COMPLETE GUIDE TO
MEDICARE COVERAGE ISSUES

A REFERENCE TO COVERED AND NONCOVERED SERVICES
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<td>• Transcutaneous Electrical Nerve Stimulation for Chronic Low Back Pain</td>
</tr>
<tr>
<td></td>
<td>• The Use of ECG-Based Signal Analysis Technology to Detect Myocardial Infarction or</td>
</tr>
<tr>
<td></td>
<td>• Coronary Artery Disease</td>
</tr>
</tbody>
</table>

New Programs of All-Inclusive Care for the Elderly (PACE) Manual

The Centers for Medicare and Medicaid Services (CMS) has assigned Pub. 100-11 to the Internet Only Manual System to define and explain Programs of All-Inclusive Care for the Elderly, or PACE, including instructions on this program. This is a Medicare program established by the Balanced Budget Act of 1997 (BBA).

This model was based on a managed care system for the elderly who receive both Medicare and Medicaid and are determined eligible for nursing home care established within their specific states. The core services include:

- Adult day care
- Case management
- Physician services
- Therapy
- Social support services

Participants are also required to:

- Be at least 55 years of age
- Live in a PACE service area

An interdisciplinary team comprised of professional and paraprofessional staff assesses participants' needs, develops care plans, and delivers all necessary services including acute care services and when necessary, nursing facility services which are integrated for a seamless provision of total care. PACE programs provide social and medical services primarily in an adult day health center, supplemented by in-home and referral services in accordance with the participant's needs. The PACE service package must include all Medicare- and Medicaid-covered services, and other services determined necessary by the interdisciplinary team for the care of the PACE participant.

Source: Programs of All-Inclusive Care for the Elderly Manual; additional information can be found at: https://www.cms.gov/Manuals/IO/Mod1?PubType=none&FilterByDID=-99&sortByDID=1&sortOrder=ascending&ItemID=CMS019036&NumPerPage=10


CMS has assigned Pub. 100-25 to the Internet Only Manual system to the Information Security Acceptable Risk Safeguards Manual, which provides parameters to CMS and other contractors regarding required security levels in order to protect information and information systems.

The National Institute of Standards and Technology (NIST) Special Publication 800-53 versions 3 and NIST 800-63 version 1.0 established a set of cyber security standards which included input from CMS policies and guidelines as well as other federal and non-federal sources and other...
Autologous Cellular Immunotherapy Treatment of Metastatic Prostate Cancer

CMS has determined that evidence supports the use of sipuleucel-T, PROVENGE, in cases of asymptomatic and/or minimally symptomatic metastatic hormone refractory prostate cancer. This study has determined autologous cellular therapy in these cases is reasonable under the 1802(a)(1)(A) of the Social Security Act.

In 2009, about 192,280 new cases of prostate cancer were reported with approximately 27,369 deaths due to the disease. The approximate age of men diagnosed with prostate cancer is 72 years old. Patients with castration resistant metastatic prostate cancer have a survival rate of less than two years. In 2010, the Food and Drug Administration (FDA) approved sipuleucel-T for patients meeting this criterion, which differs in the specific approach of chemotherapy. This immunotherapy for the treatment of prostate cancer is the first to receive FDA approval.

The goal of this therapy is to train the body’s defenses to destroy or prevent the spread and growth of the cancer cells. Typical chemotherapy is performed with drugs produced by pharmaceutical companies purchased and distributed through the pharmacy. Once a patient qualifies for immunotherapy with sipuleucel-T, it is developed for the specific patient using his own white blood cells.

Leukapheresis takes the patient’s white blood cells that are sent to the lab where they are exposed to FAP204, a molecule developed that binds prostate acid phosphatase (PAP) with granulocyte/macrophage colony stimulating factor (GM-CSF). PAP is the antigen connected to prostate cancer cells and GM-CSF is the protein that targets a receptor on the white blood cells. So, PAP serves to alter the function of the white blood cells and GM-CSF motivates the cells to take action. Once this process is complete, the white blood cells are returned to the patient via infusion. This dose of protocol consists of three infusions every two weeks for a total treatment period of four weeks.

Source: Transmittal 133, July 8, 2011

Magnetic Resonance Imaging (MRI) in Medicare Beneficiaries with FDA-Approved Implanted Permanent Pacemakers (PMs) for use in an MRI Environment

CMS has made revisions to NCD 220.2 regarding the use of MRI in patients with pacemakers. The information gathered indicates improved outcomes for this service when the permanent pacemakers are utilized within the FDA-approved standards and instructions within the MRI. As of July 7, 2011 this is the only exception to the current contraindication section of the NCD.

Source: Transmittal 134, August 26, 2011
Prospective Billing for Refills of DMEPOS Items Provided on a Recurring Basis

Changes have been made in chapter 5, sections 5.2.5 and 5.2.6 of the Medicare Program Integrity Manual regarding the billing and applicable time frames for refills on DMEPOS items.

Suppliers need to be aware that the billing of DMEPOS items provided on a recurring basis should be based on prospective use rather than retrospective use. An example would be an order for 75 units of enteral nutrition for one month. Once the supplier delivers the applicable number of units, a bill can be generated with the date of delivery serving as the date of service. In retrospective billing, the supplier would not submit the initial claim, but instead would wait for billing upon sending out the next 75 units to "replace" what was used—this practice is not allowed.

Additional instruction is directed to DME MACs, DME PSCs, and ZPICs and applies to products typically provided as refills to an original order. It is necessary for the supplier to contact the beneficiary prior to sending the refill and not automatically ship the refill based on the original order even if previously indicated by the beneficiary. This is necessary to be sure the products are still needed, current supplies are running low, and to make sure no changes are required. This contract must be made 14 days before scheduled ship date and not sooner with delivery of the product 10 calendar days before current supply is exhausted. It is up to the DME MAC to allow claims processing time on refills within these guidelines.

Changes to the Laboratory National Coverage Determination (NCD) Edit Software for October 2011

Changes are made to the Lab NCDs on a quarterly basis based on coding analysis decisions and updates to the current ICD-9-CM code. While the complete file is not yet available in the Medicare National Coverage Determinations (NCD) Coding Policy Manual and Change Report, CMS has posted a transmittal indicating the following changes effective in October of this year:

<table>
<thead>
<tr>
<th>NCD</th>
<th>Deleted ICD-9-CM codes on list covered by Medicare</th>
<th>Added ICD-9-CM codes on list covered by Medicare</th>
</tr>
</thead>
<tbody>
<tr>
<td>190.14 HIV Testing (Diagnosis)</td>
<td>512.8</td>
<td>512.80, 512.82, 512.83</td>
</tr>
</tbody>
</table>

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Patients on Dialysis and Patients not on Dialysis

T reatment of Anemia in Adults with CKD including Erythropoiesis Stimulating Agents (ESAs) for Patients with graft versus host disease refractory to immunosuppressive drug therapy

●

Patients with acute cardiac allograft rejection refractory to immunosuppressive drug therapy

●

Symptomatic treatment of skin disorders such as Cutaneous T-cell Lymphoma (CTCL), which has not been responsive to other treatments

●

Patients with acute cardiac allograft rejection refractory to immunosuppressive drug therapy

●

Patients with graft versus host disease refractory to immunosuppressive drug therapy

All other conditions treated with ECP are not covered. This request for information is to determine if enough evidence warrants the addition of treatment for those patients suffering from progressive branchi oretinal obliterative syndrome as a result of long allografts.

Source: CMS website

Erythropoiesis Stimulating Agents (ESAs) for Treatment of Anemia in Adults with CKD including Patients on Dialysis and Patients not on Dialysis

CMS will not be issuing a National Coverage Determination at this time on the topic based on currently available information. A request was made to establish limits on the use of ESAs within this patient population.

It was initially suggested that prior ESA use may contribute to the success of kidney transplants in patients with chronic kidney disease and CMS requested a technology assessment from an outside source.

Typically ESAs have been utilized to treat anemia however FDA approval comes with warnings indicating elevated risk for death, cardiovascular incidents, and stroke in some patients suffering from chronic renal failure.

Although CMS researched this topic extensively, the agency failed to identify any high-quality randomized clinical trials that could conclude with confidence that ESAs provide clinical benefits other than increasing hemoglobin or to determine the role of adverse events including death, tumor progression, and cardiovascular thromboembolic events in generic patients (i.e., the largest growing segment of the population with renal failure).

Source: CMS website

Anti-VEGF Treatment of Diabetic Macular Edema

The Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) is looking into evidence of treatment with anti-vascular endothelial growth factor (anti-VEGF) for diabetic macular edema (DME) and its effectiveness and/or positive health outcomes.

Currently, treatment for this condition is focal and grid laser, and the agency is pursuing information about studies using anti-VEGF instead, for which there is no established NCD.

Diabetic retinopathy may indicate damage or increased formation of small blood vessels within the retina of the eye. If these vessels begin to leak into the macula, which is the sensitive area of the retina responsible for central vision, this leads to swelling which can progress into loss of vision. It is speculated that recurrent injections of anti-VEGF could help manage the condition as well as prevent loss of vision and increase recovery time and health outcomes.

Source: CMS website

Medicare Enrollment for Ordering and Referring Services for Medicare Beneficiaries

Although the majority of physicians and practitioners enrolled in Medicare for the purpose of providing covered services to Medicare beneficiaries, there is a segment of physicians and practitioners who do not submit claims to Medicare, but still need to be enrolled in order to order or refer items or services for Medicare beneficiaries. With the implementation of a provision of the Affordable Care Act, CMS has become cognizant of these providers and their specific enrollment issues and has revised the application process for the following providers:

● Employed by the Department of Veterans Affairs (DVA);
● Employed by the Public Health Service (PHS);
● Employed by the Department of Defense (DOD) Enlist;
● Employed by federally qualified health centers (FQHC), rural health clinics (RHC) or critical access hospitals (CAH);
● Physicians in a fellowship;
● Dentist, including oral surgeons; and
● Any provider can enroll for the sole purpose of ordering or referring, regardless of who their employer is.

Those physicians and practitioners must complete the following sections of the paper form CMS-855I Medicare Enrollment Application for Physicians:

<table>
<thead>
<tr>
<th>Condition</th>
<th>ICD-9-CM Codes</th>
</tr>
</thead>
<tbody>
<tr>
<td>190.32 Gamma Glutamyl Transpeptidase</td>
<td>173.0, 173.1, 173.2, 173.3, 173.4, 173.5, 173.6, 173.7, 173.8, 173.9</td>
</tr>
<tr>
<td>190.33 Hepatitis Panel/ Acute Hepatitis Pate</td>
<td>N/A</td>
</tr>
<tr>
<td>190.34 Fecal Occult Blood Test</td>
<td>286.5</td>
</tr>
</tbody>
</table>

Source: Transmittal 2298, September 2, 2011
Creating innovation such as interactive applications and devices like
● Aid in creating long-term quality improvements that can lead to care that
● Patient empowerment such as using mobile health applications to help
health IT, including:
The Summit also focused on the benefits of electronic health records and understanding about data practices.
security policies and data practices with regards to PHR products. The
revealed that produces a standardized template to permit consumers to
their personal health information so they can participate more fully in their
private and secure manner. It is felt that it is time to put the advanced
consumers to participate in their own health care by using health IT in a

Patient’s Rights to Personal Health Information
At the recent Joint HIMSS Consumer Health IT Summit attended by
providers, consumers, and representatives from the private and public
sectors, discussions centered around the best possible way to empower
customers to participate in their own health care by using health IT in a
private and secure manner. It is felt that it is time to put the advanced
technology now available to use to help individuals gain increased access to
their personal health information so they can participate more fully in their
own medical care.
A pioneering Personal Health Record (PHR) Model Privacy Notice was
released by the DOD or DVA.
by the DVA or DOD may be active in a state other than the location of the
DOD or DVA.
Once the information is verified and approved, contractors will notify the
provider that he or she is enrolled in the program. Since the modified
application does not require the completion of section 4 but does require a
cover letter, Medicare enrollment contractors shall reject the application if
section 4 is blank and a cover letter is not attached.
Source: Transmittal 387, September 1, 2011, Medicare Program Integrity
Manual (Pub. 100-8)

Transcutaneous Electrical Nerve Stimulation for
Chronic Low Back Pain
CMS has initiated a National Coverage Analysis (NCA) to evaluate
information on TENS being used to treat chronic low back pain. They are
specifically asking for feedback on health outcomes of this treatment
within the home setting.
According to the Therapeutic and Technology Assessment Subcommittee
of the American Academy of Neurology (AAN), the use of TENS as an
ineffective treatment for this condition provided in a report from last year.
CMS is considering coverage based on section 1862(a)(1)(A) of the Social
Security Act and are particularly interested in clinical studies that would fall
within the Coverage with Evidence Development (CED) paradigm.
Source: CMS Website

The Use of ECG-Based Signal Analysis Technologies to
Detect Myocardial Ischemia or Coronary Artery Disease
The Evidence Development and Coverage Advisory Committee
(MEDCAC) has scheduled a meeting for November 9, 2011 to evaluate
information on the capabilities of ECG-based signal analysis technology
(SAECG).
Myocardial ischemia and coronary artery disease have many variables when
it comes to diagnosing the condition which makes it difficult to treat and
manage. There are currently many options for diagnosis including:
● Biomarkers
● 12 lead electrocardiogram
● Stress testing with ECG
● Coronary angiogram
Although these tests have historically been used for diagnosis, recent studies
have indicated limitations of these tests. In addition, coronary angiography,
which is regarded as the standard method for diagnosing coronary artery
disease, may also be associated with complications such as myocardial
infarction or even death.
Because of these issues, new approaches are being sought with the intention
of providing a more accurate diagnosis.
Source: CMS Website
NCD 10.3—Inpatient Hospital Pain Rehabilitation Programs (formerly CIM 35-21)

Code each modality.

Effective Date: This is a longstanding national coverage determination. The effective date of this version has not been posted.

Benefit Category: Inpatient Hospital Services

Item/Service Description

Pain rehabilitation programs are a relatively new and 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 or her pain and thereby improve his or her ability to function independently.

A hospital level pain rehabilitation program is one that employs a coordinated multidisciplinary team to deliver, in a controlled environment, a concentrated program which 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 patient physical disability, and the use of mechanical devices and/or activities to alleviate pain or modify a patient’s reaction to it (e.g., nerve stimulator, hydrotherapy, massage, i.e., 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.

Indications and Limitations of Coverage

Since pain rehabilitation programs of a closer scope than that described above would raise a question as to whether the program could be provided in a less intensive setting than an inpatient hospital basis, carefully evaluate such programs to determine whether the programs do, 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 (see NCD 30.3), biofeedback (see NCD 30.3), and, counseling services (see NCD 10.4). In determining whether the scope of a pain rehabilitation program does necessitate inpatient hospital care, evaluate only those services and devices which are covered. Although diagnostic tests may represent an appropriate part of a pain rehabilitation program, 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 NCD 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. Occasionally a program longer than 4 weeks may be required in a particular case. In such a case where there is doubt as to whether such a 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.

Revision History

09/1996: Changes to differentiate its scope from new NCD 10.4.

NCD 10.4—Outpatient Hospital Pain Rehabilitation Programs (formerly CIM 35-21.1)

Code each modality.

Effective Date: This is a longstanding national coverage determination. The effective date of this version has not been posted.

Benefit Category: Outpatient Hospital Services

Item/Service Description

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.

Indications and Limitations of Coverage

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. 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 multidisciplinary 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.
In particular patients, that the pain rehabilitation program is not reasonable and necessary under Sec. 1862(a)(1) of the law for the treatment of their conditions.

Revision History
09/1988—Clarified that coverage of services furnished under inpatient hospital pain rehabilitation programs is available if patient's pain is attributable to a physical condition, the usual methods of treatment have not been successful in alleviating it, and a significant loss of ability by patient to function independently has resulted from the pain. Effective date NA (TN S2)

NCD 10.5—Autogenous Epidural Blood Graft (Effective for services performed on and after March 1, 1980) (formerly CIM 45-11) 62273

Effective Date: March 1, 1980
Benefit Category: Physicians' Services

Indications and Limitations of Coverage
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 this 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.

NCD 20.1—Vertebral Artery Surgery (formerly CIM 35-32) 22100, 35301, 35311, 35508, 35515, 35642, 35645, 35691, 35693, 35761

Effective Date: March 1, 1980
Benefit Category: Inpatient Hospital Services
Benefit Category: Physicians' Services

Indications and Limitations of Coverage
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 result from reduction in blood flow to the brain and range from symptoms of transient ischemia to hemianopia, 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 a laterally located osteophyte anywhere in the C6(C7)-C2 course of the vertebral artery.
- Arteriolysis which frees the artery from surrounding tissue, with or without arteriectomy (removal of the vessel).

These procedures are covered 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.

Operations which 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 other arteries.
- Extravascular obstructions
- Bone tissue or osteophytes, located laterally in the C6(C7)-C2 cervical vertebral arc area of the vertebral artery, most commonly at C5-C6.
- Arterial variations—Anomalous location of the origin of the vertebral artery, a congenital aberration, and tortuosity and kinks of the vertebral artery.
- Fibrous tissue—Tissue changed as a result of manipulation of the neck or 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 so-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 abnormal variations create lesions that 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 Medicare National Coverage Determinations (Pub. 100-03)
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 reduce 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 sec. 1862(a)(1) of the Act and are not reimbursable under the program.

### NCD 20.2—Extracranial-Intracranial (EC-IC) Arterial Bypass Surgery

**Effective for services performed on or after March 27, 1991.** (formerly CIM 35-37)

<table>
<thead>
<tr>
<th>Code</th>
<th>Effective Date</th>
<th>Benefit Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>61711</td>
<td>March 27, 1991</td>
<td>Inpatient Hospital Services, Physicians Services</td>
</tr>
</tbody>
</table>

#### Indications and Limitations of Coverage

**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 to improve the blood supply to the brain and reduce the risk of having a stroke, has not been demonstrated to be any more effective than surgical intervention.

Accordingly, EC-IC arterial bypass surgery is not considered **reasonable and necessary** within the meaning of sec. 1862(a)(1) of the Act when it is performed as a treatment for ischemic cerebrovascular disease of the carotid or middle cerebral arteries.

#### Revision History

- **06-1991—Renamed to reflect current terminology for procedure and revised to provide that Medicare coverage no longer allowed when EC-IC surgery performed to treat ischemic cerebrovascular disease of carotid or middle cerebral arteries. Effective date 03/27/1991.** (TN 47)

### NCD 20.3—Thoracic Duct Drainage (TDD) in Renal Transplants

(formerly CIM 35-58)

<table>
<thead>
<tr>
<th>Code</th>
<th>Effective Date</th>
<th>Benefit Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>33202–33203, 33215–33220, 33223–33226, 33240–33249</td>
<td>January 27, 2005</td>
<td>Inpatient Hospital Services, Physicians Services</td>
</tr>
</tbody>
</table>

#### Item/Service Description

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-transplant and post-transplant in conjunction with more conventional immunotherapy.

#### Indications and Limitations of Coverage

TDD is performed on an inpatient basis, and the inpatient stay is covered when furnished to a kidney transplant recipient or an individual approved to receive kidney transplantation in a hospital approved to perform kidney transplantation.

### NCD 20.4—Implantable Automatic Defibrillators

(formerly CIM 35-85)

<table>
<thead>
<tr>
<th>Code</th>
<th>Effective Date</th>
<th>Benefit Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>33202–33203, 33215–33220, 33223–33226, 33240–33249</td>
<td>January 27, 2005</td>
<td>Inpatient Hospital Services, Physicians Services</td>
</tr>
</tbody>
</table>

#### Item/Service Description

A. General

The implantable automatic defibrillator is an electronic device designed to detect and treat life-threatening tachyarrhythmias. The device consists of a pulse generator and electrodes for sensing and defibrillating.

#### Indications and Limitations of Coverage

1. **Covered Indications**
   1. Documented episode of cardiac arrest due to ventricular fibrillation (VF), not due to a transient or reversible cause (effective July 1, 1991).
   2. Documented sustained ventricular tachyarrhythmia (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 (effective July 6, 1999).
   3. Documented familial or inherited conditions with a high risk of life-threatening VT, such as long QT syndrome or hypertrophic cardiomyopathy (effective July 1, 1999).
Pending National Decisions

In 1990, Medicare declared its commitment to having an open, understandable and predictable coverage process for items and services provided by the program. Medicare provides for broad coverage of many medical and health care services, including hospital services, skilled nursing facility services, home health services, and physician services. Medicare does not provide an all inclusive list of services covered by Medicare and does not usually specify which medical devices, surgical procedures or diagnostic services should be included or excluded from coverage. The general guideline is that items and services must be reasonable and necessary for the diagnosis and treatment of illness or injury. The local carriers make most coverage and policy decisions. CMS, however, has authority to make coverage policies that apply nationwide. The process is described in the introduction chapter of this book.

This chapter includes national coverage decisions that are either pending, a decision has been issued, but not yet finalized by adding them to the Medicare National Coverage Determination Manual. The decisions are based on medical and scientific evidence, including medical literature and data, discussions with medical experts, and technology assessments. Some of the issues are reconsiderations for changing a previously decided coverage topic. When the decision is approved or denied and issued as an addition to the Medicare National Coverage Determination Manual, it will be removed from this chapter.

The decision summaries for closed reviews that were included in the previous updates are listed in the Decision Summary section. There is a section for the Medicare Evidence Development Coverage Advisory Committee (MCAC), formerly the Medicare Coverage Advisory Committee (MCAC), reviews at the end of the Pending National Decisions chapter. Issues being reviewed by the MCAC were previously included in the Open Coverage Analyses section. However, this chapter includes national coverage decisions that are either pending, a decision has been issued, but not yet finalized by adding them to the Medicare National Coverage Determination Manual. The decisions are based on medical and scientific evidence, including medical literature and data, discussions with medical experts, and technology assessments. Some of the issues are reconsiderations for changing a previously decided coverage topic. When the decision is approved or denied and issued as an addition to the Medicare National Coverage Determination Manual, it will be removed from this chapter.

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Intensive Behavioral Therapy for Cardiovascular Disease

Issue:

The Medicare Evidence Development Coverage Advisory Committee (MedCAC) recommends that CMS consider a national coverage determination (NCD) for aspirin counseling for treatment of cardiovascular disease, which is recommended with a grade A by the USPSTF. The requestor asked CMS to cover this service once every 5 years or more frequently such as when relevant new risk factors are identified for at-risk individuals who do not already have coronary artery disease or cardiovascular disease. After reviewing the requestor’s letter and the various preventive services that the USPSTF has given a grade A or grade B rating in recent years, CMS has decided to initiate a national coverage analysis (NCA) for Intensive Behavioral Therapy for Cardiovascular Disease, which includes assessment and counseling regarding aspirin use to prevent cardiovascular disease, blood pressure measurement, counseling and intervention; and healthy diet counseling as the form of intensive behavioral counseling for patients with hyperlipidemia and other known risk factors for cardiovascular and diet related chronic conditions.

Benefit Category:

Additional Preventative Services

Responsible Party Name(s):

Jason M. Spangler, MD, Chief Medical Officer, Partnership for Prevention

Responsible Letter(s):

View Letter

Proposed Decision Memo Due Date:

08/11/2011

Proposed Decision Memo Public Comment Period:

02/11/2011–03/13/2011

Lead Analyst(s):

Jamie Hermansen, MPP
jamie.hermansen@cms.hhs.gov
410-786-2064

Lead Medical Officer(s):

Joseph Chao, MD, MS

Actions Taken:

February 11, 2011

CMS opens the national coverage analysis and a 30-day public comment period begins.

March 13, 2011

The initial 30-day public comment period closes.

August 10, 2011

The proposed decision memorandum is posted and the 30-day public comment period begins.

Over the past 25 years, Congress has expanded the Medicare benefit to include various preventive services to the Medicare Part B program such as Pap smear and screening pelvic exams, screening mammograms, colorectal cancer screening tests, and diabetes screening tests. Effective January 1, 2009, CMS was allowed to add coverage of “additional preventive services” if certain statutory requirements are made, as provided under section 101(a) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. Law 110-275). Patients and Providers Act of 2008 (MIPPA) (Pub. Law 110-275). Among other things, this new benefit allows CMS to add 62 CFR 410.64 to cover “additional preventive services” if it determines through the NCDS process that the service is recommended with a grade A (strongly recommends) or grade B (recommends) rating by the United States Preventive Services Task Force (USPSTF) and meets certain other requirements.

On October 29, 2010, CMS received a formal request from Partnership for Prevention asking that CMS institute a national coverage determination (NCD) for aspirin counseling for treatment of