MTWA testing is performed using standard ambulatory ECG equipment.

B. Nationally Covered Indications

Effective for dates of service on and after March 21, 2006, MTWA diagnostic testing is covered for the evaluation of patients at risk for SCD, only when the SA method is used.

C. Nationally Non-Covered Indications

N/A

D. Other

Effective for dates of service on and after January 21, 2015, A/B MACs acting within their respective jurisdictions may determine coverage of MTWA diagnostic testing for the evaluation of patients at risk for SCD using all other methods.

(This NCD last reviewed January 2015.)

20.31 – Intensive Cardiac Rehabilitation (ICR) Programs
(Rev. 125, Issued: 09-24-10, Effective: 08-12-10, Implementation: 10-25-10)

Intensive cardiac rehabilitation (ICR) refers to a physician-supervised program that furnishes cardiac rehabilitation services more frequently and often in a more rigorous manner. As required by §1861(eee)(4)(A) of the Social Security Act (the Act), an ICR program must show, in peer-reviewed published research, that it accomplished one or more of the following for its patients: (1) positively affected the progression of coronary heart disease; (2) reduced the need for coronary bypass surgery; and, (3) reduced the need for percutaneous coronary interventions. The ICR program must also demonstrate through peer-reviewed published research that it accomplished a statistically significant reduction in five or more of the following measures for patients from their levels before cardiac rehabilitation services to after cardiac rehabilitation services: (1) low density lipoprotein; (2) triglycerides; (3) body mass index; (4) systolic blood pressure; (5) diastolic blood pressure; and, (6) the need for cholesterol, blood pressure, and diabetes medications. Individual ICR programs must be approved through the national coverage determination process to ensure that they demonstrate these accomplishments.

20.31.1 - The Pritikin Program (Effective August 12, 2010)
(Rev. 125, Issued: 09-24-10, Effective: 08-12-10, Implementation: 10-25-10)

A. General

The Pritikin diet was designed and adopted by Nathan Pritikin in 1955. The diet was modeled after the diet of the Tarahumara Indians in Mexico, which consisted of 10% fat, 13% protein, 75-80% carbohydrates and provided 15-20 grams per day of crude fiber with only 75 mg/day of cholesterol. Over the years, the Pritikin Program (also known as the Pritikin Longevity Program) evolved into a comprehensive program that is provided in a physician's office and incorporates a specific diet (10%-15% of calories from fat, 15%-20% from protein, 65%-75% from complex carbohydrates), exercise, and counseling lasting 21-26 days. An optional residential component is also available for participants.

B. Nationally Covered Indications

Effective for claims with dates of service on and after August 12, 2010, the Pritikin Program meets the intensive cardiac rehabilitation (ICR) program requirements set forth by Congress in §1861(eee)(4)(A) of the Social Security Act and in regulations at 42 C.F.R. §410.49(c) and, as such, has been included on the list of approved ICR programs available at http://www.cms.gov/MedicareApprovedFacilitie/.

C. Nationally Non-Covered Indications

Effective August 12, 2010, if a specific ICR program is not included on the list as a Medicare-approved ICR program, it is non-covered.

D. Other

N/A

(This NCD last reviewed August 2010.)

20.31.2 – Ornish Program for Reversing Heart Disease (Effective August 12, 2010)
(Rev. 125, Issued: 09-24-10, Effective: 08-12-10, Implementation: 10-25-10)

A. General

The Ornish Program for Reversing Heart Disease (also known as the Multisite Cardiac Lifestyle Intervention Program, the Multicenter Cardiac Lifestyle Intervention Program, and the Lifestyle Heart Trial Program) was initially described in the 1970s and incorporates comprehensive lifestyle modifications including exercise, a low-fat diet, smoking cessation, stress management training, and group support sessions. Over the years, the Ornish Program has been refined but continues to focus on these specific risk

factors.

B. Nationally Covered Indications

Effective for claims with dates of service on and after August 12, 2010, the Ornish Program for Reversing Heart Disease meets the Intensive Cardiac Rehabilitation (ICR) program requirements set forth by Congress in §1861(eee)(4)(A) of the Social Security Act, and in regulations at 42 C.F.R. §410.49(c) and, as such, has been included on the list of approved ICR programs available at http://www.cms.gov/MedicareApprovedFacilitie/.

C. Nationally Non-Covered Indications

Effective August 12, 2010, if a specific ICR program is not included on the list as a Medicare- approved ICR program, it is non-covered.

D. Other

N/A

(This NCD last reviewed August 2010.)

20.31.3 – Benson-Henry Institute Cardiac Wellness Program (Effective May 6, 2014)

(Rev. 175, Issued: 10-03-14, Effective: 05-06-14, Implementation: 11-04-14)

General

The fundamental concepts of the Benson-Henry Institute Cardiac Wellness Program were developed by Herbert Benson, MD, over 40 years ago. Benson states that "in the middle 1960s, when I noticed that people's blood pressures were higher during visits to my office than at other times and wondered whether stress wasn't causing that rise. Stress wasn't on the radar then, so I began investigating a connection between stress and hypertension." (http://www.ideafit.com/fitness-library/mind-body-medicine-balanced-approach) The Cardiac Wellness Program is a multi-component intervention program that includes supervised exercise, behavioral interventions, and counseling, and is designed to reduce cardiovascular risk and improve health outcomes.

B. Nationally Covered Indications

Effective for claims with dates of service on and after May 6, 2014, the Benson-Henry Institute Cardiac Wellness Program meets the Intensive Cardiac Rehabilitation (ICR) program requirements set forth by Congress in §1861(eee)(4)(A) of the Social Security Act, and in regulations at 42 C.F.R. §410.49(c) and, as such, has been included on the list of approved ICR programs available at http://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/.

C. Nationally Non-Covered Indications

Effective May 6, 2014, if a specific ICR program is not included on the above-noted list as a Medicare-approved ICR program, it is non-covered.

D. Other

N/A

(This NCD last reviewed May 6, 2014.)

20.32 – Transcatheter Aortic Valve Replacement (TAVR)
(Rev. 10179, Issued: 06-10-20, Effective: 06-21-19, Implementation: 06-12-20

A. General

Transcatheter aortic valve replacement (TAVR - also known as TAVI or transcatheter aortic valve implantation) is used in the treatment of aortic stenosis. A bioprosthetic valve is inserted percutaneously using a catheter and implanted in the orifice of the aortic valve.

B. Nationally Covered Indications

The Centers for Medicare & Medicaid Services (CMS) covers transcatheter aortic valve replacement (TAVR) under Coverage with Evidence Development (CED) with the following conditions:

A. TAVR is covered for the treatment of symptomatic aortic valve stenosis when furnished according to a Food and Drug Administration (FDA)-approved indication and when all of the following conditions are met:

1. The procedure is furnished with a complete aortic valve and implantation system that has received FDA premarket approval (PMA) for that system's FDA approved indication.

2. The patient (preoperatively and postoperatively) is under the care of a heart team: a cohesive, multi-disciplinary, team of medical professionals. The heart team concept embodies collaboration and dedication across medical specialties to offer optimal patient-centered care. The heart team includes the following:

    a. Cardiac surgeon and an interventional cardiologist experienced in the care and treatment of aortic stenosis who have:
        i. independently examined the patient face-to-face, evaluated the patient’s suitability for surgical aortic valve replacement (SAVR), TAVR or medical or palliative therapy;
        ii. documented and made available to the other heart team members the rationale for their clinical judgment.

b. Providers from other physician groups as well as advanced patient practitioners, nurses, research personnel and administrators.

3. The heart team's interventional cardiologist(s) and cardiac surgeon(s) must jointly participate in the intra-operative technical aspects of TAVR.

4. TAVR must be furnished in a hospital with the appropriate infrastructure that includes but is not limited to:
   a. On-site heart valve surgery and interventional cardiology programs,
   b. Post-procedure intensive care facility with personnel experienced in managing patients who have undergone open-heart valve procedures,
   c. Appropriate volume requirements per the applicable qualifications below:

There are two sets of qualifications; the first set outlined below is for hospital programs and heart teams without previous TAVR experience and the second set is for those with TAVR experience.

Qualifications to begin a TAVR program for hospitals without TAVR experience:

The hospital program must have the following:

a. ≥ 50 open heart surgeries in the previous year prior to TAVR program initiation, and;
b. ≥ 20 aortic valve related procedures in the 2 years prior to TAVR program initiation, and;
c. ≥ 2 physicians with cardiac surgery privileges, and;
d. ≥ 1 physician with interventional cardiology privileges, and;
e. ≥ 300 percutaneous coronary interventions (PCIs) per year.

Qualifications to begin a TAVR program for heart teams without TAVR experience:

The heart team must include:

a. Cardiovascular surgeon with:
   i. ≥ 100 career open heart surgeries of which ≥ 25 are aortic valve related; and,
b. Interventional cardiologist with:
   i. Professional experience of ≥ 100 career structural heart disease procedures; or, ≥ 30 left-sided structural procedures per year; and,
   ii. Device-specific training as required by the manufacturer.

Qualifications for hospital programs with TAVR experience:

The hospital program must maintain the following:

a. ≥ 50 AVRs (TAVR or SAVR) per year including ≥ 20 TAVR procedures in the prior year ; or,
b. ≥ 100 AVRs (TAVR or SAVR) every 2 years, including ≥ 40 TAVR procedures in the prior 2 years; and,
c. ≥ 2 physicians with cardiac surgery privileges; and,
d. ≥ 1 physician with interventional cardiology privileges, and
e. ≥ 300 percutaneous coronary interventions (PCIs) per year; and,

5. The heart team and hospital are participating in a prospective, national, audited registry that: 1) consecutively enrolls TAVR patients; 2) accepts all manufactured devices; 3) follows the patient for at least one year; and, 4) complies with relevant regulations relating to protecting human research subjects, including 45 CFR Part 46 and 21 CFR Parts 50 & 56.

   The following outcomes must be tracked by the registry; and the registry must be designed to permit identification and analysis of patient, practitioner and facility level variables that predict each of these outcomes:

   i. Stroke;
   ii. All-cause mortality;
   iii. Transient Ischemic Attacks (TIAs);
   iv. Major vascular events;
   v. Acute kidney injury;
   vi. Repeat aortic valve procedures;
   vii. New permanent pacemaker implantation;
   viii. Quality of Life (QoL).

6. The registry shall collect all data necessary and have a written executable analysis plan in place to address the following questions (to appropriately address some questions, Medicare claims or other outside data may be necessary). Specifically, for the CED question iv, this must be addressed through a composite metric. For the below CED questions (i-iv), the results must be reported publicly as described in CED criterion k.

   i. When performed outside a controlled clinical study, how do outcomes and adverse events compare to the pivotal clinical studies?
   ii. What is the long term durability of the device?
   iii. What are the long term outcomes and adverse events?
   iv. What morbidity and procedure-related factors contribute to TAVR patients outcomes?

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. TAVR is covered for uses that are not expressly listed as an FDA-approved indication when performed within a clinical study that fulfills all of the following:

1. The heart team's interventional cardiologist(s) and cardiac surgeon(s) must jointly participate in the intra-operative technical aspects of TAVR.

2. As a fully-described, written part of its protocol, the clinical research study must critically evaluate not only each patient's quality of life pre- and post-TAVR (minimum of 1 year), but must also address at least one of the following questions:

    - What is the incidence of stroke?
    - What is the rate of all-cause mortality?
    - What is the incidence of new permanent pacemaker implantation?
    - What is the incidence of transient ischemic attacks (TIAs)?
    - What is the incidence of major vascular events?
    - What is the incidence of acute kidney injury?
    - What is the incidence of repeat aortic valve procedures?

3. The clinical study 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 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 research 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 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 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 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 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. The information will be reviewed, and approved studies will be identified on the CMS Website.

Director, Coverage and Analysis Group
Re: TAVR 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. TAVR)] [name of sponsor/primary investigator]"

C. Nationally Non-Covered Indications

TAVR is not covered for patients in whom existing co-morbidities would preclude the expected benefit from correction of the aortic stenosis.

D. Other

NA

(This NCD last reviewed June 2019)

20.33 - Transcatheter Edge-to-Edge Repair (TEER) for Mitral Valve Regurgitation

(Rev. 12112; Issued: 06-29-23; Effective: 07- 31-23; Implementation: 07-31- 23)

A. General

Transcatheter Edge-to-Edge Repair (TEER) of the mitral valve is used in the treatment of mitral regurgitation. TEER approximates the anterior and posterior mitral valve leaflets by grasping them with a clipping device in an approach similar to a treatment developed in cardiac surgery called the Alfieri stitch.

B. Nationally Covered Indications

The Centers for Medicare & Medicaid Services (CMS) covers TEER of the mitral valve under Coverage with Evidence Development (CED) with the following conditions:

A. For the treatment of symptomatic moderate-to-severe or severe functional mitral regurgitation (MR) when the patient remains symptomatic despite stable doses of maximally tolerated guideline-directed medical therapy (GDMT) plus cardiac resynchronization therapy, if appropriate, or for the treatment of significant symptomatic degenerative MR when furnished according to a Food and Drug Administration (FDA)-approved indication and when all of the following conditions are met:

1. The procedure is furnished with a mitral valve TEER system that has received FDA premarket approval (PMA).

2. The patient (preoperatively and postoperatively) is under the care of a heart team: a cohesive, multidisciplinary, team of medical professionals. The heart team concept embodies collaboration and dedication across medical specialties to offer optimal patient-centered care. The heart team must include the following members with experience and training as specified:

a. Cardiac surgeon
    i. With ≥ 20 mitral valve surgeries per year or ≥ 40 over two years, 50% of which are mitral valve repairs; and,
    ii. Who is board eligible or certified in cardiothoracic surgery or similar foreign equivalent.
b. Interventional cardiologist
    i. With professional experience of ≥ 50 career structural heart disease procedures; or ≥ 30 left-sided structural procedures per year; and,
    ii. With participation in ≥ 20 career trans-septal interventions including 10 as primary or co-primary operator; and,
    iii. Who is board eligible or certified in interventional cardiology or similar foreign equivalent.
c. Interventional echocardiographer (cardiologist or anesthesiologist)
    i. With professional experience of ≥ 10 trans-septal guidance procedures and ≥ 30 structural heart procedures; and,
    ii. Who is board eligible or certified in transesophageal echocardiography with advanced training as required for privileging by the hospital where the TEER is performed.
d. Heart failure cardiologist experienced in treating patients with advanced heart failure (only required for functional MR patients); and,
e. Providers from other physician groups as well as advanced patient practitioners, nurses, research personnel, and administrators.

3. Each patient's suitability for surgical mitral valve repair, TEER, or palliative therapy must be evaluated, documented, and made available to other heart team members. Additionally, for patients with functional MR, the heart team heart failure cardiologist must document that the patient has persistent symptoms despite maximally tolerated GDMT and cardiac resynchronization therapy, if appropriate, as described below:

    a. For patients with functional MR: the heart team interventional cardiologist and heart team heart failure cardiologist independently evaluate the patient using information in the medical record and a face-to-face examination. To decrease patient burden, the heart team heart failure cardiologist may meet this requirement through a review of the patient's records and images if the patient has an established relationship with a cardiologist experienced in treating patients with advanced heart failure.

    b. For patients with degenerative MR: the heart team interventional cardiologist and heart team cardiac surgeon must independently evaluate the patient using information in the medical record and a face-to-face examination.

4. An interventional cardiologist or cardiac surgeon from the heart team must perform the mitral valve TEER and an interventional echocardiographer from the heart team must perform transesophageal echocardiography during the procedure. The interventional echocardiographer may not also furnish anesthesiology during the same procedure. The interventional cardiologist and cardiac surgeon may jointly participate in the intra-operative technical aspects of TEER as appropriate. All physicians who participate in the procedure must have device-specific training as required by the manufacturer.

5. Mitral valve TEERs must be furnished in a hospital with appropriate infrastructure and experience that includes, but is not limited to:

    a. On-site heart valve surgery and interventional cardiology programs;
    b. Post-procedure intensive care facility with personnel experienced in managing patients who have undergone open-heart procedures;
    c. Hospital volume requirements below must be met and maintained:
        i. ≥ 20 mitral valve surgical procedures for severe MR per year or ≥ 40 over two years, of which at least 10 (or 20 over two years) must be mitral valve repairs; and,
        ii. ≥ 2 physicians with cardiac surgery privileges experienced in valvular surgery; and,
        iii. ≥ 1 physician with interventional cardiology privileges; and,
        iv. ≥ 300 percutaneous coronary interventions (PCIs) per year.

6. The heart team and hospital are participating in a prospective, national, audited registry that: 1) comprehensively enrolls TEER patients; 2) accepts all

manufactured devices; 3) follows the patient for at least one year; and, 4) complies with relevant regulations relating to protecting human research subjects, including 45 Code of Federal Regulations (CFR) Part 46 and 21 CFR Parts 50 & 56.

The following outcomes must be tracked by the registry, and the registry must be designed to permit identification and analysis of patient, practitioner, and facility level variables that predict each of these outcomes:

a. Stroke;
b. All-cause mortality;
c. Repeat TEER or other mitral procedures;
d. Transient Ischemic Attacks (TIAs);
e. Major vascular events;
f. Renal complications;
g. Functional capacity; and
h. Quality of Life (QoL).

7. The registry shall collect all data necessary and have a written executable analysis plan in place to address the following questions. Specifically, for the CED question d, this must be addressed through a composite metric. For the below CED questions (a-e), the results must be reported publicly as described in CED criterion k.

a. When TEER procedures are performed outside a controlled clinical study, how do outcomes and adverse events compare to the pivotal clinical studies?
b. How do outcomes and adverse events in subpopulations compare to patients in the pivotal clinical studies?
c. What is the long-term (≥ 5 year) durability of the device?
d. What are the long-term (≥ 5 year) outcomes and adverse events?
e. How do the demographics of registry patients compare to the pivotal studies?

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. Mitral valve TEERs are covered for uses that are not expressly listed as an FDA-approved indication when performed within a clinical study that fulfills all of the following:

1. An interventional cardiologist or cardiac surgeon must perform the mitral valve TEER and an interventional echocardiographer must perform transesophageal echocardiography during the procedure. The interventional echocardiographer may not also furnish anesthesiology during the same procedure. The

interventional cardiologist and cardiac surgeon may jointly participate in the intra-operative technical aspects of TEER as appropriate. All physicians who participate in the procedure must have device specific training as required by the manufacturer.

2. As a fully-described, written part of its protocol, the clinical research trial must critically evaluate the following questions at 12 months or longer follow-up:

    a. What is the rate of all-cause mortality in the intervention group?
    b. What is the rate of re-operations (open surgical or transcatheter) of the mitral valve in the intervention group?
    c. What is the rate of moderate-to-severe or severe MR in the intervention groups?

3. As a fully-described, written part of its protocol, the clinical research study must critically evaluate not only each patient's quality of life pre- and post-TEER (minimum 1 year), but must also address at least one of the following questions:

    a. What is the incidence of stroke?
    b. What is the incidence of TIAs?
    c. What is the incidence of major vascular events?
    d. What is the incidence of renal complications?
    e. What is the incidence of worsening MR?
    f. What is the change in quality of life after TEER?
    g. What is the change in the patient's functional capacity after TEER?

4. The clinical study 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 (NCD).
    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 research 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 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 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 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 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. The information will be reviewed, and approved studies will be identified on the CMS Website.

Director, Coverage and Analysis Group
Re: TEER 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 TEER [name of sponsor/primary investigator]"

C. Nationally Non-Covered Indications

TEER of the mitral valve is not covered under the following circumstances:

1. For patients in whom existing co-morbidities would preclude the expected benefit from a mitral valve TEER procedure.
2. In patients with untreated severe aortic stenosis.

D. Other

CMS will consider published, peer-reviewed evidence periodically, following the effective date of this NCD and reconsider the policy when appropriate. The NCD will expire 10 years from the effective date if it is not reconsidered during that time. Upon expiration, coverage will be at the discretion of the Medicare Administrative Contractors.

20.34 - Percutaneous Left Atrial Appendage Closure (LAAC)
(Rev. 192, Issued: 05-06-16, Effective: 02-08-16, Implementation: 10-03-16)

A. General

Patients with atrial fibrillation (AF), an irregular heartbeat, are at an increased risk of stroke. The left atrial appendage (LAA) is a tubular structure that opens into the left atrium and has been shown to be one potential source for blood clots that can cause strokes. While thinning the blood with anticoagulant medications has been proven to

prevent strokes, percutaneous LAA closure (LAAC) has been studied as a non-pharmacologic alternative for patients with AF.

B. Nationally Covered Indications

The Centers for Medicare & Medicaid Services (CMS) covers percutaneous LAAC for non-valvular atrial fibrillation (NVAF) through Coverage with Evidence Development (CED) with the following conditions:

a. LAAC devices are covered when the device has received Food and Drug Administration (FDA) Premarket Approval (PMA) for that device's FDA-approved indication and meet all of the conditions specified below:

The patient must have:

- A CHADS2 score ≥ 2 (Congestive heart failure, Hypertension, Age >75, Diabetes, Stroke/transient ischemia attack/thromboembolism) or CHA2DS2-VASc score ≥ 3 (Congestive heart failure, Hypertension, Age ≥ 65, Diabetes, Stroke/transient ischemia attack/thromboembolism, Vascular disease, Sex category)

- A formal shared decision making interaction with an independent non-interventional physician using an evidence-based decision tool on oral anticoagulation in patients with NVAF prior to LAAC. Additionally, the shared decision making interaction must be documented in the medical record.

- A suitability for short-term warfarin but deemed unable to take long-term oral anticoagulation following the conclusion of shared decision making, as LAAC is only covered as a second line therapy to oral anticoagulants. The patient (preoperatively and postoperatively) is under the care of a cohesive, multidisciplinary team (MDT) of medical professionals. The procedure must be furnished in a hospital with an established structural heart disease (SHD) and/or electrophysiology (EP) program.

The procedure must be performed by an interventional cardiologist(s), electrophysiologist(s), or cardiovascular surgeon (s) that meet the following criteria:

- Has received training prescribed by the manufacturer on the safe and effective use of the device prior to performing LAAC; and,

- Has performed ≥ 25 interventional cardiac procedures that involve transeptal puncture through an intact septum; and,

- Continues to perform ≥ 25 interventional cardiac procedures that involve transeptal puncture through an intact septum, of which at least 12 are LAAC, over a 2-year period.

The patient is enrolled in, and the MDT and hospital must participate in, a prospective, national, audited registry that: 1) consecutively enrolls LAAC patients, and, 2) tracks the following annual outcomes for each patient for a period of at least 4 years from the time of the LAAC:

- Operator-specific complications
- Device-specific complications including device thrombosis
- Stroke, adjudicated, by type
- Transient Ischemic Attack (TIA)
- Systemic embolism
- Death
- Major bleeding, by site and severity

The registry must be designed to permit identification and analysis of patient, practitioner, and facility level factors that predict patient risk for these outcomes. The registry must collect all data necessary to conduct analyses adjusted for relevant confounders, and have a written executable analysis plan in place to address the following questions:

- How do the outcomes listed above compare to outcomes in the pivotal clinical trials in the short term (≤12 months) and in the long term (≥ 4 years)?

- What is the long term (≥ 4 year) durability of the device?

- What are the short term (≤12 months) and the long term (≥4 years) device-specific complications including device thromboses?

To appropriately address some of these questions, Medicare claims or other outside data may be necessary.

Registries must be reviewed and approved by CMS. Potential registry sponsors must submit all registry documentation to CMS for approval, including the written executable analysis plan and auditing plan. CMS will review the qualifications of candidate registries to ensure that the approved registry follows standard data collection practices, and collects data necessary to evaluate the patient outcomes specified above. The registry's national clinical trial number must be recorded on the claim.

Consistent with section 1142 of the Social Security Act (the Act), the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that CMS determines address the above-listed research questions and the a-m criteria listed in Section c. of this decision.

All approved registries will be posted on the CED website located at: https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html.

b. LAAC is covered for NVAF patients not included in Section a. of this decision when performed within an FDA-approved randomized controlled trial (RCT) if such trials meet the criteria established below:

As a fully-described written part of its protocol, the RCT must critically answer, in comparison to optimal medical therapy, the following questions:

- As a primary endpoint, what is the true incidence of ischemic stroke and systemic embolism?

- As a secondary endpoint, what is cardiovascular mortality and all-cause mortality?

FDA-approved RCTs must be reviewed and approved by CMS. Consistent with section 1142 of the Act, AHRQ supports clinical research studies that CMS determines address the above-listed research questions and the a-m criteria listed in Section c. of this decision.

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 in section c. of this decision, as well as the investigator's contact information, to the address below.

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

c. All clinical studies, RCTs and registries submitted for review 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 Code of Federal Regulations (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.

C. Nationally Non-Covered Indications

LAAC is non-covered for the treatment of NVAF when not furnished under CED according to the above-noted criteria.

(This NCD last reviewed February 2016.)

20.35 - Supervised Exercise Therapy (SET) for Symptomatic Peripheral Artery Disease (PAD)

(Rev. 207, Issued: 05-11-18, Effective: 05-25-17, Implementation: 07-02-18)

A. General

Research has shown supervised exercise therapy (SET) to be an effective, minimally invasive method to alleviate the most common symptom associated with peripheral artery disease (PAD) – intermittent claudication (IC). SET has been shown to be significantly more effective than unsupervised exercise, and could prevent the progression of PAD and lower the risk of cardiovascular events that are prevalent in these patients. SET has also been shown to perform at least as well as more invasive revascularization treatments that are covered by Medicare.

B. Nationally Covered Indications

Effective for services performed on or after May 25, 2017, the Centers for Medicare & Medicaid Services has determined that the evidence is sufficient to cover SET for beneficiaries with IC for the treatment of symptomatic PAD. Up to 36 sessions over a 12-week period are covered if all of the following components of a SET program are met. The SET program must:

- consist of sessions lasting 30-60 minutes comprising a therapeutic exercise-training program for PAD in patients with claudication;
- be conducted in a physician's office;
- be delivered by qualified auxiliary personnel necessary to ensure benefits exceed harms, and who are trained in exercise therapy for PAD; and
- be under the direct supervision of a physician (as defined in 1861(r)(1)), physician assistant, or nurse practitioner/clinical nurse specialist (as identified in 1861(aa)(5)) who must be trained in both basic and advanced life support techniques.

Beneficiaries must have a face-to-face visit with the physician responsible for PAD treatment to obtain the referral for SET. At this visit, the beneficiary must receive information regarding cardiovascular disease and PAD risk factor reduction, which could include education, counseling, behavioral interventions, and outcome assessments.

C. Nationally Non-Covered Indications

SET is non-covered for beneficiaries with absolute contraindications to exercise as determined by their primary physician.

D. Other

Medicare Administrative Contractors (MACs) have the discretion to cover SET beyond the nationally covered 36 sessions over a 12-week period. MACs may cover an additional 36 sessions over an extended period of time. A second referral is required for these additional sessions

(This NCD last reviewed May 2017.)

20.37 – Transcatheter Tricuspid Valve Replacement (TTVR)
(Rev. 13800; Issued:05-28-26; Effective: 03-19-25; Implementation: 01-05-26)

A. General

Transcatheter Tricuspid Valve Replacement (TTVR) is used in the treatment of tricuspid regurgitation.

B. Nationally Covered Indications

The Centers for Medicare & Medicaid Services (CMS) covers transcatheter tricuspid valve replacement (TTVR) for the treatment of symptomatic tricuspid regurgitation (TR) under Coverage with Evidence Development (CED) according to the provisions below:
Coverage Criteria:

TTVR is covered when furnished according to a Food and Drug Administration (FDA) market-authorized indication and all the following conditions are met:

1. Patient Criteria

Despite optimal medical therapy (OMT), patients must have symptomatic TR with tricuspid valve replacement being considered as appropriate by a heart team.

2. Physician Criteria

The patient (preoperatively and postoperatively) is under the care of a heart team, which includes, at minimum, the following:

a) Cardiac surgeon;
b) Interventional cardiologist;
c) Cardiologist with training and experience in heart failure management;
d) Electrophysiologist;
e) Multi-modality imaging specialists; and
f) Interventional echocardiographer

All of the specialists listed above must have experience in the care and treatment of TR.

3. CED Study Criteria

The TTVR items and services are furnished in the context of a CMS-approved CED study. CMS-approved CED study protocols must: include only those patients who meet the criteria in section B.1; furnish items and services only through practitioners who meet the criteria in section B.2; and include all of the following:

a) Primary outcomes of all-cause mortality, hospitalizations, or a composite of these, through a minimum of 24 months. For composite outcome measures, physiologic, patient-reported, and other relevant health outcomes should be co-directional (i.e., all outcomes comprising the composite outcome should demonstrate movement in the same direction). Each component of a composite outcome must be individually reported.

b) An active comparator.

c) A care management plan that includes the experience and role of each member of the heart team described in section B.2.

d) Design sufficient for subgroup analyses by:

• Age;
• Sex;
• Race and ethnicity;
• Practitioner and facility level variables that predict the primary outcomes of the study;

• Left ventricular ejection fraction (by guideline-defined subgroups);
• Previous tricuspid surgery or intervention;
• Severe aortic or mitral stenosis or regurgitation;
• Patients with chronic kidney disease;
• Patients with indwelling cardiac implantable electronic devices;

e) CMS-approved CED studies must adhere to the following scientific standards (criteria 1-17 below) that have been identified by the Agency for Healthcare Research and Quality (AHRQ) as set forth in Section VI. of CMS' Coverage with Evidence Development Guidance Document, published August 7, 2024. https://www.cms.gov/medicare-coverage-database/view/medicare-coverage-document.aspx?mcdid=38

1. Sponsor/Investigator: The study is conducted by sponsors/investigators with the resources and skills to complete it successfully.

2. Milestones: A written plan is in place that describes a detailed schedule for completion of key study milestones, including study initiation, enrollment progress, interim results reporting, and results reporting, to ensure timely completion of the CED process.

3. Study Protocol: The CED study is registered with ClinicalTrials.gov and a complete final protocol, including the statistical analysis plan, is delivered to CMS prior to study initiation. The published protocol includes sufficient detail to allow a judgment of whether the study is fit-for-purpose and whether reasonable efforts will be taken to minimize the risk of bias. Any changes to approved study protocols should be explained and publicly reported.

4. Study Context: The rationale for the study is supported by scientific evidence and study results are expected to fill the specified CMS-identified evidence deficiency and provide evidence sufficient to assess health outcomes.

5. Study Design: The study design is selected to safely and efficiently generate valid evidence of health outcomes. The sponsors/investigators minimize the impact of confounding and biases on inferences through rigorous design and appropriate statistical techniques. If a contemporaneous comparison group is not included, this choice should be justified, and the sponsors/investigators discuss in detail how the design contributes useful information on issues such as durability or adverse event frequency that are not clearly answered in comparative studies.

6. Study Population: The study population reflects the demographic and clinical diversity among the Medicare beneficiaries who are the intended population of the intervention, particularly when there is good clinical or scientific reason to expect that the results observed in premarket studies might not be observed in older adults or subpopulations identified by other clinical or demographic factors. At a minimum, this includes attention to the intended population's racial and ethnic backgrounds, sex, age, disabilities, important comorbidities, and, dependent on data availability, relevant health related

social needs. For instance, more than half of Medicare beneficiaries are women so study designs should, as appropriate, consider the prevalence in women of the condition being studied as well as in the clinical trial and subsequent data reporting and analyses.

7. Subgroup Analyses: The study protocol explicitly discusses beneficiary subpopulations affected by the item or service under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion requirements effect enrollment of these populations, and a plan for the retention and reporting of said populations in the trial. In the protocol, the sponsors/investigators describe plans for analyzing demographic subpopulations as well as clinically relevant subgroups as identified in existing evidence. Description of plans for exploratory analyses, as relevant subgroups emerge, are also included.

8. Care Setting: When feasible and appropriate for answering the CED question, data for the study should come from beneficiaries in their expected sites of care.

9. Health Outcomes: The primary health outcome(s) for the study are those important to patients and their caregivers and that are clinically meaningful. A validated surrogate outcome that reliably predicts these outcomes may be appropriate for some questions. Generally, when study sponsors propose using surrogate endpoints to measure outcomes, they should cite validation studies published in peer-reviewed journals to provide a rationale for assuming these endpoints predict the health outcomes of interest. The cited validation studies should be longitudinal and demonstrate a statistical association between the surrogate endpoint and the health outcomes it is thought to predict.

10. Objective Success Criteria: In consultation with CMS and AHRQ, sponsors/investigators establish an evidentiary threshold for the primary health outcome(s) so as to demonstrate clinically meaningful differences with sufficient precision.

11. Data Quality: The data are generated or selected with attention to provenance, bias, completeness, accuracy, sufficiency of duration of observation to demonstrate durability of health outcomes, and sufficiency of sample size as required by the question.

12. Construct Validity: Sponsors/investigators provide information about the validity of drawing warranted conclusions about the study population, primary exposure(s) (intervention, control), health outcome measures, and core covariates when using either primary data collected for the study about individuals or proxies of the variables of interest, or existing (secondary) data about individuals or proxies of the variables of interest.

13. Sensitivity Analyses: Sponsors/investigators will demonstrate robustness of results by conducting pre-specified sensitivity testing using alternative variable or model specifications as appropriate.

14. Reporting: Final results are provided to CMS and submitted for publication or reported in a publicly accessible manner within 12 months of the study's primary completion date. Wherever possible, the study is submitted for peer review with the goal of publication using a reporting guideline appropriate for the study design and structured to enable replication. If peer-reviewed publication is not possible, results may also be published in an online 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 incomplete results).

15. Sharing: The sponsors/investigators commit to making study data publicly available by sharing data, methods, analytic code, and analytical output with CMS or with a CMS-approved third party. The study should comply with all applicable laws regarding subject privacy, including 45 CFR § 164.514 within the regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and 42 CFR, Part 2: Confidentiality of Substance Use Disorder Patient Records.

16. Governance: The protocol describes the information governance and data security provisions that have been established to satisfy Federal security regulations issued pursuant to HIPAA and codified at 45 CFR Parts 160 and 164 (Subparts A & C), United States Department of Health and Human Services (HHS) regulations at 42 CFR, Part 2: Confidentiality of Substance Use Disorder Patient and HHS regulations at 45 CFR Part 46, regarding informed consent for clinical study involving human subjects. In addition to the requirements under 42 CFR and 45 CFR, studies that are subject to FDA regulation must also comply with regulations at 21 CFR Parts 50 and 56 regarding the protection of human subjects and institutional review boards, respectively.

17. Legal: The study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals, although it is acceptable for a study to test a reduction in toxicity of a product relative to standard of care or an appropriate comparator. For studies that involve researching the safety and effectiveness of new drugs and biological products aimed at treating life-threatening or severely debilitating diseases, refer to additional requirements set forth in 21 CFR § 312.81(a).

Consistent with section 1142 of the Social Security Act, AHRQ supports clinical research studies that CMS determines meet all the criteria and standards identified above.

C. Other Uses of TTVR

1. *Transcatheter tricuspid valve replacement (TTVR) is not covered for patients outside of a CMS-approved study.*
2. *Nothing in this NCD would preclude coverage of TTVR through NCD 310.1 (Clinical Trial Policy) or through the Investigational Device Exemption (IDE) Policy.*

(This NCD last reviewed March 2025.)

20.38- Transcatheter Edge-to-Edge Repair for Tricuspid Valve Regurgitation (T-TEER)

(Rev. 13801; Issued: 05-28-26; Effective: 07-02-25; Implementation: 01-05-26)

A. General

Transcatheter Edge-to-Edge Repair for Tricuspid Valve Regurgitation (T-TEER) is used in the treatment of tricuspid regurgitation.

B. Nationally Covered Indications

The Centers for Medicare & Medicaid Services (CMS) covers tricuspid transcatheter edge-to-edge repair (T-TEER) for the treatment of symptomatic tricuspid regurgitation (TR) under Coverage with Evidence Development (CED) according to the provisions below:

Coverage Criteria:

T-TEER is covered when furnished according to a Food and Drug Administration (FDA) market-authorized indication and all the following conditions are met:

1. Patient Criteria

Despite optimal medical therapy (OMT), patients must have symptomatic TR with tricuspid valve repair being considered as appropriate by a heart team.

2. Physician Criteria

The patient (preoperatively and postoperatively) is under the care of a heart team, which includes, at minimum, the following:

g) Cardiac surgeon;
h) Interventional cardiologist;
i) Cardiologist with training and experience in heart failure management; and
j) Interventional echocardiographer

All the specialists listed above must have experience in the care and treatment of TR.

3. CED Study Criteria

The T-TEER items and services are furnished in the context of a CMS-approved CED study. CMS-approved CED study protocols must: include only those patients who meet the criteria in section B.1; furnish items and services only through practitioners who meet the criteria in section B.2; and include all of the following:

a) Primary outcomes of all-cause mortality, hospitalizations, or a composite of these, through a minimum of 24 months. For composite outcome measures, physiologic, patient-reported, and other relevant health outcomes should be co-directional (i.e., all outcomes comprising the composite outcome should demonstrate movement in the same direction). Each component of a composite outcome must be individually reported.

b) An active comparator.

c) A care management plan that includes the experience and role of each member of the heart team described in section B.2.

d) Design sufficient for subgroup analyses by:
• Practitioner and facility level variables that predict the primary outcomes of the study;
• Clinically important patient demographic factors;
• Left ventricular ejection fraction (by guideline-defined subgroups);
• Previous tricuspid surgery or intervention;
• Severe aortic or mitral stenosis or regurgitation;
• Patients with chronic kidney disease;
• Patients with indwelling cardiac implantable electronic devices;
• Patients with greater than mild right ventricular dysfunction;
• Patients with hepatic dysfunction; and
• Grade of post-repair residual TR.

e) CMS-approved CED studies must adhere to the following scientific standards (criteria 1-17 below) that have been identified by the Agency for Healthcare Research and Quality (AHRQ) as set forth in Section VI. of CMS' Coverage with Evidence Development Guidance Document, published August 7, 2024. https://www.cms.gov/medicare-coverage-database/view/medicare-coverage-document.aspx?mcdid=38

1. Sponsor/Investigator: The study is conducted by sponsors/investigators with the resources and skills to complete it successfully.

2. Milestones: A written plan is in place that describes a detailed schedule for completion of key study milestones, including study initiation, enrollment progress, interim results reporting, and results reporting, to ensure timely completion of the CED process.

3. Study Protocol: The CED study is registered with ClinicalTrials.gov and a complete final protocol, including the statistical analysis plan, is delivered to CMS prior to study initiation. The published protocol includes sufficient detail to allow a judgment of whether the study is fit-for-purpose and whether reasonable efforts will be taken to minimize the risk of bias. Any changes to approved study protocols should be explained and publicly reported.

4. Study Context: The rationale for the study is supported by scientific evidence and study results are expected to fill the specified CMS-identified evidence deficiency and provide evidence sufficient to assess health outcomes.

5. Study Design: The study design is selected to safely and efficiently generate valid evidence of health outcomes. The sponsors/investigators minimize the impact of confounding and biases on inferences through rigorous design and appropriate statistical techniques. If a contemporaneous comparison group is not included, this choice should be justified, and the sponsors/investigators discuss in detail how the design contributes useful information on issues such as durability or adverse event frequency that are not clearly answered in comparative studies.

6. Study Population: The study population reflects the demographic and clinical diversity among the Medicare beneficiaries who are the intended population of the intervention, particularly when there is good clinical or scientific reason to expect that the results observed in premarket studies might not be observed in older adults or subpopulations identified by other clinical or demographic factors.

7. Subgroup Analyses: The study protocol explicitly discusses beneficiary subpopulations affected by the item or service under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion requirements effect enrollment of these populations, and a plan for the retention and reporting of said populations in the trial. In the protocol, the sponsors/investigators describe plans for analyzing demographic subpopulations as well as clinically relevant subgroups as identified in existing evidence. Description of plans for exploratory analyses, as relevant subgroups emerge, are also included.

8. Care Setting: When feasible and appropriate for answering the CED question, data for the study should come from beneficiaries in their expected sites of care.
9. Health Outcomes: The primary health outcome(s) for the study are those important to patients and their caregivers and that are clinically meaningful. A validated surrogate outcome that reliably predicts these outcomes may be appropriate for some questions. Generally, when study sponsors propose using surrogate endpoints to measure outcomes, they should cite validation studies published in peer-reviewed journals to provide a rationale for assuming these endpoints predict the health outcomes of interest. The cited validation studies should be longitudinal and demonstrate a statistical association between the surrogate endpoint and the health outcomes it is thought to predict.

10. Objective Success Criteria: In consultation with CMS and AHRQ, sponsors/investigators establish an evidentiary threshold for the primary health outcome(s) so as to demonstrate clinically meaningful differences with sufficient precision.

11. Data Quality: The data are generated or selected with attention to provenance, bias, completeness, accuracy, sufficiency of duration of observation to demonstrate durability of health outcomes, and sufficiency of sample size as required by the question.

12. Construct Validity: Sponsors/investigators provide information about the validity of drawing warranted conclusions about the study population, primary exposure(s) (intervention, control), health outcome measures, and core covariates when using either primary data collected for the study about individuals or proxies of the variables of interest, or existing (secondary) data about individuals or proxies of the variables of interest.

13. Sensitivity Analyses: Sponsors/investigators will demonstrate robustness of results by conducting pre-specified sensitivity testing using alternative variable or model specifications as appropriate.

14. Reporting: Final results are provided to CMS and submitted for publication or reported in a publicly accessible manner within 12 months of the study's primary completion date. Wherever possible, the study is submitted for peer review with the goal of publication using a reporting guideline appropriate for the study design and structured to enable replication. If peer-reviewed publication is not possible, results may also be published in an online 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 incomplete results).

15. Sharing: The sponsors/investigators commit to making study data publicly available by sharing data, methods, analytic code, and analytical output with CMS or with a CMS-approved third party. The study should comply with all applicable laws regarding subject privacy, including 45 CFR § 164.514 within the regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and 42 CFR, Part 2: Confidentiality of Substance Use Disorder Patient Records.

16. Governance: The protocol describes the information governance and data security provisions that have been established to satisfy Federal security regulations issued pursuant to HIPAA and codified at 45 CFR Parts 160 and 164 (Subparts A & C), United States Department of Health and Human Services (HHS) regulations at 42 CFR, Part 2: Confidentiality of Substance Use Disorder Patient and HHS regulations at 45 CFR Part 46, regarding informed consent for clinical study involving human subjects. In addition to the requirements under 42 CFR and 45 CFR, studies that are subject to FDA regulation must also comply with regulations at 21 CFR Parts 50 and 56 regarding the protection of human subjects and institutional review boards, respectively.

17. Legal: The study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals, although it is acceptable for a study to test a reduction in toxicity of a product relative to standard of care or an appropriate comparator. For studies that involve researching the safety and effectiveness of new drugs and biological products aimed at treating life-threatening or severely debilitating diseases, refer to additional requirements set forth in 21 CFR § 312.81(a).

Consistent with section 1142 of the Social Security Act, AHRQ supports clinical research studies that CMS determines meet all the criteria and standards identified above.

C. Other Uses of T-TEER

1. *Tricuspid transcatheter edge-to-edge repair (T-TEER) is not covered for patients outside of a CMS-approved study.*
2. *Nothing in this NCD would preclude coverage of T-TEER through NCD 310.1 (Clinical Trial Policy) or through the Investigational Device Exemption (IDE) Policy.*

(This NCD last reviewed July 2025.)

20.39 –Cardiac Contractility Modulation (CCM) for Heart Failure (HF)
(Rev. 13806, Issued: 05-28-26, Effective: 10-28- 25, Implementation: 04- 06-26)

A. General

Cardiac Contractility Modulation (CCM) is used in the treatment of heart failure (HF).

B. Nationally Covered Indications

The Centers for Medicare & Medicaid Services (CMS) covers CCM for HF management under Coverage with Evidence Development (CED) when furnished according to a Food and Drug Administration (FDA) market-authorized indication and all of the following conditions are met:

1. Patient Criteria

Patients must meet the FDA market-authorized indications for use and remain symptomatic despite at least 3 months of optimized guideline-directed medical therapy (GDMT) as determined by the heart team prior to CCM implantation.

Patients are excluded from coverage if they meet any of the following criteria:

- *Meet any of the contraindications in the FDA labeling; or,*
- *Have had a heart transplant; or,*
- *Are younger than 18 years old*

2. CED Study Criteria

The CCM and related items and services are furnished in the context of a CMS-approved CED study. CMS-approved CED study protocols must: include only those patients who meet the criteria in section B.1; and include all of the following:

a) Primary outcomes of all-cause mortality, HF hospitalizations, or a composite of these, through a minimum of 24 months. Each component of a composite outcome must be individually reported.

b) An active comparator.

c) A care management plan that identifies members, roles, and responsibilities of the clinical team that performs the follow-up CCM patient management.

d) Design sufficient for subgroup analyses by:

- *Age (Stratify <65, 65-74, 75+)*
- *Other clinically important patient demographic factors*
- *Ischemic cardiomyopathy versus non-ischemic cardiomyopathy;*
- *No CRT, CRT (cardiac resynchronization therapy);*
- *Left ventricular ejection fraction (LVEF) ≥35% versus <35%;*
- *Systolic blood pressure ≥ median versus < median;*
- *Diabetic vs non-diabetic*

e) In addition, CMS-approved CED studies must adhere to the following scientific standards (criteria 1-17 below) that have been identified by the Agency for Healthcare Research and Quality (AHRQ) as set forth in Section VI. of CMS' Coverage with Evidence Development Guidance Document, published August 7. 2024 (the "CED Guidance Document") https://www.cms.gov/medicare-coverage-database/view/medicare-coverage-document.aspx?mcdid=38

1. Sponsor/Investigator: The study is conducted by sponsors/investigators with the resources and skills to complete it successfully.

2. Milestones: A written plan is in place that describes a detailed schedule for completion of key study milestones, including study initiation, enrollment progress, interim results reporting, and results reporting, to ensure timely completion of the CED process.

3. Study Protocol: The CED study is registered with ClinicalTrials.gov and a complete final protocol, including the statistical analysis plan, is delivered to CMS prior to study initiation. The published protocol includes sufficient detail to allow a judgment of whether the study is fit-for-purpose and whether reasonable efforts will be taken to minimize the risk of bias. Any changes to approved study protocols should be explained and publicly reported.

4. Study Context: The rationale for the study is supported by scientific evidence and study results are expected to fill the specified CMS-identified evidence deficiency and provide evidence sufficient to assess health outcomes.

5. Study Design: The study design is selected to safely and efficiently generate valid evidence of health outcomes. The sponsors/investigators minimize the impact of confounding and biases on inferences through rigorous design and appropriate statistical techniques. If a contemporaneous comparison group is not included, this choice should be justified, and the sponsors/investigators discuss in detail how the design contributes useful information on issues such as durability or adverse event frequency that are not clearly answered in comparative studies.

6. Study Population: The study population reflects the demographic and clinical diversity among the Medicare beneficiaries who are the intended population of the intervention, particularly when there is good clinical or scientific reason to expect that the results observed in premarket studies might not be observed in older adults or subpopulations identified by other clinical or demographic factors.

7. Subgroup Analyses: The study protocol explicitly discusses beneficiary subpopulations affected by the item or service under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion requirements effect enrollment of these populations, and a plan for the retention and reporting of said populations in the trial. In the protocol, the sponsors/investigators describe plans for analyzing demographic subpopulations as well as clinically relevant subgroups as identified in existing evidence. Description of plans for exploratory analyses, as relevant subgroups emerge, are also included.

8. Care Setting: When feasible and appropriate for answering the CED question, data for the study should come from beneficiaries in their expected sites of care.

9. Health Outcomes: The primary health outcome(s) for the study are those important to patients and their caregivers and that are clinically meaningful. A validated surrogate outcome that reliably predicts these outcomes may be appropriate for some questions. Generally, when study sponsors propose using surrogate endpoints to measure outcomes, they should cite validation studies published in peer-reviewed journals to provide a rationale for assuming these endpoints predict the health outcomes of interest. The cited validation studies should be longitudinal and demonstrate a statistical association between the surrogate endpoint and the health outcomes it is thought to predict.

10. Objective Success Criteria: In consultation with CMS and AHRQ, sponsors/investigators establish an evidentiary threshold for the primary health outcome(s) to demonstrate clinically meaningful differences with sufficient precision.

11. Data Quality: The data are generated or selected with attention to provenance, bias, completeness, accuracy, sufficiency of duration of observation to demonstrate durability of health outcomes, and sufficiency of sample size as required by the question.

12. Construct Validity: Sponsors/investigators provide information about the validity of drawing warranted conclusions about the study population, primary exposure(s) (intervention, control), health outcome measures, and core covariates when using either

primary data collected for the study about individuals or proxies of the variables of interest, or existing (secondary) data about individuals or proxies of the variables of interest.

13. Sensitivity Analyses: Sponsors/investigators will demonstrate robustness of results by conducting prespecified sensitivity testing using alternative variable or model specifications as appropriate.

14. Reporting: Final results are provided to CMS and submitted for publication or reported in a publicly accessible manner within 12 months of the study's primary completion date. Wherever possible, the study is submitted for peer review with the goal of publication using a reporting guideline appropriate for the study design and structured to enable replication. If peer-reviewed publication is not possible, results may also be published in an online 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 incomplete results).

15. Sharing: The sponsors/investigators commit to making study data publicly available by sharing data, methods, analytic code, and analytical output with CMS or with a CMS-approved third party. The study should comply with all applicable laws regarding subject privacy, including 45 CFR § 164.514 within the regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and 42 CFR, Part 2: Confidentiality of Substance Use Disorder Patient Records.

16. Governance: The protocol describes the information governance and data security provisions that have been established to satisfy Federal security regulations issued pursuant to HIPAA and codified at 45 CFR Parts 160 and 164 (Subparts A & C), United States Department of Health and Human Services (HHS) regulations at 42 CFR, Part 2: Confidentiality of Substance Use Disorder Patient and HHS regulations at 45 CFR Part 46, regarding informed consent for clinical study involving human subjects. In addition to the requirements under 42 CFR and 45 CFR, studies that are subject to FDA regulation must also comply with regulations at 21 CFR Parts 50 and 56 regarding the protection of human subjects and institutional review boards, respectively.

17. Legal: The study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals, although it is acceptable for a study to test a reduction in toxicity of a product relative to standard of care or an appropriate comparator. For studies that involve researching the safety and effectiveness of new drugs and biological products aimed at treating life-threatening or severely debilitating diseases, refer to additional requirements set forth in 21 CFR § 312.81(a).

Consistent with section 1142 of the Social Security Act, AHRQ supports clinical research studies that CMS determines meet all the criteria and standards identified above.

C. Other Uses of CCM

1. *CCM for HF management is not covered for patients outside of a CMS-approved study.*
2. *Nothing in this NCD would preclude coverage of CCM for HF management through NCD 310.1 (Clinical Trial Policy) or through the Investigational Device Exemption (IDE) Policy.*

(This NCD last reviewed October 2025.)

20.40 – Renal Denervation for Uncontrolled Hypertension
(Rev. 13802; Issued: 05-28-26; Effective: 10-28-25; Implementation: 04-06-26)

A. General
Renal Denervation (RDN) is used in the treatment of uncontrolled hypertension.

B. Coverage Criteria

The Centers for Medicare & Medicaid Services (CMS) covers radiofrequency renal denervation (rfRDN) and ultrasound renal denervation (uRDN) (collectively RDN) for uncontrolled hypertension when furnished according to a Food and Drug Administration (FDA) market-authorized indication and all the following conditions are met:

1. Patient Criteria
The patient meets all the following criteria:

(a) Diagnosis of uncontrolled hypertension (≥ 140 mm Hg systolic blood pressure and > 90 mm Hg diastolic blood pressure) despite active management by a clinician with primary responsibility for blood pressure management.

(b) Uncontrolled hypertension diagnosed using either ambulatory blood pressure monitoring or serial home blood pressure readings.

(c) On lifestyle modifications and stable doses of maximally tolerated guideline-directed medical therapy (GDMT), with assessment of adherence to the prescribed regimen, for at least six weeks before referral for RDN.

(d) As clinically appropriate, secondary hypertension must be evaluated and treated before determining that blood pressure remains uncontrolled. At a minimum, patients must be screened for primary aldosteronism, obstructive sleep apnea, and drug or alcohol induced hypertension before referral to RDN.

(e) The patient has no contraindications to RDN, consistent with the FDA labeling of the device used.

(f) The primary clinicians must coordinate management of the patient for a minimum of six months before referral for RDN, during which the patient had at least three encounters, with no more than two of the three encounters being virtual.

(g) No prior RDN procedure.

2. Physician Criteria

RDN is furnished by clinicians who meet the following criteria, as applicable:

(a) Clinicians referring Medicare beneficiaries must have longitudinal responsibility for hypertension management.

(b) Physicians performing RDN must have interventional and endovascular skills to perform effective RDN treatments. Additionally, they must be able to manage potential complications either themselves or with institutional support from colleagues who are immediately available to assist in emergency management.

(c) Physicians performing RDN without prior endovascular training or renovascular expertise must complete at least ten supervised cases of diagnostic/therapeutic renovascular procedures, half as primary operator. Additionally, they must complete at least five proctored RDN cases with each approved device used in their practice.
(d) Physicians performing RDN with prior endovascular training and active endovascular experience must complete at least five proctored RDN cases with each approved device used in their practice.

3. Facility Criteria

The RDN device and related items and services are furnished at facilities meeting the following criteria:

(a) Facilities performing RDN must have a hypertension program with contributions from a hypertension clinician with longitudinal patient management responsibility, a hypertension navigator, and access to relevant medical specialties (e.g., internal medicine, endocrinology, sleep medicine, cardiology, and nephrology) as appropriate.

(b) Preprocedural imaging capabilities (e.g., ultrasound, Computed Tomography Angiography, Magnetic Resonance Angiography).

(c) An appropriate interventional cardiology or radiology suite.

4. CED Study Criteria

The RDN device and related items and services are furnished in the context of a CMS-approved CED study. CMS-approved CED study protocols must: include only those patients who meet the criteria in section B.1; furnish items and services only through practitioners who meet the criteria in section B.2; furnish items and services at facilities meeting the criteria in section B.3; and include all of the following:

(a) One or more primary outcomes of ambulatory systolic blood pressure (ASBP), ambulatory diastolic blood pressure (ADBP), home systolic blood pressure (HSBP), home diastolic blood pressure (HDBP), office systolic blood pressure (OSBP), office diastolic blood pressure (ODBP), worsening renal function, cerebrovascular accident, acute myocardial infarction, incidence of new-onset heart failure, cardiovascular mortality, all-cause mortality, or a composite of these, through a minimum of 24 months. Each component of a composite outcome must be individually reported.

(b) An active comparator.

(c) Design sufficient for subgroup analyses by:

- *Age (Stratify <65, 65-74, 75+);*
- *Other clinically important patient demographic factors;*
- *Chronic kidney disease (Stratify by CKD Stages);*
- *Progression of CKD;*
- *Hypertension phenotype (e.g., resistant hypertension vs. uncontrolled for any reason);*
- *Medication adherence.*

(d) In addition, CMS-approved CED studies must adhere to the scientific standards (criteria 1-17 below) that have been identified by the Agency for Healthcare Research and Quality (AHRQ) as set forth in Section VI. of CMS' Coverage with Evidence Development Guidance Document, published August 7, 2024 (the "CED Guidance Document").

1. *Sponsor/Investigator: The study is conducted by sponsors/investigators with the resources and skills to complete it successfully.*
2. *Milestones: A written plan is in place that describes a detailed schedule for completion of key study milestones, including study initiation, enrollment progress, interim results reporting, and results reporting, to ensure timely completion of the CED process.*
3. *Study Protocol: The CED study is registered with ClinicalTrials.gov and a complete final protocol, including the statistical analysis plan, is delivered to CMS prior to study initiation. The published protocol includes sufficient detail to allow a judgment of whether the study is fit-for-purpose and whether reasonable efforts will be taken to minimize the risk of bias. Any changes to approved study protocols should be explained and publicly reported.*

4. *Study Context: The rationale for the study is supported by scientific evidence and study results are expected to fill the specified CMS-identified evidence deficiency and provide evidence sufficient to assess health outcomes.*

5. *Study Design: The study design is selected to safely and efficiently generate valid evidence of health outcomes. The sponsors/investigators minimize the impact of confounding and biases on inferences through rigorous design and appropriate statistical techniques. If a contemporaneous comparison group is not included, this choice should be justified, and the sponsors/investigators discuss in detail how the design contributes useful information on issues such as durability or adverse event frequency that are not clearly answered in comparative studies.*

6. *Study Population: The study population reflects the demographic and clinical diversity among the Medicare beneficiaries who are the intended population of the intervention, particularly when there is good clinical or scientific reason to expect that the results observed in premarket studies might not be observed in older adults or subpopulations identified by other clinical or demographic factors.*

7. *Subgroup Analyses: The study protocol explicitly discusses beneficiary subpopulations affected by the item or service under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion requirements effect enrollment of these populations, and a plan for the retention and reporting of said populations in the trial. In the protocol, the sponsors/investigators describe plans for analyzing demographic subpopulations as well as clinically-relevant subgroups as identified in existing evidence. Description of plans for exploratory analyses, as relevant subgroups emerge, are also included.*

8. *Care Setting: When feasible and appropriate for answering the CED question, data for the study should come from beneficiaries in their expected sites of care.*

9. *Health Outcomes: The primary health outcome(s) for the study are those important to patients and their caregivers and that are clinically meaningful. A validated surrogate outcome that reliably predicts these outcomes may be appropriate for some questions. Generally, when study sponsors propose using surrogate endpoints to measure outcomes, they should cite validation studies published in peer-reviewed journals to provide a rationale for assuming these endpoints predict the health outcomes of interest. The cited validation studies should be longitudinal and demonstrate a statistical association between the surrogate endpoint and the health outcomes it is thought to predict.*

10. *Objective Success Criteria: In consultation with CMS and AHRQ, sponsors/investigators establish an evidentiary threshold for the primary health outcome(s) so as to demonstrate clinically meaningful differences with sufficient precision.*

11. *Data Quality: The data are generated or selected with attention to provenance, bias, completeness, accuracy, sufficiency of duration of observation to demonstrate durability of health outcomes, and sufficiency of sample size as required by the question.*

12. *Construct Validity: Sponsors/investigators provide information about the validity of drawing warranted conclusions about the study population, primary exposure(s) (intervention, control), health outcome measures, and core covariates when using either primary data collected for the study about individuals or proxies of the variables of interest, or existing (secondary) data about individuals or proxies of the variables of interest.*

13. *Sensitivity Analyses: Sponsors/investigators will demonstrate robustness of results by conducting pre-specified sensitivity testing using alternative variable or model specifications as appropriate.*

14. *Reporting: Final results are provided to CMS and submitted for publication or reported in a publicly accessible manner within 12 months of the study's primary completion date. Wherever possible, the study is submitted for peer review with the goal of publication using a reporting guideline appropriate for the study design and structured to enable replication. If peer-reviewed publication is not possible, results may also be published in an online 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 incomplete results).*

15. *Sharing: The sponsors/investigators commit to making study data publicly available by sharing data, methods, analytic code, and analytical output with CMS or with a CMS-approved third party. The study should comply with all applicable laws regarding subject privacy, including 45 CFR § 164.514 within the regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and 42 CFR, Part 2: Confidentiality of Substance Use Disorder Patient Records.*

16. *Governance: The protocol describes the information governance and data security provisions that have been established to satisfy Federal security regulations issued pursuant to HIPAA and codified at 45 CFR Parts 160 and 164 (Subparts A & C), United States Department of Health and Human Services*

(HHS) regulations at 42 CFR, Part 2: Confidentiality of Substance Use Disorder Patient and HHS regulations at 45 CFR Part 46, regarding informed consent for clinical study involving human subjects. In addition to the requirements under 42 CFR and 45 CFR, studies that are subject to FDA regulation must also comply with regulations at 21 CFR Parts 50 and 56 regarding the protection of human subjects and institutional review boards, respectively.

17. *Legal: The study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals, although it is acceptable for a study to test a reduction in toxicity of a product relative to standard of care or an appropriate comparator. For studies that involve researching the safety and effectiveness of new drugs and biological products aimed at treating life-threatening or severely-debilitating diseases, refer to additional requirements set forth in 21 CFR § 312.81(a).*

Consistent with section 1142 of the Act, AHRQ supports clinical research studies that CMS determines meet all the criteria and standards identified above.

C. National Non-Covered Indications

RDN is not covered for patients outside of a CMS-approved study.

D. Other

Nothing in this NCD would preclude coverage of RDN through NCD 310.1 (Clinical Trial Policy) or through the Investigational Device Exemption (IDE) Policy.
(This NCD last reviewed October 28, 2025)

30 - Complementary and Alternative Medicine
(Rev. 1, 10-03-03)

30.1 - Biofeedback Therapy
(Rev. 1, 10-03-03)
CIM 35-27

Biofeedback therapy provides visual, auditory or other evidence of the status of certain body functions so that a person can exert voluntary control over the functions, and thereby alleviate an abnormal bodily condition. Biofeedback therapy often uses electrical devices to transform bodily signals indicative of such functions as heart rate, blood pressure, skin temperature, salivation, peripheral vasomotor activity, and gross muscle tone into a tone or light, the loudness or brightness of which shows the extent of activity in the function being measured.

Biofeedback therapy differs from electromyography which is a diagnostic procedure used

to record and study the electrical properties of skeletal muscle. An electromyography device may be used to provide feedback with certain types of biofeedback. Biofeedback therapy is covered under Medicare only when it is reasonable and necessary for the individual patient for muscle re-education of specific muscle groups or for treating pathological muscle abnormalities of spasticity, incapacitating muscle spasm, or weakness, and more conventional treatments (heat, cold, massage, exercise, support) have not been successful. This therapy is not covered for treatment of ordinary muscle tension states or for psychosomatic conditions. (See the Medicare Benefit Policy Manual, Chapter 15, for general coverage requirements about physical therapy requirements.)

30.1.1 - Biofeedback Therapy for the Treatment of Urinary Incontinence

(Rev. 1, 10-03-03)
CIM 35-27.1

Biofeedback Therapy for the Treatment of Urinary Incontinence

This policy applies to biofeedback therapy rendered by a practitioner in an office or other facility setting.

Biofeedback is covered for the treatment of stress and/or urge incontinence in cognitively intact patients who have failed a documented trial of pelvic muscle exercise (PME) training. Biofeedback is not a treatment, per se, but a tool to help patients learn how to perform PME. Biofeedback-assisted PME incorporates the use of an electronic or mechanical device to relay visual and/or auditory evidence of pelvic floor muscle tone, in order to improve awareness of pelvic floor musculature and to assist patients in the performance of PME.

A failed trial of PME training is defined as no clinically significant improvement in urinary incontinence after completing four weeks of an ordered plan of pelvic muscle exercises to increase periurethral muscle strength.

Contractors may decide whether or not to cover biofeedback as an initial treatment modality.

Home use of biofeedback therapy is not covered.

30.2 - Thermogenic Therapy

(Rev. 1, 10-03-03)
CIM 35-6

Not Covered

Thermogenic therapy which is the production of artificial fever, has been in use since 1919 in the treatment of certain types of resistant infectious diseases, rheumatoid arthritis

and Sydenham's chorea. Regardless of the medium by which the fever is induced, this modality is not scientifically accepted for the treatment of any specific disease. Since the advent of potent antibiotics, the procedure has for all practical purposes been replaced as a mode of treatment. Therefore, thermogenic therapy is not considered reasonable and necessary for the treatment of an illness or injury as required by §1862(a)(1) of the Act. (Of course, where other covered services are needed and it would be reasonable and necessary that they be furnished on an inpatient hospital basis, payment would not be excluded for the inpatient stay, notwithstanding the fact that reimbursement may not be made for thermogenic therapy furnished during the hospital stay.)

30.3 - Acupuncture

(Rev. 10337, Issued: 08-27-20, Effective: 01-21-20, Implementation: 06-24 - 20 - A/B MACs; 10-05-20-SSM Edits; 01- 04-21 - BR 13 CWF only)

A. General

Acupuncture is the selection and manipulation of specific acupuncture points by a variety of needling and non-needling techniques.

B. Nationally Covered Indications

Effective for claims with dates of service on and after January 21, 2020, acupuncture is only covered for chronic low back pain under section 1862(a)(1)(A) of the Social Security Act (the Act). See National Coverage Determination section 30.3.3 for specific coverage criteria.

C. Nationally Non-Covered Indications

Medicare reimbursement for acupuncture, as an anesthetic, or as an analgesic or for other therapeutic purposes, may not be made unless the specific indication is excepted. All indications for acupuncture outside of NCD section 30.3.3 remain non-covered.

D. Other

N/A

(This NCD last reviewed January 2020.)

30.3.1 – Acupuncture for Fibromyalgia (Effective April 16, 2004)

(Rev. 10337, Issued: 08-27-20, Effective: 01-21-20, Implementation: 06-24 - 20 - A/B MACs; 10-05-20-SSM Edits; 01- 04-21 - BR 13 CWF only)

A. General

Acupuncture is the selection and manipulation of specific acupuncture points by a variety of needling and non-needling techniques.

B. Nationally Covered Indications

N/A for acupuncture for fibromyalgia.

C. Nationally Non-Covered Indications

Effective for claims with dates of service on and after April 16, 2004, after careful reconsideration of its initial non-coverage determination for acupuncture, the Centers for Medicare & Medicaid Services (CMS) concludes that there is no convincing evidence for the use of acupuncture for pain relief in patients with fibromyalgia. Study design flaws presently prohibit assessing acupuncture's utility for improving health outcomes. Accordingly, CMS determines that acupuncture is not considered reasonable and necessary for the treatment of fibromyalgia within the meaning of §1862(a)(1) of the Social Security Act, and the national non-coverage determination for acupuncture for fibromyalgia continues.

D. Other

N/A

(This NCD last reviewed April 2004.)

30.3.2 – Acupuncture for Osteoarthritis (Effective April 16, 2004)

(Rev. 10337, Issued: 08-27-20, Effective: 01-21-20, Implementation: 06-24 - 20 - A/B MACs; 10-05-20-SSM Edits; 01- 04-21 - BR 13 CWF only)

A. General

Acupuncture is the selection and manipulation of specific acupuncture points by a variety of needling and non-needling techniques.

B. Nationally Covered Indications

N/A for acupuncture for osteoarthritis.

C. Nationally Non-Covered Indications

Effective for claims with dates of service on and after April 16, 2004, after careful reconsideration of its initial non-coverage determination for acupuncture, the Centers for Medicare & Medicaid Services (CMS) concludes that there is no convincing evidence for the use of acupuncture for pain relief in patients with osteoarthritis. Study design flaws presently prohibit assessing acupuncture's utility for improving health outcomes. Accordingly, CMS determines that acupuncture is not considered reasonable and necessary for the treatment of osteoarthritis within the meaning of §1862(a)(1) of

the Social Security Act, and the national non-coverage determination for acupuncture for osteoarthritis continues.

D. Other

N/A

(This NCD last reviewed April 2004.)

30.3.3 – Acupuncture for Chronic Lower Back Pain (cLBP)

(Rev. 10337, Issued: 08-27-20, Effective: 01-21-20, Implementation: 06-24 - 20 - A/B MACs; 10-05-20-SSM Edits; 01- 04-21 - BR 13 CWF only)

A. General

Acupuncture is the selection and manipulation of specific acupuncture points by a variety of needling and non-needling techniques.

B. Nationally Covered Indications

Effective for services performed on or after January, 21, 2020, CMS will cover acupuncture for Medicare patients with chronic Lower Back Pain (cLBP.) Up to 12 visits in 90 days are covered for Medicare beneficiaries under the following circumstance:

- For the purpose of this decision, cLBP is defined as:
    - Lasting 12 weeks or longer;
    - nonspecific, in that it has no identifiable systemic cause (i.e., not associated with metastatic, inflammatory, infectious, etc. disease);
    - not associated with surgery; and,
    - not associated with pregnancy.

- An additional 8 sessions will be covered for those patients demonstrating an improvement.

- No more than 20 acupuncture treatments may be administered annually.

- Treatment must be discontinued if the patient is not improving or is regressing.

Physicians (as defined in 1861(r)(1) of the Social Security Act (the Act) may furnish acupuncture in accordance with applicable state requirements.

Physician assistants (PAs), nurse practitioners (NPs)/clinical nurse specialists (CNSs) (as identified in 1861(aa)(5) of the Act), and auxiliary personnel may furnish acupuncture if they meet all applicable state requirements and have:

- a masters or doctoral level degree in acupuncture or Oriental Medicine from a school accredited by the Accreditation Commission on Acupuncture and Oriental

Medicine (ACAOM); and,

- a current, full, active, and unrestricted license to practice acupuncture in a State, Territory, or Commonwealth (i.e. Puerto Rico) of the United States, or District of Columbia.

Auxiliary personnel furnishing acupuncture must be under the appropriate level of supervision of a physician, PA, or NP/CNS required by our regulations at 42 CFR §§ 410.26 and 410.27.

C. Nationally Non-Covered Indications

All types of acupuncture including dry needling for any condition other than cLBP are non-covered by Medicare.

D. Other

N/A

(This NCD last reviewed January 2020.)

30.4 - Electrosleep Therapy (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 Electrosleep Therapy. 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.

30.5 - Transcendental Meditation

(Rev. 1, 10-03-03)
CIM 35-92

Not Covered

Transcendental meditation (TM) is a skill that is claimed to produce a state of rest and relaxation when practiced effectively. Typically, patients are taught TM techniques over the course of several sessions by persons trained in TM. The patient then uses the TM technique on his or her own to induce the relaxed state. Proponents of TM have urged that Medicare cover the training of patients to practice TM when it is medically prescribed as treatment for mild hypertension, as adjunctive therapy in the treatment of essential hypertension, or as the sole or adjunctive treatment of anxiety and other psychological stress-related disorders.

After review of this issue, CMS has concluded that the evidence concerning the medical

efficacy of TM is incomplete at best and does not demonstrate effectiveness and that a professional level of skill is not required for the training of patients to engage in TM.

Although many articles have been written about application of TM for patients with certain forms of hypertension and anxiety, there are no rigorous scientific studies that demonstrate the effectiveness of TM for use as an adjunct medical therapy for such conditions. Accordingly, neither TM nor the training of patients for its use are covered under the Medicare program.

30.6 - Intravenous Histamine Therapy

(Rev. 1, 10-03-03)
CIM 35-19

The only accepted and scientifically valid medical use of histamine is diagnostic, including tests to assess:

- The ability of the stomach to secrete acid;
- The integrity of peripheral sensory nerves (e.g., in leprosy);
- The circulatory competency in limb extremities; and
- The presence of a pheochromocytoma.

However, there is no scientifically valid clinical evidence that histamine therapy is effective for any condition regardless of the method of administration, nor is it accepted or widely used by the medical profession. Therefore, histamine therapy cannot be considered reasonable and necessary, and program payment for such therapy is not made.

30.7 - Laetrile and Related Substances

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

Not Covered

Laetrile (and the other drugs called by the various terms mentioned below) have been used primarily in the treatment or control of cancer. Although the terms "Laetrile," "laetrile," "amygdalin," "Sarcarcinase," "vitamin B-17," and "nitriloside" have been used interchangeably, the chemical identity of the substances to which these terms refer has varied.

The FDA has determined that neither Laetrile nor any other drug called by the various terms mentioned above, nor any other product which might be characterized as a "nitriloside" is generally recognized (by experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs) to be safe and effective for any therapeutic use. Therefore, use of this drug cannot be considered to be reasonable and necessary within the meaning of §1862(a)(1) of the Act and program payment may not be made for its use or any services furnished in connection with its administration.

A hospital stay only for the purpose of having laetrile (or any other drug called by the terms mentioned above) administered is not covered. Also, program payment may not be made for laetrile (or other drug noted above) when it is used during the course of an otherwise covered hospital stay.

30.8 - Cellular Therapy

(Rev. 1, 10-03-03)
CIM 35-5

Not Covered

Cellular therapy involves the practice of injecting humans with foreign proteins like the placenta or lungs of unborn lambs. Cellular therapy is without scientific or statistical evidence to document its therapeutic efficacy and, in fact, is considered a potentially dangerous practice. Accordingly, cellular therapy is not considered reasonable and necessary within the meaning of §1862 (a) (1) of the Act.

30.9 - Transillumination Light Scanning, or Diaphanography

(Rev. 1, 10-03-03)
CIM 50-46

Not Covered

While transillumination light scanning, or diaphanography, for use in detection of cancer and other diseases of the breast, appears safe, the usefulness of this instrumentation, when compared to existing modes of cancer and other breast disease detection, has not clearly been established. Further study of this technology is needed to determine its role in breast cancer diagnosis. Program payment may not be made for this procedure at this time.

40 - Endocrine System and Metabolism

(Rev. 1, 10-03-03)

40.1 - Diabetes Outpatient Self-Management Training

(Rev. 1, 10-03-03)
CIM 80-2

Refer to 42 CFR 410.140 - 410.146 for conditions that must be met for Medicare coverage.

40.2 - Home Blood Glucose Monitors

(Rev. 48, Issued: 03-17-06; Effective/Implementation Dates: 06-19-06)
CIM 60-11

There are several different types of blood glucose monitors that use reflectance meters to determine blood glucose levels. Medicare coverage of these devices varies, with respect

to both the type of device and the medical condition of the patient for whom the device is prescribed.

Reflectance colorimeter devices used for measuring blood glucose levels in clinical settings are not covered as durable medical equipment for use in the home because their need for frequent professional re-calibration makes them unsuitable for home use. However, some types of blood glucose monitors which use a reflectance meter specifically designed for home use by diabetic patients may be covered as durable medical equipment, subject to the conditions and limitations described below.

Blood glucose monitors are meter devices that read color changes produced on specially treated reagent strips by glucose concentrations in the patient's blood. The patient, using a disposable sterile lancet, draws a drop of blood, places it on a reagent strip and, following instructions which may vary with the device used, inserts it into the device to obtain a reading. Lancets, reagent strips, and other supplies necessary for the proper functioning of the device are also covered for patients for whom the device is indicated. Home blood glucose monitors enable certain patients to better control their blood glucose levels by frequently checking and appropriately contacting their attending physician for advice and treatment. Studies indicate that the patient's ability to carefully follow proper procedures is critical to obtaining satisfactory results with these devices. In addition, the cost of the devices, with their supplies, limits economical use to patients who must make frequent checks of their blood glucose levels. Accordingly, coverage of home blood glucose monitors is limited to patients meeting the following conditions:

1. The patient has been diagnosed as having diabetes;

2. The patient's physician states that the patient is capable of being trained to use the particular device prescribed in an appropriate manner. In some cases, the patient may not be able to perform this function, but a responsible individual can be trained to use the equipment and monitor the patient to assure that the intended effect is achieved. This is permissible if the record is properly documented by the patient's physician; and

3. The device is designed for home rather than clinical use.

There is also a blood glucose monitoring system designed especially for use by those with visual impairments. The monitors used in such systems are identical in terms of reliability and sensitivity to the standard blood glucose monitors described above. They differ by having such features as voice synthesizers, automatic timers, and specially designed arrangements of supplies and materials to enable the visually impaired to use the equipment without assistance.

These special blood glucose monitoring systems are covered under Medicare if the following conditions are met:

- The patient and device meet the three conditions listed above for coverage of standard home blood glucose monitors; and

- The patient's physician certifies that he or she has a visual impairment severe enough to require use of this special monitoring system.

The additional features and equipment of these special systems justify a higher reimbursement amount than allowed for standard blood glucose monitors. Separately identify claims for such devices and establish a separate reimbursement amount for them.

40.3 - Closed-Loop Blood Glucose Control Device (CBGCD)

(Rev. 1, 10-03-03)
CIM 35-70

The closed-loop blood glucose control device (CBGCD) is a hospital bedside device designed for short-term management of patients with insulin dependent diabetes mellitus (Type I). It consists of a rapid on-line glucose analyzer; a computer with a controller for the calculation and control of the infusion of either insulin or dextrose; a multi-channel infusion system; and a printer designed to record continuous glucose values and to provide cumulative totals of the substances infused. Its primary use is for the stabilization of Type I diabetics during periods of stress, such as trauma, labor and delivery, and surgery, when there are wide fluctuations in blood sugar levels. It serves to temporarily correct abnormal blood glucose levels (hyper- or hypo-glycemia) and this correction is made by infusion of either insulin or dextrose. Its use is generally limited to a 24- to 48-hour period because of potential complications; (e.g., sepsis, thromboses, and nonportability, etc.). The CBGCD requires specialized training for use and interpretation of its diagnostic and therapeutic contribution and continuous observation by specially trained medical personnel.

Use of the CBGCD is covered for short-term management of insulin dependent diabetics in crisis situations, in a hospital inpatient setting, and only under the direction of specially trained medical personnel.

40.4 - Insulin Syringe

(Rev. 1, 10-03-03)
CIM 45-3

Medical supplies are covered under §1861(s)(2)(A) of the Act only when they are furnished incident to a physician's professional services. To be covered under this provision an insulin syringe must have been used by the physician or under his/her direct personal supervision, and the insulin injection must have been given in an emergency situation (e.g., diabetic coma).

The use of an insulin syringe by a diabetic would not meet the requirements of §1861(s)(2)(A) of the Act. See the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §30.

40.5 – Treatment of Obesity

(Rev. 158, Issued: 12-23-13, Effective: 09-24-13, Implementation: 12-17-13)

Please note section 40.5 has been removed from the NCD Manual and incorporated into NCD 100.1.

40.7 – Outpatient Intravenous Insulin Treatment (Effective December 23, 2009)

(Rev. 117, Issued: 03-09-10, Effective Date: 12-23-09; Implementation Date: 04-05-10)

A. General

The term outpatient intravenous (IV) insulin therapy (OIVIT) refers to an outpatient regimen that integrates pulsatile or continuous intravenous infusion of insulin via any means, guided by the results of measurement of:

- respiratory quotient; and/or
- urine urea nitrogen (UUN); and/or
- arterial, venous, or capillary glucose; and/or
- potassium concentration; and

performed in scheduled recurring periodic intermittent episodes.

This regimen is also sometimes termed Cellular Activation Therapy (CAT), Chronic Intermittent Intravenous Insulin Therapy (CIIT), Hepatic Activation Therapy (HAT), Intercellular Activation Therapy (iCAT), Metabolic Activation Therapy (MAT), Pulsatile Intravenous Insulin Treatment (PIVIT), Pulse Insulin Therapy (PIT), and Pulsatile Therapy (PT).

In OIVIT, insulin is intravenously administered in the outpatient setting for a variety of indications. Most commonly, it is delivered in pulses, but it may be delivered as a more conventional drip solution. The insulin administration is adjunctive to the patient's routine diabetic management regimen (oral agent or insulin-based) or other disease management regimen, typically performed on an intermittent basis (often weekly), and frequently performed chronically without duration limits. Glucose or other carbohydrate is available ad libitum (in accordance with patient desire).

B. Nationally Covered Indications

N/A

C. Nationally Non-Covered Indications

Effective for claims with dates of service on and after December 23, 2009, the Centers for Medicare and Medicaid Services (CMS) determines that the evidence does not support a conclusion that OIVIT improves health outcomes in Medicare beneficiaries.

Therefore, CMS has determined that OIVIT is not reasonable and necessary for any indication under section 1862(a)(1)(A) of the Social Security Act. Services comprising an OIVIT regimen are nationally non-covered under Medicare when furnished pursuant to an OIVIT regimen (see subsection A. above).

D. Other

Individual components of OIVIT may have medical uses in conventional treatment regimens for diabetes and other conditions. Coverage for such other uses may be determined by other local or national Medicare determinations, and do not pertain to OIVIT. For example, see Pub. 100-03, NCD Manual, Section 40.2, Home Blood Glucose Monitors, Section 40.3, Closed-loop Blood Glucose Control Devices (CBGCD), Section 190.20, Blood Glucose Testing, and Section 280.14, Infusion Pumps, as well as Pub. 100-04, Claims Processing Manual, Chapter 18, Section 90, Diabetics Screening.

(This NCD last reviewed December 2009.)

50 - Ear, Nose and Throat (ENT)

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

50.1 - Speech Generating Devices

(Rev. 184, Issued: 08-21-15, Effective: 07-29-15, Implementation: 09-21-15)

A. General

Speech generating devices are considered to fall within the durable medical equipment (DME) benefit category established by §1861(n) of the Social Security Act. They are covered for patients who suffer from a severe speech impairment and have a medical condition that warrants the use of a device based on the following definitions.

Speech generating devices are defined as durable medical equipment that provides an individual who has a severe speech impairment with the ability to meet his or her functional, speaking needs. Speech generating devices are speech aids consisting of devices or software that generate speech and are used solely by the individual who has a severe speech impairment. The speech is generated using one of the following methods:

- digitized audible/verbal speech output, using prerecorded messages;
- synthesized audible/verbal speech output which requires message formulation by spelling and device access by physical contact with the device-direct selection techniques;
- synthesized audible/verbal speech output which permits multiple methods of message formulation and multiple methods of device access; or

- software that allows a computer or other electronic device to generate audible/verbal speech.

Other covered features of the device include the capability to generate email, text, or phone messages to allow the patient to "speak" or communicate remotely, as well as the capability to download updates to the covered features of the device from the manufacturer or supplier of the device.

If a speech generating device is limited to use by a patient with a severe speech impairment and is primarily used for the purpose of generating speech, it is not necessary for the device to be dedicated only to audible/verbal speech output to be considered DME. Computers and tablets are generally not considered DME because they are useful in the absence of an illness or injury.

B. Nationally Covered Indications

N/A

C. Nationally Non-Covered Indications

Internet or phone services or any modification to a patient's home to allow use of the speech generating device are not covered by Medicare because such services or modifications could be used for non-medical equipment such as standard phones or personal computers. In addition, specific features of a speech generating device that are not used by the individual who has a severe speech impairment to meet his or her functional speaking needs are not covered. This would include any computing hardware or software not necessary to allow for generation of audible/verbal speech, email, text or phone messages, such as hardware or software used to create documents and spreadsheets or play games or music, and any other function a computer can perform that is not directly related to meeting the functional speaking communication needs of the patient, including video communications or conferencing. These features of a speech generating device do not fall within the scope of § 1861(n) of the Social Security Act and the cost of these features are the responsibility of the beneficiary. Suppliers of speech generating devices are encouraged to furnish the beneficiary with a voluntary Advance Beneficiary Notice (ABN), or similar notice, which informs that these features are not covered and to alert the beneficiary of the expense of these features.

D. Other

A/B MACs acting within their respective jurisdictions have discretion to cover or not cover speech generating devices based on their individual reasonable and necessary determinations.

(This NCD last reviewed July 2015.)

50.2 - Electronic Speech Aids

(Rev. 1, 10-03-03)
CIM 65-5

Electronic speech aids are covered under Part B as prosthetic devices when the patient has had a laryngectomy or his larynx is permanently inoperative. There are two types of speech aids. One operates by placing a vibrating head against the throat; the other amplifies sound waves through a tube which is inserted into the user's mouth. A patient who has had radical neck surgery and/or extensive radiation to the anterior part of the neck would generally be able to use only the "oral tube" model or one of the more sensitive and more expensive "throat contact" devices.

Cross-reference:

The Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §120.

50.3 - Cochlear Implantation (Effective April 4, 2005)

(Rev. 11875; Issued:02-23-23; Effective: 09-26-22; Implementation: 03-24-23)

A. General

A cochlear implant device is an electronic instrument, part of which is implanted surgically to stimulate auditory nerve fibers, and part of which is worn or carried by the individual to capture, analyze, and code sound. Cochlear implant devices are available in single-channel and multi-channel models. The purpose of implanting the device is to provide awareness and identification of sounds and to facilitate communication for persons who are moderately to profoundly hearing impaired.

B. Nationally Covered Indications

Effective for services performed on or after September 26, 2022, cochlear implantation may be covered for treatment of bilateral pre- or post-linguistic, sensorineural, moderate-to-profound hearing loss in individuals who demonstrate limited benefit from amplification. Limited benefit from amplification is defined by test scores of less than or equal to 60% correct in the best-aided listening condition on recorded tests of open-set sentence recognition. Patients must meet all of the following criteria.

- Diagnosis of bilateral moderate-to-profound sensorineural hearing impairment with limited benefit from appropriate hearing (or vibrotactile) aids;
- Cognitive ability to use auditory clues and a willingness to undergo an extended program of rehabilitation;
- Freedom from middle ear infection, an accessible cochlear lumen that is structurally suited to implantation, and freedom from lesions in the auditory nerve and acoustic areas of the central nervous system;

- No contraindications to surgery; and
- The device must be used in accordance with Food and Drug Administration (FDA)-approved labeling.

C. Nationally Non-Covered Indications

Medicare beneficiaries not meeting all of the coverage criteria for cochlear implantation listed in Section B are deemed not eligible for Medicare coverage except as described in Section D below.

D. Other

CMS may provide coverage of cochlear implants for beneficiaries not meeting the coverage criteria listed in Section B when performed in the context of FDA-approved category B investigational device exemption clinical trials as defined at 42 CFR 405.201 or as a routine cost in clinical trials under section 310.1 of the National Coverage Determinations Manual titled Routine Costs in Clinical Trials.

(This NCD last reviewed September 2022)

50.4 - Tracheostomy Speaking Valve

(Rev. 1, 10-03-03)
CIM 65-16

A trachea tube has been determined to satisfy the definition of a prosthetic device, and the tracheostomy speaking valve is an add on to the trachea tube which may be considered a medically necessary accessory that enhances the function of the tube. In other words, it makes the system a better prosthesis. As such, a tracheostomy speaking valve is covered as an element of the trachea tube which makes the tube more effective.

50.5 - Oxygen Treatment of Inner Ear/Carbon Therapy

(Rev. 1, 10-03-03)
CIM 35-29

Not Covered

Oxygen (95 percent) and carbon dioxide (5 percent) inhalation therapy for inner ear disease, such as endolymphatic hydrops and fluctuant hearing loss, is not reasonable and necessary. The therapeutic benefit deriving from this procedure is highly questionable.

50.6 - Tinnitus Masking (RETIRED)

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

This section of the NCD Manual was retired December 18, 2014.

50.7 - Cochleostomy With Neurovascular Transplant for Meniere's

Disease
(Rev. 1, 10-03-03)
CIM 35-50

Not Covered

Meniere's disease (or syndrome) is a common cause of paroxysmal vertigo. Meniere's syndrome is usually treated medically. When medical treatment fails, surgical treatment may be required.

While there are two recognized surgical procedures used in treating Meniere's disease (decompression of the endolymphatic hydrops and labyrinthectomy), there is no scientific evidence supporting the safety and effectiveness of cochleostomy with neurovascular transplant in treatment of Meniere's syndrome. Accordingly, Medicare does not cover cochleostomy with neurovascular transplant for treatment of Meniere's disease.

50.8 - Ultrasonic Surgery
(Rev. 1, 10-03-03)
CIM 35-4

Reimbursement may be made for ultrasonic surgery when required in the treatment of patients with severe and recurrent episodes of vertigo due to Meniere's syndrome. This procedure utilizes a machine that produces ultrasonic waves of high intensity and frequency that selectively irradiate certain portions of the inner ear thereby destroying the tissue. The procedure is usually done under local anesthesia, and requires the services of a surgeon and another individual who is responsible for calibrating the electrical equipment, and who assists in observing certain physical changes (e.g., movement of the eyes, "nystagmus") indicative of inner ear reaction to the ultrasonic destruction. Except in rare instances the desired result is achieved with one treatment. At present, there are two different approaches being used to apply the ultrasound to the inner ear: one through the lateral semicircular canal and, more recently, a simpler approach from a technical viewpoint, through the round window.

60 - Emergency Medicine
(Rev. 1, 10-03-03)

No coverage determinations.

70 - Evaluation and Management of Patients - Office/hospital/home
(Rev. 1, 10-03-03)

70.1 - Consultations With a Beneficiary's Family and Associates
(Rev. 1, 10-03-03)
CIM 35-14

In certain types of medical conditions, including when a patient is withdrawn and

uncommunicative due to a mental disorder or comatose, the physician may contact relatives and close associates to secure background information to assist in diagnosis and treatment planning. When a physician contacts his patient's relatives or associates for this purpose, expenses of such interviews are properly chargeable as physician's services to the patient on whose behalf the information was secured. If the beneficiary is not an inpatient of a hospital, Part B reimbursement for such an interview is subject to the special limitation on payments for physicians' services in connection with mental, psychoneurotic, and personality disorders.

A physician may also have contacts with a patient's family and associates for purposes other than securing background information. In some cases, the physician will provide counseling to members of the household. Family counseling services are covered only where the primary purpose of such counseling is the treatment of the patient's condition.

For example, two situations where family counseling services would be appropriate are as follows: (1) where there is a need to observe the patient's interaction with family members; and/or (2) where there is a need to assess the capability of and assist the family members in aiding in the management of the patient. Counseling principally concerned with the effects of the patient's condition on the individual being interviewed would not be reimbursable as part of the physician's personal services to the patient. While to a limited degree, the counseling described in the second situation may be used to modify the behavior of the family members, such services nevertheless are covered because they relate primarily to the management of the patient's problems and not to the treatment of the family member's problems.

Cross-references:

The Medicare Benefit Policy Manual, Chapter 6, "Hospital Services Covered Under Part B,"§20.

The Medicare Claims Processing Manual, Chapter 12, "Physician/Practitioner Billing," §10.

The Medicare General Information, Eligibility, and Entitlement Manual, Chapter 3, "Deductibles, Coinsurance Amounts, and Payment Limitations," §30.

70.2 - Consultation Services Rendered by a Podiatrist in a Skilled Nursing Facility

(Rev. 1, 10-03-03)
CIM 50-8

Consultation services rendered by a podiatrist in a skilled nursing facility are covered if the services are reasonable and necessary and do not come within any of the specific statutory exclusions. Section 1862(a)(13) of the Act excludes payment for the treatment of flat foot conditions, the treatment of subluxations of the foot, and routine foot care. To determine whether the consultation comes within the foot care exclusions, apply the same

rule as for initial diagnostic examinations, i.e., where services are performed in connection with specific symptoms or complaints which suggest the need for, covered services, the services are covered regardless of the resulting diagnosis. The exclusion of routine physician examinations is also pertinent and would generally exclude podiatric consultation performed on all patients in a skilled nursing facility on a routine basis for screening purposes, except in those cases where a specific foot ailment is involved. Section 1862(a)(7) of the Act excludes payment for routine physical checkups. (See the Medicare Benefit Policy Manual, Chapter 16, "General Exclusions from Coverage," §90 and §100.)

70.2.1 - Services Provided for the Diagnosis and Treatment of Diabetic Sensory Neuropathy with Loss of Protective Sensation (aka Diabetic Peripheral Neuropathy)

(Rev. 1, 10-03-03)
CIM 50-8.1

Presently, peripheral neuropathy, or diabetic sensory neuropathy, is the most common factor leading to amputation in people with diabetes. In diabetes, sensory neuropathy is an anatomically diffuse process primarily affecting sensory and autonomic fibers; however, distal motor findings may be present in advanced cases. Long nerves are affected first, with symptoms typically beginning insidiously in the toes and then advancing proximally. This leads to loss of protective sensation (LOPS), whereby a person is unable to feel minor trauma from mechanical, thermal, or chemical sources. When foot lesions are present, the reduction in autonomic nerve functions may also inhibit wound healing.

Diabetic sensory neuropathy with LOPS is a localized illness of the feet and falls within the regulation's exception to the general exclusionary rule (see 42 CFR 411.15(l)(1)(i)). Foot exams for people with diabetic sensory neuropathy with LOPS are reasonable and necessary to allow for early intervention in serious complications that typically afflict diabetics with the disease.

Effective for services furnished on or after July 1, 2002, Medicare covers, as a physician service, an evaluation (examination and treatment) of the feet no more often than every six months for individuals with a documented diagnosis of diabetic sensory neuropathy and LOPS, as long as the beneficiary has not seen a foot care specialist for some other reason in the interim. LOPS shall be diagnosed through sensory testing with the 5.07 monofilament using established guidelines, such as those developed by the National Institute of Diabetes and Digestive and Kidney Diseases guidelines. Five sites should be tested on the plantar surface of each foot, according to the National Institute of Diabetes and Digestive and Kidney Diseases guidelines. The areas must be tested randomly since the loss of protective sensation may be patchy in distribution, and the patient may get clues if the test is done rhythmically. Heavily callused areas should be avoided. As suggested by the American Podiatric Medicine Association, an absence of sensation at two or more sites out of 5 tested on either foot when tested with the 5.07 Semmes-Weinstein monofilament must be present and documented to diagnose peripheral

neuropathy with loss of protective sensation.

The examination includes:

1. A patient history, and

2. A physical examination that must consist of at least the following elements:

   - Visual inspection of forefoot and hindfoot (including toe web spaces);
   - Evaluation of protective sensation;
   - Evaluation of foot structure and biomechanics;
   - Evaluation of vascular status and skin integrity;
   - Evaluation of the need for special footwear; and

3 Patient education.

A. Treatment includes, but is not limited to:

- Local care of superficial wounds;
- Debridement of corns and calluses; and
- Trimming and debridement of nails.

The diagnosis of diabetic sensory neuropathy with LOPS should be established and documented prior to coverage of foot care. Other causes of peripheral neuropathy should be considered and investigated by the primary care physician prior to initiating or referring for foot care for persons with LOPS.

70.3 - Physician's Office within an Institution - Coverage of Services and Supplies Incident to a Physician's Services

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

Coverage of Services and Supplies Incident to a Physician's Services

Where a physician establishes an office within a nursing home or other institution, coverage of services and supplies furnished in the office must be determined in accordance with the "incident to a physician's professional service" provision (see the Medicare Benefit Policy Manual, Chapter 6, "Hospital Services Covered Under Part B," §20.4.1 or the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §60.1) as in any physician's office. A physician's office within an institution must be confined to a separately identified part of the facility which is used solely as the physician's office and cannot be construed to extend throughout the entire institution. Thus, services performed outside the "office" area would be subject to the coverage rules applicable to services furnished outside the office setting.

In order to accurately apply the criteria in the Medicare Benefit Policy Manual, Chapters 6, §20.4.1, or Chapter 15, "Covered Medical and Other Health Services," §60.1, the A/B MAC gives consideration to the physical proximity of the institution and physician's office. When his office is located within a facility, a physician may not be reimbursed for services, supplies, and use of equipment which fall outside the scope of services "commonly furnished" in physician's offices generally, even though such services may be furnished in his institutional office. Additionally, make a distinction between the physician's office practice and the institution, especially when the physician is administrator or owner of the facility. Thus, for their services to be covered under the criteria in the Medicare Benefit Policy Manual, Chapter 6, §20.4.1, or the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §60.1, the auxiliary medical personnel must be members of the office staff rather than of the institution's staff, and the cost of supplies must represent an expense to the physician's office practice. Finally, services performed by the employees of the physician outside the "office" area must be directly supervised by the physician; his presence in the facility as a whole would not suffice to meet this requirement. (In any setting, of course, supervision of auxiliary personnel in and of itself is not considered a "physician's professional service" to which the services of the auxiliary personnel could be an incidental part, i.e., in addition to supervision, the physician must perform or have performed a personal professional service to the patient to which the services of the auxiliary personnel could be considered an incidental part.) Denials for failure to meet any of these requirements would be based on §1861(s)(2)(A) of the Social Security Act.

Establishment of an office within an institution would not modify rules otherwise applicable for determining coverage of the physician's personal professional services within the institution. However, in view of the opportunity afforded to a physician who maintains such an office for rendering services to a sizable number of patients in a short period of time or for performing frequent services for the same patient, claims for physicians' services rendered under such circumstances would require careful evaluation by the A/B MAC to assure that payment is made only for services that are reasonable and necessary.

Cross-reference:

The Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services."

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

70.4 - Pronouncement of Death

(Rev. 1, 10-03-03)
CIM 50-19

According to established legal principles, an individual is not considered deceased until there has been official pronouncement of death. An individual is therefore considered to

have expired as of the time he/she is pronounced dead by a person who is legally authorized to make such a pronouncement, usually a physician. Reasonable and necessary medical services rendered up to and including pronouncement of death by a physician are covered diagnostic or therapeutic services.

70.5 - Hospital and Skilled Nursing Facility Admission Diagnostic Procedures

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

These instructions describe the application of the reasonable and necessary payment exclusion to diagnostic procedures, such as chest x-rays, urinalysis, etc. provided to patients upon admission to a hospital or skilled nursing facility.

The major factors which support a determination that a diagnostic procedure performed as part of the admitting procedure to a hospital or skilled nursing facility is reasonable and necessary, are:

A. The test is specifically ordered by the admitting physician (or a hospital or skilled nursing facility staff physician having responsibility for the patient where there is no admitting physician): i.e., it is not furnished under the standing orders of a physician for his patients;

B. The test is medically necessary for the diagnosis or treatment of the individual patient's condition; and

C. The test does not unnecessarily duplicate the same test performed on an outpatient basis prior to admission or performed in connection with a recent hospital or skilled nursing facility admission.

Where the A/B MAC has not already done so, consult with the Quality Improvement Organizations (QIOs) to obtain information gathered by the QIOs on a sample basis as to whether x-rays and diagnostic tests are being specifically ordered as described under subsection (A).

80 - Eye

(Rev. 1, 10-03-03)

80.1 - Hydrophilic Contact Lens for Corneal Bandage

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

Some hydrophilic contact lenses are used as moist corneal bandages for the treatment of acute or chronic corneal pathology, such as bulbous keratopathy, dry eyes, corneal ulcers and erosion, keratitis, corneal edema, descemetocele, corneal ectasis, Mooren's ulcer,

anterior corneal dystrophy, neurotrophic keratoconjunctivitis, and for other therapeutic reasons.

Payment may be made under §1861(s)(2) of the Social Security Act for a hydrophilic contact lens approved by the Food and Drug Administration (FDA) and used as a supply incident to a physician's service. Payment for the lens is included in the payment for the physician's service to which the lens is incident. A/B MACs are authorized to accept an FDA letter of approval or other FDA published material as evidence of FDA approval. (See §80.4 for coverage of a hydrophilic contact lens as a prosthetic device.) See the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," and the Medicare Benefit Policy Manual, Chapter 6, "Hospital Services Covered Under Part B," §20.4.

80.2 - Photodynamic Therapy

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

Photodynamic therapy is a medical procedure which involves the infusion of a photosensitive (light-activated) drug with a very specific absorption peak. This drug is chemically designed to have a unique affinity for the diseased tissue intended for treatment. Once introduced to the body, the drug accumulates and is retained in diseased tissue to a greater degree than in normal tissue. Infusion is followed by the targeted irradiation of this tissue with a non-thermal laser, calibrated to emit light at a wavelength that corresponds to the drug's absorption peak. The drug then becomes active and locally treats the diseased tissue.

Ocular Photodynamic Therapy (OPT)

Ocular Photodynamic Therapy (OPT) is used in the treatment of ophthalmologic diseases. OPT is only covered when used in conjunction with verteporfin (see section 80.3, "Photosensitive Drugs").

- Classic Subfoveal Choroidal Neovascular (CNV) Lesions - OPT is covered with a diagnosis of neovascular age-related macular degeneration (AMD) with predominately classic subfoveal choroidal neovascular (CNV) lesions (where the area of classic CNV occupies ≥50% of the area of the entire lesion) at the initial visit as determined by a fluorescein angiogram (FA). Subsequent follow-up visits will require either an optical coherence tomography or an FA to access treatment response. There are no requirements regarding visual acuity, lesion size, and number of re-treatments.

- Occult Subfoveal CNV Lesions - OPT is non-covered for patients with a diagnosis of AMD with occult and no classic CNV lesions.

Other Conditions - Use of OPT with verteporfin for other types of AMD (e.g., patients with minimally classic CNV lesions, atrophic, or dry AMD) is non-covered. OPT with

verteporfin for other ocular indications such as pathologic myopia or presumed ocular histoplasmosis syndrome, is eligible for coverage through individual A/B MAC discretion.

80.2.1 - Ocular Photodynamic Therapy (OPT) - Effective April 3, 2013

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

A. General

Ocular Photodynamic Therapy (OPT) is used in the treatment of ophthalmologic diseases; specifically, for age-related macular degeneration (AMD), a common eye disease among the elderly. OPT involves the infusion of an intravenous photosensitizing drug called verteporfin followed by exposure to a laser. OPT is only covered when used in conjunction with verteporfin.

Effective July 1, 2001, OPT with verteporfin was approved for a diagnosis of neovascular AMD with predominately classic subfoveal choroidal neovascularization (CNV) lesions (where the area of classic CNV occupies ≥50% of the area of the entire lesion) at the initial visit as determined by a fluorescein angiogram (FA).

On October 17, 2001, the Centers for Medicare & Medicaid Services (CMS) announced its "intent to cover" OPT with verteporfin for AMD patients with occult and no classic subfoveal CNV as determined by an FA. The October 17, 2001, decision was never implemented.

On March 28, 2002, after thorough review and reconsideration of the October 17, 2001, intent to cover policy, CMS determined that the current non-coverage policy for OPT for verteporfin for AMD patients with occult and no classic subfoveal CNV as determined by an FA should remain in effect.

Effective August 20, 2002, CMS issued a non-coverage instruction for OPT with verteporfin for AMD patients with occult and no classic subfoveal CNV as determined by an FA.

B. Nationally Covered Indications

Effective April 1, 2004, OPT with verteporfin continues to be approved for a diagnosis of neovascular AMD with predominately classic subfoveal CNV lesions (where the area of classic CNV occupies ≥50% of the area of the entire lesion) at the initial visit as determined by an FA. (CNV lesions are comprised of classic and/or occult components.) Subsequent follow-up visits require either an optical coherence tomography (OCT) (effective April 3. 2013) or an FA (effective April 1, 2004) to access treatment response. There are no requirements regarding visual acuity, lesion size, and number of re-treatments when treating predominantly classic lesions.

In addition, after thorough review and reconsideration of the August 20, 2002, non-coverage policy, CMS determines that the evidence is adequate to conclude that OPT with verteporfin is reasonable and necessary for treating:

1. Subfoveal occult with no classic CNV associated with AMD; and,

2. Subfoveal minimally classic CNV (where the area of classic CNV occupies <50% of the area of the entire lesion) associated with AMD.

The above 2 indications are considered reasonable and necessary only when:

1. The lesions are small (4 disk areas or less in size) at the time of initial treatment or within the 3 months prior to initial treatment; and,

2. The lesions have shown evidence of progression within the 3 months prior to initial treatment. Evidence of progression must be documented by deterioration of visual acuity (at least 5 letters on a standard eye examination chart), lesion growth (an increase in at least 1 disk area), or the appearance of blood associated with the lesion.

C. Nationally Non-Covered Indications

Other uses of OPT with verteporfin to treat AMD not already addressed by CMS will continue to be non-covered. These include, but are not limited to, the following AMD indications:

- Juxtafoveal or extrafoveal CNV lesions (lesions outside the fovea),
- Inability to obtain a fluorescein angiogram,
- Atrophic or "dry" AMD.

D. Other

The OPT with verteporfin for other ocular indications, such as pathologic myopia or presumed ocular histoplasmosis syndrome, continue to be eligible for local coverage determinations through individual A/B MAC discretion.

80.3 - Photosensitive Drugs

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

Photosensitive drugs are the light-sensitive agents used in photodynamic therapy. Once introduced into the body, these drugs selectively identify and adhere to diseased tissue. The drugs remain inactive until they are exposed to a specific wavelength of light, by means of a laser, that corresponds to their absorption peak. The activation of a photosensitive drug results in a photochemical reaction which treats the diseased tissue without affecting surrounding normal tissue.

Verteporfin

Verteporfin, a benzoporphyrin derivative, is an intravenous lipophilic photosensitive drug with an absorption peak of 690 nm. This drug was first approved by the Food and Drug Administration on April 12, 2000, and subsequently, approved for inclusion in the United States Pharmacopoeia on July 18, 2000, meeting Medicare's definition of a drug when used in conjunction with ocular photodynamic therapy (OPT) (see section 80.2, "Photodynamic Therapy") when furnished intravenously incident to a physician's service. For patients with age-related macular degeneration (AMD), verteporfin is only covered with a diagnosis of neovascular AMD with predominately classic subfoveal choroidal neovascular (CNV) lesions (where the area of classic CNV occupies ≥50% of the area of the entire lesion) at the initial visit as determined by a fluorescein angiogram (FA). Subsequent follow-up visits will require either an optical coherence tomography or an FA to access treatment response. OPT with verteporfin is covered for the above indication and will remain non-covered for all other indications related to AMD (see section 80.2). OPT with verteporfin for use in non-AMD conditions is eligible for coverage through individual A/B MAC discretion.

80.3.1 - Verteporfin - Effective April 3, 2013

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

A. General

Verteporfin, a benzoporphyrin derivative, is an intravenous lipophilic photosensitive drug with an absorption peak of 690 nm. Verteporfin was first approved by the Food and Drug Administration on April 12, 2000, and subsequently approved for inclusion in the United States Pharmacopoeia on July 18, 2000, meeting Medicare's definition of a drug as defined under §1861(t)(1) of the Social Security Act. Verteporfin is only covered when used in conjunction with ocular photodynamic therapy (OPT) when furnished intravenously incident to a physician's service.

B. Nationally Covered Indications

Effective April 1, 2004, OPT with verteporfin is covered for patients with a diagnosis of neovascular age-related macular degeneration (AMD) with:

- Predominately classic subfoveal choroidal neovascularization (CNV) lesions (where the area of classic CNV occupies ≥50% of the area of the entire lesion) at the initial visit as determined by a fluorescein angiogram (FA). (CNV lesions are comprised of classic and/or occult components.) Subsequent follow-up visits require either an optical coherence tomography (effective April 3, 2013) or an FA (effective April 1, 2004) to access treatment response.

There are no requirements regarding visual acuity, lesion size, and number of retreatments when treating predominantly classic lesions.

- Subfoveal occult with no classic CNV associated with AMD.

- Subfoveal minimally classic CNV (where the area of classic CNV occupies <50% of the area of the entire lesion) associated with AMD.

The above 2 indications are considered reasonable and necessary only when:

1. The lesions are small (4 disk areas or less in size) at the time of initial treatment or within the 3 months prior to initial treatment; and,

2. The lesions have shown evidence of progression within the 3 months prior to initial treatment. Evidence of progression must be documented by deterioration of visual acuity (at least 5 letters on a standard eye examination chart), lesion growth (an increase in at least 1 disk area), or the appearance of blood associated with the lesion.

C. Nationally Non-Covered Indications

Other uses of OPT with verteporfin to treat AMD not already addressed by the Centers for Medicare & Medicaid Services will continue to be non-covered. These include, but are not limited to, the following AMD indications: juxtafoveal or extrafoveal CNV lesions (lesions outside the fovea), inability to obtain an FA, or atrophic or "dry" AMD.

D. Other

The OPT with verteporfin for other ocular indications, such as pathologic myopia or presumed ocular histoplasmosis syndrome, continue to be eligible for local coverage determinations through individual A/B MAC discretion.

80.4 - Hydrophilic Contact Lenses

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

Hydrophilic contact lenses are eyeglasses within the meaning of the exclusion in §1862(a)(7) of the Social Security Act and are not covered when used in the treatment of non-diseased eyes with spherical ametrophia, refractive astigmatism, and/or corneal astigmatism. Payment may be made under the prosthetic device benefit, however, for hydrophilic contact lenses when prescribed for an aphakic patient.

A/B MACs are authorized to accept a Food and Drug Administration (FDA**)** letter of approval or other FDA-published material as evidence of FDA approval. (See §80.1 for coverage of a hydrophilic lens as a corneal bandage.)

Cross-references:

The Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §100 and §120.

The Medicare Benefit Policy Manual, Chapter 16, "General Exclusions from Coverage," §20 and §90.

80.5 - Scleral Shell

(Rev. 1, 10-03-03)
CIM 65.3

Scleral shell (or shield) is a catchall term for different types of hard scleral contact lenses. A scleral shell fits over the entire exposed surface of the eye as opposed to a corneal contact lens which covers only the central non-white area encompassing the pupil and iris. Where an eye has been rendered sightless and shrunken by inflammatory disease, a scleral shell may, among other things, obviate the need for surgical enucleation and prosthetic implant and act to support the surrounding orbital tissue. In such a case, the device serves essentially as an artificial eye. In this situation, payment may be made for a scleral shell under §1861(s)(8) of the Act.

Scleral shells are occasionally used in combination with artificial tears in the treatment of "dry eye" of diverse etiology. Tears ordinarily dry at a rapid rate, and are continually replaced by the lacrimal gland. When the lacrimal gland fails, the half-life of artificial tears may be greatly prolonged by the use of the scleral contact lens as a protective barrier against the drying action of the atmosphere. Thus, the difficult and sometimes hazardous process of frequent installation of artificial tears may be avoided. The lens acts in this instance to substitute, in part, for the functioning of the diseased lacrimal gland and would be covered as a prosthetic device in the rare case when it is used in the treatment of "dry eye."

Cross-references:

The Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §120 and §130

The Medicare Benefit Policy Manual, Chapter 1, "Inpatient Hospital Services," §40 and §120.1.

80.6 - Intraocular Photography

(Rev. 1, 10-03-03)
CIM 35-39

Intraocular photography is covered when used for the diagnosis of such conditions as macular degeneration, retinal neoplasms, choroid disturbances and diabetic retinopathy,

or to identify glaucoma, multiple sclerosis and other central nervous system abnormalities. Make Medicare payment for the use of this procedure by an opthalmologist in these situations when it is reasonable and necessary for the individual patient to receive these services.

80.7 - Refractive Keratoplasty

(Rev. 1, 10-03-03)
CIM 35-54

Not Covered

Refractive keratoplasty is surgery to reshape the cornea of the eye to correct vision problems such as myopia (nearsightedness) and hyperopia (farsightedness). Refractive keratoplasty procedures include keratomileusis, in which the front of the cornea is removed, frozen, reshaped, and stitched back on the eye to correct either near or farsightedness; keratophakia, in which a reshaped donor cornea is inserted in the eye to correct farsightedness; and radial keratotomy, in which spoke-like slits are cut in the cornea to weaken and flatten the normally curved central portion to correct nearsightedness.

The correction of common refractive errors by eyeglasses, contact lenses or other prosthetic devices is specifically excluded from coverage. The use of radial keratotomy and/or keratoplasty for the purpose of refractive error compensation is considered a substitute or alternative to eye glasses or contact lenses which are specifically excluded by §1862 (a)(7) of the Act (except in certain cases in connection with cataract surgery). In addition, many in the medical community consider such procedures cosmetic surgery which is excluded by §§1862 (a)(10) of the Act. Therefore, radial keratotomy and keratoplasty to treat refractive defects are not covered.

80.7.1 - Keratoplasty

(Rev. 1, 10-03-03)

Keratoplasty that treats specific lesions of the cornea, such as phototherapeutic keratectomy that removes scar tissue from the visual field, deals with an abnormality of the eye and is not cosmetic surgery. Such cases may be covered under §1862(a)(1)(A) of the Act.

The use of lasers to treat ophthalmic disease constitutes opthalmalogic surgery. Coverage is restricted to practitioners who have completed an approved training program in ophthalmologic surgery.

80.8 - Endothelial Cell Photography

(Rev. 1, 10-03-03)
CIM 50-38

Endothelial cell photography involves the use of a specular microscope to determine the

endothelial cell count. It is used by ophthalmologists as a predictor of success of ocular surgery or certain other ocular procedures. Endothelial cell photography is a covered procedure under Medicare when reasonable and necessary for patients who meet one or more of the following criteria:

- Have slit lamp evidence of endothelial dystrophy (cornea guttata),
- Have slit lamp evidence of corneal edema (unilateral or bilateral),
- Are about to undergo a secondary intraocular lens implantation,
- Have had previous intraocular surgery and require cataract surgery,
- Are about to undergo a surgical procedure associated with a higher risk to corneal endothelium; i.e., phacoemulsification, or refractive surgery (see §80.7 for excluded refractive procedures),
- With evidence of posterior polymorphous dystrophy of the cornea or irido-corneal-endothelium syndrome, or
- Are about to be fitted with extended wear contact lenses after intraocular surgery.

When a presurgical examination for cataract surgery is performed and the conditions of this section are met, if the only visual problem is cataracts, endothelial cell photography is covered as part of the presurgical comprehensive eye examination or combination brief/intermediate examination provided prior to cataract surgery, and not in addition to it. (See §10.1)

80.9 - Computer Enhanced Perimetry

(Rev. 1, 10-03-03)
CIM 50-49

Computer enhanced perimetry involves the use of a micro-computer to measure visual sensitivity at preselected locations in the visual field. It is a covered service when used in assessing visual fields in patients with glaucoma or other neuropathologic defects.

80.10 - Phaco-Emulsification Procedure - Cataract Extraction

(Rev. 1, 10-03-03)
CIM 35-9

In view of recommendations of authoritative sources in the field of ophthalmology, the subject technique is viewed as an accepted procedure for removal of cataracts. Accordingly, program reimbursement may be made for necessary services furnished in connection with cataract extraction utilizing the phaco-emulsification procedure.

80.11 - Vitrectomy

(Rev. 48, Issued: 03-17-06; Effective/Implementation Dates: 06-19-06)
CIM - 35-16

Vitrectomy may be considered reasonable and necessary for the following conditions: vitreous loss incident to cataract surgery, vitreous opacities due to vitreous hemorrhage or other causes, retinal detachments secondary to vitreous strands, proliferative retinopathy,

and vitreous retraction. See chapter 23 of the Medicare Claims Processing Manual for how to determine payment for physician vitrectomy services and the Medicare Claims Processing Manual, Chapter 14, "Ambulatory Surgical Centers," §40, for how to determine payment for ASC facility vitrectomy services. Also, see the Medicare Claims Processing Manual, Chapter 23, "Fee Schedule Administration and Coding Requirements," §20.9, to identify when, for Medicare payment purposes, certain vitrectomy codes are included in other codes or when codes for other services include vitrectomy codes.

80.12 - Intraocular Lenses (IOLs)

(Rev. 1, 10-03-03)
CIM 65-7

An intraocular lens, or pseudophakos, is an artificial lens which may be implanted to replace the natural lens after cataract surgery. Intraocular lens implantation services, as well as the lens itself, may be covered if reasonable and necessary for the individual. Implantation services may include hospital, surgical, and other medical services, including preimplantation ultrasound (A-scan) eye measurement of one or both eyes.

Cross-reference:

The Medicare Benefit Policy Manual, Chapter 6,"Hospital Services Covered Under Part B," §10.

The Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §120.

The Medicare Benefit Policy Manual, Chapter 16, "General Exclusions from Coverage," §20 and §90.

Transmittals Issued for this Chapter

Rev.#	Issue Date	Subject	Impl. Date	CR
R13806NCD	05/28/2026	Cardiac Contractility Modulation (CCM) for Heart Failure (HF)	04/06/2026	14311
R13802NCD	05/28/2026	NCD 20.40- Renal Denervation (RDN) for Uncontrolled Hypertension	04/06/2026	14302
R13801NCD	05/28/2026	NCD 20.38 - Transcatheter Edge-to-Edge Repair for Tricuspid Valve Regurgitation (T-TEER)	01/05/2026	14200
R13800NCD	05/28/2026	NCD 20.37 - Transcatheter Tricuspid Valve Replacement (TTVR)	01/05/2026	14149
R13716NCD	04/03/2026	Cardiac Contractility Modulation (CCM) for Heart Failure (HF)- - Rescinded and replaced by Transmittal 13806	04/06/2026	14311
R13695NCD	03/19/2026	NCD 20.40- Renal Denervation (RDN) for Uncontrolled Hypertension- Rescinded and replaced by Transmittal 13802	04/06/2026	14302
R13672NCD	03/09/2026	Cardiac Contractility Modulation (CCM) for Heart Failure (HF)- Rescinded and replaced by Transmittal 13716	04/06/2026	14311
R13640NCD	02/13/2026	NCD 20.40- Renal Denervation (RDN) for Uncontrolled Hypertension- Rescinded and replaced by Transmittal 13695	04/06/2026	14302
R13612NCD	01/30/2026	NCD 20.40- Renal Denervation (RDN) for Uncontrolled Hypertension- Rescinded and replaced by Transmittal 13640	04/06/2026	14302
R13538NCD	12/19/2025	Cardiac Contractility Modulation (CCM) for Heart Failure (HF)- Rescinded and replaced by Transmittal 13672	04/06/2026	14311
R13522NCD	12/11/2025	NCD 20.40- Renal Denervation (RDN) for Uncontrolled Hypertension-- Rescinded and replaced by Transmittal 13612	04/06/2026	14302
R13427NCD	09/22/2025	NCD 20.37 - Transcatheter Tricuspid Valve Replacement (TTVR)- Rescinded and replaced by Transmittal 13800	01/05/2026	14149

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R13366NCD	08/14/2025	NCD 20.38 - Transcatheter Edge-to-Edge Repair for Tricuspid Valve Regurgitation (T-TEER)- Rescinded and replaced by Transmittal 13801	01/05/2026	14200
R13343NCD	07/31/2025	NCD 20.37 - Transcatheter Tricuspid Valve Replacement (TTVR)- Rescinded and replaced by Transmittal 13427	01/05/2026	14149
R12571NCD	04/11/2024	National Coverage Determination (NCD) 20.7 Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting	05/13/2024	13512
R12112NCD	06/29/2023	Technical Revisions Only to the National Coverage Determination (NCD) Manual, Publication (Pub) 100-03	07/31/2023	13220
R11892NCD	03/09/2023	Technical Revisions Only to the National Coverage Determination (NCD) Manual	04/10/2023	13105
R11875NCD	02/23/2023	National Coverage Determination (NCD) 50.3 - Cochlear Implantation Manual Update	03/24/2023	13073
R10985NCD	09/08/2021	Claims Processing Instructions for National Coverage Determination 20.33 - Transcatheter Edge-to-Edge Repair [TEER] for Mitral Valve Regurgitation	10/08/2021	12361
R10838NCD	06/08/2021	National Coverage Determination (NCD) Removal	06/22/2021	12254
R10837NCD	06/11/2021	National Coverage Determination (NCD) 20.9.1 Ventricular Assist Devices (VADs)	07/27/2021	12290
R10797NCD	05/20/2021	National Coverage Determination (NCD) Removal- Rescinded and replaced by Transmittal 10838	06/22/2021	12254
R10337NCD	08/27/2020	National Coverage Determination (NCD30.3.3): Acupuncture for Chronic Low Back Pain (cLBP)	10/05/2020	11755
R10128NCD	05/08/2020	National Coverage Determination (NCD30.3.3): Acupuncture for Chronic Low Back Pain (cLBP)- Rescinded and replaced by	10/05/2020	11755

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		Transmittal 10337		
R10073NCD	05/01/2020	National Coverage Determination (NCD) 20.19 Ambulatory Blood Pressure Monitoring (ABPM)	06/16/2020	11650
R10179NCD	06/10/2020	NCD (20.32) Transcatheter Aortic Valve Replacement (TAVR)	06/12/2020	11660
R217NCD	03/13/2020	NCD (20.32) Transcatheter Aortic Valve Replacement (TAVR)- Rescinded and replaced by Transmittal 10179	06/12/2020	11660
R213NCD	02/15/2019	National Coverage Determination (NCD) 20.4 Implantable Cardiac Defibrillators (ICDs)	03/26/2019	10865
R209NCD	11/21/2018	National Coverage Determination (NCD) 20.4 Implantable Cardiac Defibrillators (ICDs) – Rescinded and replaced by Transmittal 211	02/26/2019	10865
R212NCD	01/18/2019	Update to Pub. 100-03 to Provide Language-Only Changes for the New Medicare Card Project	02/19/2019	11118
R207NCD	05/11/2018	Supervised Exercise Therapy (SET) for Symptomatic Peripheral Artery Disease (PAD)	07/02/2018	10295
R206NCD	04/03/2018	Supervised Exercise Therapy (SET) for Symptomatic Peripheral Artery Disease (PAD)- Rescinded and replaced by Transmittal 207	07/02/2018	10295
R204NCD	02/02/2018	Supervised Exercise Therapy (SET) for Symptomatic Peripheral Artery Disease (PAD)	04/03/2018	10295
R203NCD	11/17/2017	Hyperbaric Oxygen (HBO) Therapy (Section C, Topical Application of Oxygen)	12/18/2017	10220
R201NCD	08/28/2017	National Coverage Determination (NCD20.8.4): Leadless Pacemakers	08/29/2017	10117
R192NCD	05/06/2016	Percutaneous Left Atrial Appendage Closure (LAAC)	10/03/2016	9638
R187NCD	12/102015	National Coverage Determination (NCD) for Single Chamber and Dual Chamber Permanent Cardiac Pacemakers - This CR rescinds and fully replaces CR 8525	01/13/2016	9078

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R186NCD	10/26/2015	National Coverage Determination (NCD) for Single Chamber and Dual Chamber Permanent Cardiac Pacemakers - This CR rescinds and fully replaces CR 8525 – Rescinded and replaced by Transmittal 187	07/06/2015	9078
R184NCD	08/21/2015	Update to Pub. 100-03, National Coverage Determination Manual, Chapter 1, Part 1, Section 50.1 Speech Generating Device	09/21/2015	9281
R182NCD	05/22/2015	NCD20.30 Microvolt T-wave Alternans (MTWA)	06/23/2015	9162
R180NCD	03/06/2015	Removal of Multiple National Coverage Determinations Using Expedited Process	04/06/2015	9095
R179NCD	02/20/2015	National Coverage Determination (NCD) for Single Chamber and Dual Chamber Permanent Cardiac Pacemakers - This CR rescinds and fully replaces CR 8525 – Rescinded and replaced by Transmittal 186	07/06/2015	9078
R178NCD	12/05/2014	Transcatheter Mitral Valve Repair (TMVR)-National Coverage Determination (NCD)	04/06/2015	9002
R175NCD	10/03/2014	Intensive Cardiac Rehabilitation Program - Benson-Henry Institute Cardiac Wellness Program	11/04/2014	8894
R173NCD	09/04/2014	Pub 100-03, Chapter 1, Language-only Update	Upon Implement ation of ICD-10	8506
R172NCD	08/29/2014	Ventricular Assist Devices for Bridge-to-Transplant and Destination Therapy	09/30/2014	8803
R170NCD	07/10/2014	National Coverage Determination (NCD) for Single Chamber and Dual Chamber Permanent Cardiac Pacemakers – Fully rescinded and replaced by CR 9078	To Be Determined	8525
R161NCD	02/06/2014	National Coverage Determination (NCD) for Single Chamber and Dual Chamber Permanent Cardiac	07/07/2014	8525

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		Pacemakers – Rescinded and replaced by Transmittal 170		
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
R155NCD	06/14/2013	Ocular Photodynamic Therapy (OPT) with Verteporfin for Macular Degeneration	07/16/2013	8292
R151NCD	02/08/2013	Change of Address for Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting Facility Approval and Recertification Letter Submission	03/11/2013	8199
R149NCD	11/30/2012	Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP)	01/07/2013	7836
R147NCD	09/24/2012	National Coverage Determination (NCD) for Transcatheter Aortic Valve Replacement	01/07/2013	7897
R145NCD	08/03/2012	National Coverage Determination (NCD) for Transcatheter Aortic Valve Replacement – Rescinded and replaced by Transmittal 147	01/07/2013	7897
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
R129NCD	12/08/2010	Ventricular Assist Devices (VAD) as Destination Therapy	01/06/2011	7220
R128NCD	11/19/2010	Ventricular Assist Devices (VAD) as Destination Therapy - Rescinded and replaced by Transmittal 129	01/06/2011	7220
R125NCD	09/24/2010	Intensive Cardiac Rehabilitation (ICR) Programs-Dr. Ornish's	10/25/2010	7113

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		Program for Reversing Heart Disease and the Pritikin Program		
R117NCD	03/09/2010	Outpatient Intravenous Insulin Treatment (Therapy)	04/05/2010	6775
R116NCD	03/05/2010	Repeal of Section 20.10, Cardiac Rehabilitation (CR) Program	04/05/2010	6855
R115NCD	03/05/2010	Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent With Stenting	04/05/2010	6839
R114NCD	02/22/2010	Outpatient Intravenous Insulin Treatment (Therapy) – Rescinded and replaced by Transmittal 117	03/08/2010	6775
R112NCD	02/05/2010	Outpatient Intravenous Insulin Treatment (Therapy) - Rescinded and replaced by Transmittal 114	03/08/2010	6775
R98NCD	12/24/2008	Percutaneous Transluminal Angioplasty of the Carotid Artery Concurrent With Stenting	01/26/2009	6301
R95NCD	09/10/2008	Artificial Hearts	12/01/2008	6185
R93NCD	08/29/2008	Artificial Hearts - Replaced by Transmittal 95	10/06/2008	6185
R88NCD	07/25/2008	Microvolt T-Wave Alterans (MTWA)	08/25/2008	6154
R87NCD	07/11/2008	Percutaneous Transluminal Angioplasty (PTA) With Stenting	08/11/2008	6137
R81NCD	04/04/2008	Percutaneous Transluminal Angioplasty (PTA)	05/05/2008	5984
R77NCD	09/12/2007	Percutaneous Transluminal Angioplasty (PTA)	07/30/2007	5660
R71NCD	06/29/2007	Percutaneous Transluminal Angioplasty (PTA) - Replaced by Transmittal 77	07/30/2007	5660
R68NCD	04/13/2007	Ventricular Assist Devices (VADs)	05/14/2007	5516
R64NCD	01/05/2007	Intracranial Percutaneous Transluminal Angioplasty (PTA) with Stenting	02/05/2007	5432
R63NCD	12/15/2006	Cardiac Output Monitoring by Thoracic Electrical Bioimpedance (TEB)	01/16/2007	5414
R54NCD	04/28/2006	Bariatric Surgery for Treatment of Morbid Obesity	05/30/2006	5013
R53NCD	04/21/2006	Clarification on Billing Requirements for Percutaneous Transluminal Angioplasty (PTA)	N/A	5022

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		Concurrent with the Placement of an Investigational or FDA-Approved Carotid Stent		
R52NCD	04/21/2006	Cardiac Rehabilitation Programs	06/21/2006	4401
R50NCD	03/31/2006	External Counterpulsation Therapy	04/03/2006	4350
R49NCD	03/24/2006	Microvolt T-Wave Alternans (MTWA) Diagnostic Testing	04/03/2006	4351
R48NCD	03/17/2006	Technical Corrections to the NCD Manual	06/19/2006	4278
R46NCD	01/27/2006	Cardiac Catheterization Performed in Other Than a Hospital Setting	02/27/2006	4280
R42NCD	07/01/2005	Cochlear Implantation	07/25/2005	3796
R39NCD	06/24/2005	Cochlear Implantation - Replaced by Revision 42	07/05/2005	3796
R33NCD	04/22/2005	Percutaneous Transluminal Angioplasty (PTA	07/05/2005	3811
R29NCD	03/04/2005	Implantable Automatic Defibrillators	04/04/2005	3604
R26NCD	12/10/2004	Electrocardiographic Services	10/10/2004	3590
R25NCD	10/15/2004	Percutaneous Transluminal Angioplasty (PTA)	10/12/2004	3489
R23NCD	10/01/2004	Treatment of Obesity	10/01/2004	3502
R16NCD	06/25/2004	Cardiac Pacemaker	04/30/2004	3369
R12NCD	04/30/2004	Cardiac Pacemakers - Replaced by Revision 16	04/30/2004	3290
R11NCD	04/16/2004	Noncoverage of Acupuncture for Fibromyalgia/Osteoarthritis	04/06/2004	3250
R10NCD	04/06/2004	Re-release of NCD Manual	N/A	N/A
R09NCD	04/01/2004	NCD - Ocular Photodynamic Therapy (OPT) With Verteporfin for Age-Related Macular Degeneration (AMD)	04/01/2004	3191
R06NCD	01/23/2004	Cardiac Output Monitoring by Thoracic Electrical Bioimpedance	02/23/2004	2689
R02NCD	10/17/2003	Artificial hearts and Related Devices	10/01/2003	2958
R01NCD	10/01/2003	Initial Release of Manual	N/A	N/A

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