



# HEALTH CARE FRAUD REPORT



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## The Government's Investigation of Medicare Billing for ICDs is Based on a Flawed Legal Premise

### Introduction



By **JESSE A. WITTEN** AND **DAVID M. GLASER**

*Jesse A. Witten is a partner in the Washington office of Drinker Biddle & Reath LLP. He wishes to thank Mark H.M. Sosnowsky and Lee Roach, of Drinker Biddle & Reath LLP, for their assistance with this article. He can be reached at [Jesse.Witten@dbr.com](mailto:Jesse.Witten@dbr.com). David Glaser is a partner in the Minneapolis office of Fredrikson & Byron PA. He wishes to thank Katherine A. Burkhart for her assistance with this article. He can be reached at [dglaser@fredlaw.com](mailto:dglaser@fredlaw.com). Witten and Glaser represent hospitals under investigation for alleged improper Medicare billing for ICD implantations.*

**T**he government is investigating numerous hospitals throughout the country for allegedly billing Medicare for non-covered procedures involving the implantation of implantable cardioverter defibrillators ("ICDs").

The underlying legal premise of the investigation appears to be that Medicare covers only ICD implantations that fit within the criteria of a National Coverage Determination ("NCD") issued by the Centers for Medicare & Medicaid Services ("CMS") for ICD implantation. That premise, however, is incorrect.

NCDs can describe indications that are covered, indications that are not covered, or both. The NCD for ICDs describes indications for which Medicare provides coverage, but does not limit Medicare coverage for patients who do not meet the NCD criteria. Rather, determining Medicare coverage for patients who are outside the NCD criteria requires a case-by-case evaluation as to whether the procedure is reasonable and necessary.

According to the *CMS National Coverage Determinations Manual* ("NCD Manual"), an NCD does not restrict coverage unless the NCD contains a statement explicitly excluding coverage. Here, the relevant NCD does not explicitly disavow coverage for ICDs that do not fall within the NCD. In other words, the NCD describes circumstances in which an ICD implantation is covered, but does not exclude coverage in other circumstances.

Indeed, there can be no dispute that ICD implantation may be reasonable and necessary for specific patients who happen not to satisfy the terms of the NCD. One example is former Vice President Dick Cheney

who received an ICD for primary prevention. Mr. Cheney did not fit within the NCD's indications for coverage (because he did not satisfy the enrollment criteria for the clinical studies on which the NCD's primary prevention indications were based),<sup>1</sup> but his world-renowned cardiologists believed that he needed an ICD to protect him from sudden death due to cardiac arrest.

According to the Heart Rhythm Foundation (a professional society for professionals in cardiac pacing and electrophysiology), "the day Vice President Richard Cheney received his ICD was a step forward in the care of people who have survived a heart attack. . . . [B]ecause of the type of heart disease Mr. Cheney has, it's likely that some day he will need his ICD to protect him from dying suddenly from cardiac arrest. . . ."

## Background

The Health Care Financing Administration (now CMS) first issued an NCD for ICDs in 1999. CMS revised the NCD in October 2003 and again in January 2005. The 2005 version is currently in effect and is published at Section 20.4 of the NCD Manual.<sup>2</sup>

The current NCD describes nine separate indications for which Medicare provides coverage for implantation of an ICD. Two of the nine indications describe patients who have a past history of arrhythmia, and implantation of an ICD in such patients is referred to as "secondary prevention."

The remaining seven indications in the NCD describe patients who do not have a history of arrhythmia but who are at elevated risk of sudden death due to cardiac arrest because of a variety of clinical factors. Implanting an ICD in a patient without a prior history of arrhythmia is referred to as "primary prevention."

For patients who have had a recent myocardial infarction ("MI") or revascularization procedure (i.e., coronary artery bypass graft ("CABG") or percutaneous transluminal coronary angioplasty ("PTCA")), the NCD sets forth certain timing parameters. Under the current version of the NCD, to fit within one of the seven primary prevention indications, the patient must not have had an acute MI within the past 40 days or a CABG or PTCA within the past three months. See NCD Manual § 20.4.

The 2003 version of the NCD contained different time frames for primary prevention for patients who had experienced an MI or who had a prior CABG or PTCA. The 2003 NCD is commonly referred to as using a "30-day" time frame, although the document used different time frames for different indications, and never actually refers to 30 days. The time period was four weeks for one indication and one month for another. Similarly, for one primary prevention indication, the 2003 version did not discuss any time frame for patients with a prior CABG or PTCA.

<sup>1</sup> Vice President Cheney would not have satisfied the NCD's indications for coverage for primary prevention because his ejection fraction was too high, not because of a recent MI or PTCA/CABG. See Transcript of Meeting of CMS Medical Coverage Advisory Committee (Feb. 12, 2003) at 188; <http://transcripts.cnn.com/TRANSCRIPTS/0106/30/se.01.html>

<sup>2</sup> The NCD Manual is available at [www.cms.gov/Manuals/IOM/itemdetail.asp?filterType=none&filterByDID=99&sortByDID=1&sortOrder=ascending&itemID=CMS014961&intNumPerPage=10](http://www.cms.gov/Manuals/IOM/itemdetail.asp?filterType=none&filterByDID=99&sortByDID=1&sortOrder=ascending&itemID=CMS014961&intNumPerPage=10).

The government is investigating whether hospitals billed for non-covered ICD implantations of primary prevention cases because the procedures were performed either within 30 days of an acute MI or within three months of a CABG or PTCA. The government's position appears to be that as a result of the NCD, Medicare does not cover primary prevention cases under either of those circumstances.

## Analysis

### A. An NCD Does Not State When an Item or Service Is Non-Covered Unless Coverage Is "Explicitly" Excluded by the NCD

Medicare Part A provides beneficiaries with coverage for inpatient and outpatient hospital services, among other things, and Part B covers, among other things, physicians' services. See 42 U.S.C. §§ 1395d, 1395k & 1395x(s).

The Medicare Act does not list specific items or services that are covered; instead, it provides coverage to beneficiaries unless the items or services "are not reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. § 1395y(a)(1)(A).<sup>3</sup> CMS has never promulgated regulations to interpret the statutory term "reasonable and necessary." See 68 Fed. Reg. 55634 (Sept. 26, 2003).

Under the Medicare Act, the Secretary of HHS may decide coverage issues through National Coverage Determinations. See 42 U.S.C. § 1395ff(f). An NCD is "a determination by the Secretary of whether a particular item or service is covered nationally under Medicare." 42 C.F.R. § 405.1060(a). In issuing an NCD, CMS must determine Medicare coverage for a given item or service based on the "reasonable and necessary" criteria set forth in 42 U.S.C. § 1395y(a)(1)(A). See 64 Fed. Reg. 22619, 22621 (April 27, 1999); 68 Fed. Reg. 55634, 55636 (Sept. 26, 2003).

A "national coverage determination does not 'fill the gaps' in the statute or 'supplement' it. Thus, it creates no new law. Rather, it interprets the statutory language 'reasonable and necessary' as applied to a particular medical service or method of treatment." *Friedrich v. Sec'y of Health and Human Servs.*, 894 F.2d 829, 837 (6th Cir. 1990) (citations omitted). See also *Erringer v. Thompson*, 371 F.3d 625, 628 (9th Cir. 2004) (NCD reflects Secretary's interpretation of "reasonable and necessary" in context of particular items and services).

CMS issues NCDs in the form of a manual instruction, program instruction, or notice in the Federal Register. See 68 Fed. Reg. 55634, 55635 (Sept. 26, 2003) (distinguishing a Decision Memorandum from the NCD itself). CMS compiles and publishes NCDs in its NCD Manual.

The NCD Manual explains that if an NCD does not "explicitly exclude" coverage for certain indications, coverage for such indications will be based on whether the procedure was reasonable and necessary in light of "the law, regulations, rulings and general program in-

<sup>3</sup> The Act does specifically exclude certain services and treatments regardless of whether they are "reasonable and necessary," such as certain expenses for dental treatment, foot conditions, eye examinations, eyeglasses, or hearing aids or hearing exams. 42 U.S.C. § 1395y(7), (12) & (13).

structions.” The Foreword to the NCD Manual (adopted in current form in October 2003) provides in part:

The National Coverage Determinations Manual describes whether specific medical items, services, treatment procedures, or technologies can be paid for under Medicare. National coverage decisions have been made on the items addressed in this manual. All decisions that items, services, etc. are not covered are based on § 1862(a)(1) of the Act (the “not reasonable and necessary” exclusion) [42 U.S.C. § 1395y(a)(1)] unless otherwise specifically noted. . . . Where an item, service, etc. is stated to be covered, but such coverage is explicitly limited to specified indications or specified circumstances, all limitations on coverage of the items or 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 or service is provided for specified indications or circumstances but is not explicitly excluded for others, or where the item or service is not mentioned at all in the CMS Manual System the Medicare contractor is 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.**

NCD Manual, CMS Pub. 100-03, Forward (emphasis added).<sup>4</sup> Thus, if an NCD does not “explicitly exclude[]” coverage, whether the item or service was reasonable and necessary is decided on a case-by-case basis.

CMS also explained that an NCD may grant but not exclude coverage in a 2003 Federal Register Notice, which stated that “[i]n general, an NCD is a national policy statement granting, limiting, or excluding Medicare coverage for a specific medical item or service.” 68 Fed. Reg. 55634, 55635 (Sept. 26, 2003) (emphasis added).

## **B. The NCD for Implantable Cardioverter Defibrillators Lacks an Explicit Exclusion of Coverage, Unlike Many NCDs That Expressly Provide for Non-Coverage**

As noted, the NCD for ICDs in effect since January 2005 describes nine covered indications, but does not “explicitly” exclude cases that do not fall within the nine indications. Rather, it is silent regarding coverage for such cases. The NCD states merely that it does not restrict coverage that may be provided under a separate NCD for clinical trials:

<sup>4</sup> The predecessor to the NCD Manual was the “Coverage Issues Manual,” CMS Pub. 6. That publication also contained a Foreword (with a February 1991 effective date) that is substantially the same as the Foreword to the NCD Manual. The Foreword to the Coverage Issues Manual provided in pertinent part: “Where coverage of an item or service is provided for specified indications or circumstances but is not explicitly excluded for others, or where the item or service is not mentioned at all in the Manual, the Intermediary Manual, or the Carriers Manual, it is up to the Medicare contractor to make the coverage decision, in consultation with medical staff, and with the Health Care Financing Administration (HCFA), when appropriate, based on the law, regulations, rulings and general program instructions.”

All other indications for implantable automatic defibrillators not currently covered in accordance with this decision will continue to be covered under Category B IDE trials (42 CFR § 405.201) and the CMS routine clinical trials policy (NCD § 310.1).

NCD Manual, CMS Pub. 100-03, § 20.4.C.

By contrast, prior versions of the NCD did contain express statements of non-coverage. For example, the NCD in effect between October 1, 2003 and January 27, 2005 provided in relevant part:

*All other indications remain non-covered except in Category B IDE clinical trials (60 CFR 48417) or as a routine cost in clinical trials defined under CIM 30-1*

CMS Transmittal 173, Change Request 2880 (Aug. 22, 2003) (emphasis added). This explicit statement of non-coverage was deleted from the January 2005 NCD.

Many other NCDs also contain explicit statements of non-coverage. For example, the NCD for cardiac pacemakers (adopted in its current form in April 2004) states explicitly that there is no other coverage for pacemakers except as may be provided for clinical trials: “*All other indications for single-chamber cardiac pacing for which CMS has not specifically indicated coverage remain nationally noncovered, 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.*” NCD Manual, Pub. 100-03, § 20.8.C.

The pacemaker NCD also contains an identical explicit statement of non-coverage for dual chamber pacemakers. The language of the NCD for pacemakers contrasts sharply with the NCD for ICDs; the NCD for ICDs does not explicitly bar coverage for indications falling outside the NCD. Rather, it states that nothing in the NCD should be read to override the NCD for clinical trials for ICD implantations that do not fall within the NCD for ICDs.

The Appendix hereto identifies 21 NCDs that both identify covered indications and contain explicit statements of non-coverage. These 21 NCDs are unambiguous that there is no coverage unless the case falls within the NCD’s covered indications. By contrast, the NCD for ICDs contains no such unambiguous statement of non-coverage.

The difference in language between the NCD for ICDs and NCDs that restrict coverage is underscored by differences in format and headings. The format and headings used in NCDs vary depending on whether the NCD extends coverage, limits coverage, or both. The ICD NCD includes two headings related to coverage: “Covered Indications” and “Other Indications.” By contrast, NCDs that limit coverage frequently have a heading for “Nationally Non-Covered Indications.”

For example, the NCDs for colorectal cancer screening, electrical stimulation, magnetic resonance spectroscopy and percutaneous transluminal angioplasty, among other NCDs, contain a heading for “Nationally Covered Indications” and a second heading for “Nationally Non-Covered Indications.” See NCD Manual Pub. 100-03, §§ 20.7, 210.3, 220.2.1 & 270.1; see also Appendix A.

Furthermore, the content of the NCD for ICDs strongly suggests that an express statement of non-coverage would be illogical. As noted, under the current NCD, the covered indications for primary prevention describe patients who have not had an acute MI within 40 days or a CABG or PTCA within three months. There is an obvious aspect of arbitrariness to a 40-day or three-month cut-off. It would be unreasonable to take the position that there is never medical necessity on the 39<sup>th</sup> day after a heart attack, but that there is suddenly medical necessity on the 40<sup>th</sup> day.

Similarly, for post-CABG/PTCA procedures, not all three-month time periods are the same. A patient undergoing a PTCA procedure in February would have to wait 89 days for the ICD implantation to be medically necessary whereas a patient undergoing a PTCA in November would have to wait 92 days. These examples demonstrate, through *reductio ad absurdum*, that a literal application of the timing provisions of the NCD cannot logically establish a dividing line between medical necessity and lack of medical necessity.

To fit within one of the seven covered indications for primary prevention, the NCD states that the patient “must not” have had a CABG or PTCA within the past 3 months or have had an acute MI within the past 40 days. For instance, the NCD states that “Indications 3-8 (primary prevention of sudden cardiac death) must also meet the following criteria: . . . Patients must not have . . . had a CABG or PTCA within the past 3 months [or] had an acute MI within the past 40 days.” NCD Manual, § 20.4(B)(8).

That language sets forth time limitations in order for a patient to qualify for the NCD’s grant of coverage, but does not exclude coverage for those who do not qualify. Nothing in the NCD states that coverage is excluded for all primary prevention if the procedure occurs within those time frames. The prior MI or PTCA/CABG may in some cases render a procedure not reasonable and necessary, but the fact that the patient did not fit within a covered indication is not itself the reason for noncoverage.

Like the NCD for ICDs, other NCDs also refer to circumstances that “must” be present for a Medicare beneficiary to fit within an NCD’s grant of coverage but also reflect that beneficiaries who fail to meet those circumstances may nonetheless qualify for coverage. For example, the NCD for Electrical stimulation and electromagnetic therapy for the treatment of wounds explains that the procedure “will *only* be covered for chronic Stage III or Stage IV pressure ulcers, arterial ulcers, diabetic ulcers and venous stasis ulcers.” NCD Manual 270.1 (emphasis added.)

But the NCD concludes by observing that “all other uses of ES and electromagnetic therapy not otherwise specified for the treatment of wounds remain at local contractor discretion.” Similarly, the NCD for Home Prothrombin Time/International Normalized Ratio (PT/INR) Monitoring for Anticoagulation Management provides that “[t]he monitor and the home testing *must* be prescribed by a treating physician as provided at 42 CFR 410.32(a), and *all* of the following requirements *must* be met” before setting forth four conditions. NCD Manual § 190.11 (emphasis added for “must”). That NCD ends, however, by stating that “[a]ll other indications for home PT/INR monitoring not indicated as nationally covered above remain at local Medicare contractor discretion.” *Id.*

Finally, although the NCD in effect between October 1, 2003 and January 27, 2005 did contain an explicit statement of non-coverage, the statement appears to contradict the Medicare Act and, if so, would be invalid. As noted, when it adopts an NCD, CMS is supposed to be interpreting the term “reasonable and necessary,” and not making new law.

The express statement of non-coverage in the 2003 NCD is enforceable only if it does not conflict with the statute’s reasonable and necessary standard. In 2005, after analyzing additional data, CMS eliminated the explicit statement of non-coverage contained in the 2003 NCD. This deletion indicates that the explicit statement of non-coverage in 2003 did not reflect a proper interpretation of “reasonable and necessary.”

As the HHS Departmental Appeals Board has acknowledged, sometimes changes in medical practice and newer scientific studies can cause an NCD to be outdated and to inaccurately reflect the reasonable and necessary standard. *See in re Pancreas Transplants #35-82*, No A-04-89 (DAB July 1, 2005). If implantation of an ICD would have been reasonable and necessary in 2005, it would have been equally reasonable and necessary in 2003 or 2004.

For example, in *Guzzo v. Thompson*, 393 F.3d 652 (6th Cir. 2004), the Court held that the Secretary erroneously denied Medicare coverage for a cryosurgery procedure based on an NCD that the Secretary conceded was outdated in light of additional medical data. The Court found that denying coverage based on an outdated NCD “was contrary Congressional intent and the Medicare Act,” and awarded the beneficiary his attorneys’ fees because the government’s reliance on an outdated NCD was unreasonable. *Id.* at 655.

## Conclusion

The notion that Medicare only covers ICD implantations in patients who fit within one of the NCD’s covered indications is erroneous and contradicted by the NCD Manual itself. The 2005 NCD deleted an explicit statement of noncoverage which appeared in the 2003 version and which, according to the NCD Manual, is required for an NCD to bar coverage. In contrast to the 2005 NCD for ICDs, many other NCDs do contain an explicit statement of noncoverage.

## APPENDIX

### Examples of NCDs Expressly Excluding Coverage for Items or Services Not Falling Outside the NCD

Set forth below are 21 examples of NCDs that expressly state that procedures that do not fall within the NCD’s covered indications are not covered by Medicare. Citations are to sections of the CMS National Coverage Determinations Manual.

#### 20.5 - Extracorporeal Immunoabsorption (ECI) Using Protein A Columns

Other uses of these columns are currently considered to be investigational and, therefore, not reasonable and necessary under the Medicare law. (See § 1862(a)(1)(A) of the Act.)

## 20.7 - Percutaneous Transluminal Angioplasty (PTA)

### 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. The safety and efficacy of these procedures are not established.

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

### D. Other

Coverage of PTA with stenting not specifically addressed or discussed in this NCD is at local Medicare contractor discretion.

## 20.8 - Cardiac Pacemakers

### Group I: Single-Chamber Cardiac Pacemakers

#### C. Other

All other indications for single-chamber cardiac pacing for which CMS has not specifically indicated coverage remain nationally noncovered, 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

#### C. Other

All other indications for dual-chamber cardiac pacing for which CMS has not specifically indicated coverage remain nationally noncovered, 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.

## 20.9 - Artificial Hearts And Related Devices

### C. Nationally Non-Covered Indications

All other indications for the use of VADs or artificial hearts 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 NCD Manual.

## 20.20 - External Counterpulsation (ECP) Therapy for Severe Angina

### C. Nationally Non-Covered Indications

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

## 50.3 - Cochlear Implantation

### C. Nationally Non-Covered Indications

Medicare beneficiaries not meeting all of the coverage criteria for cochlear implantation listed are deemed not eligible for Medicare coverage under section 1862(a)(1)(A) of the Social Security Act.

### D. Other

All other indications for cochlear implantation not otherwise indicated as nationally covered or non-covered above remain at local contractor discretion.

## 110.4 - Extracorporeal Photopheresis

### C. Nationally Non-Covered Indications

All other indications for extracorporeal photopheresis remain noncovered.

### 110.8.1 - Stem Cell Transplantation

1. Allogeneic *Hematopoietic Stem Cell Transplantation (HSCT)*

#### B. Nationally Non-Covered Indications

Effective for services performed on or after May 24, 1996, allogeneic HSCT is not covered as treatment for multiple myeloma.

2. Autologous Stem Cell Transplantation (AuSCT)

#### C. Nationally Non-Covered Indications

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

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

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

#### D. Other

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

## 110.18 - Aprepitant for Chemotherapy-Induced Emesis

### B. Nationally Covered Indications

Effective for services performed on or after April 4, 2005, the Centers for Medicare & Medicaid Services makes the following determinations regarding the use of aprepitant in the treatment of reducing chemotherapy-induced emesis: The evidence is adequate to conclude that the use of the oral anti-emetic 3-drug combination of aprepitant (Emend®), a 5-HT<sub>3</sub> antagonist, and dexamethasone is reasonable and necessary for a specified patient population. We have defined the patient population for which the use of the oral anti-emetic 3-drug combination of aprepitant (Emend®), a 5-HT<sub>3</sub> antagonist, and dexamethasone is reasonable and necessary as only those patients who are receiving one or more of the following anti-cancer chemotherapeutic agents:

- Carmustine
- Cisplatin
- Cyclophosphamide
- Dacarbazine

- Mechllorethamine
- Streptozocin
- Doxorubicin
- Epirubicin
- Lomustine

### C. Nationally Non-Covered Indications

The evidence is adequate to conclude that aprepitant cannot function alone as a full replacement for intravenously administered anti-emetic agents for patients who are receiving highly emetogenic chemotherapy.

### 110.19 – Abarelix for the Treatment of Prostate Cancer

#### C. Nationally Non-Covered Indications

Effective March 15, 2005, CMS determines that the evidence is not adequate to conclude that abarelix is reasonable and necessary for indications other than that specified above. All other uses of abarelix are not covered. In light of the concern regarding safety risks of abarelix, off-label uses that may appear in listed statutory drug compendia on which Medicare and its contractors rely to make coverage determinations will remain noncovered unless CMS extends coverage through a reconsideration of this National Coverage Determination.

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

#### C. Nationally Non-Covered Indications

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

- Any anemia in cancer or cancer treatment patients due to folate deficiency, B-12 deficiency, iron deficiency, hemolysis, bleeding, or bone marrow fibrosis;
  - The anemia associated with the treatment of acute and chronic myelogenous leukemias (CML, AML), or erythroid cancers;
  - The anemia of cancer not related to cancer treatment;
    - Any anemia associated only with radiotherapy;
    - Prophylactic use to prevent chemotherapy-induced anemia;
    - Prophylactic use to reduce tumor hypoxia;
    - Patients with erythropoietin-type resistance due to neutralizing antibodies; and
    - Anemia due to cancer treatment if patients have uncontrolled hypertension.

### 160.18 - Vagus Nerve Stimulation (VNS)

#### C. Nationally Non-Covered Indications

Effective for services performed on or after July 1, 1999, VNS is not reasonable and necessary for all other types of seizure disorders which are medically refractory and for whom surgery is not recommended or for whom surgery has failed. Effective for services performed on or after May 4, 2007, VNS is not reasonable and necessary for resistant depression. (Information on the national coverage analysis leading to this determi-

nation can be found at: [http://www.cms.hhs.gov/mcd/viewnca.asp?where=index&nca\\_id=195.](http://www.cms.hhs.gov/mcd/viewnca.asp?where=index&nca_id=195.))

### 210.3 – Colorectal Cancer Screening Test

#### C. Nationally Non-Covered Indications

All other indications for colorectal cancer screening not otherwise specified above remain non-covered. *Non-coverage specifically includes:*

- (1) *Screening DNA (Deoxyribonucleic acid) stool tests, effective April 28, 2008, and,*
- (2) *Screening computed tomographic colonography (CTC), effective May 12, 2009.*

### 220.2 - Magnetic Resonance Imaging (MRI)

#### C. Nationally Non-Covered Indications

The Centers for Medicare & Medicaid Services (CMS) has determined that MRI of cortical bone and calcifications, and procedures involving spatial resolution of bone and calcifications, are not considered reasonable and necessary indications within the meaning of section 1862(a)(1)(A) of the Social Security Act, and are therefore non-covered.

#### D. Other

Effective June 3, 2010, all other uses of MRI or MRA for which CMS has not specifically indicated coverage or non-coverage continue to be eligible for coverage through individual local contractor discretion.

### 220.6 - Positron Emission Tomography (PET) Scans)

**NOTE:** This manual section 220.6 lists all Medicare-covered uses of PET scans. Except as set forth below in cancer indications listed as “Coverage with Evidence Development,” a particular use of PET scans is not covered unless this manual specifically provides that such use is covered. Although this section 220.6 lists some non-covered uses of PET scans, it does not constitute an exhaustive list of all non-covered uses.

### 220.6.13 - FDG PET for Dementia and Neurodegenerative

#### C. Nationally Non-Covered Indications

All other uses of FDG PET for patients with a presumptive diagnosis of dementia-causing neurodegenerative disease (e.g., possible or probable AD, clinically typical FTD, dementia of Lewy bodies, or Creutzfeldt-Jacob disease) for which CMS has not specifically indicated coverage continue to be non-covered.

### 220.6.16 – FDG PET for Infection and Inflammation

#### C. Nationally Non-Covered Indications

The CMS is continuing its national non-coverage of FDG PET for the requested indications. Based upon our review, CMS has determined that the evidence is inadequate to conclude that FDG PET for chronic osteomyelitis, infection of hip arthroplasty, and fever of unknown origin improves health outcomes in the Medicare populations, and therefore has determined that FDG PET for chronic osteomyelitis, infection of hip arthroplasty, and fever of unknown origin is not reason-

able and necessary under section 1862(a)(1)(A) of the Social Security Act.

## 220.6.17 - Positron Emission Tomography (PET) (FDG) for Oncologic Conditions)

### 4. Synopsis of New Framework

Effective for claims with dates of service on and after April 3, 2009, the CMS transitioned the prior framework—diagnosis, staging, restaging, and monitoring response to treatment—into the initial treatment strategy and subsequent treatment strategy framework. The chart below summarizes national FDG PET coverage as of November 10, 2009:

| FDG PET Coverage for Solid Tumors and Myeloma Tumor Type | Initial Treatment Strategy (formerly diagnosis & staging) | Subsequent Treatment Strategy (formerly restaging & monitoring response to treatment) |
|--|---|---|
| Colorectal   | Cover   | Cover   |
| Esophagus  | Cover   | Cover   |
| Head & Neck (not Thyroid, CNS)                           | Cover   | Cover   |
| Lymphoma   | Cover   | Cover   |
| Non-Small Cell Lung                                      | Cover   | Cover   |
| Ovary  | Cover   | Cover   |
| Brain  | Cover   | CED   |
| Cervix   | Cover w/exception*  | Cover   |
| Small Cell Lung  | Cover   | CED   |
| Soft Tissue Sarcoma                                      | Cover   | CED   |
| Pancreas   | Cover   | CED   |
| Testes   | Cover   | CED   |
| Breast (female and male)                                 | Cover w/exception*  | Cover   |
| Melanoma   | Cover w/exception*  | Cover   |
| Prostate   | Non-Cover   | CED   |
| Thyroid  | Cover   | Cover w/exception or CED*   |
| All Other Solid Tumors                                   | Cover   | CED   |
| Myeloma  | Cover   | Cover   |
| All other cancers not listed                             | CED   | CED   |

\*Cervix: Nationally non-covered for the initial diagnosis of cervical cancer related to initial treatment strategy. All other indications for initial treatment strategy for cervical cancer are nationally covered. (emphasis added).

\*Breast: Nationally non-covered for initial diagnosis and/or staging of axillary lymph nodes. Nationally covered for initial staging of metastatic disease. All other indications for initial treatment strategy for breast cancer are nationally covered.

\*Melanoma: Nationally non-covered for initial staging of regional lymph nodes. All other indications for initial treatment strategy for melanoma are nationally covered.

\*Thyroid: Nationally covered for subsequent treatment strategy of recurrent or residual thyroid cancer of follicular cell origin previously treated by thyroidectomy and radioiodine ablation and have a serum thyroglobulin >10ng/ml and have a negative I-131 whole body scan. All other indications for subsequent treatment strategy for thyroid cancer are nationally covered under CED.

## 220.6.19 – Positron Emission Tomography NaF-18 (NaF-18 PET) to Identify Bone Metastasis of Cancer

### C. Nationally Non-Covered Indications

Effective February 26, 2010, CMS determines that the evidence is not sufficient to determine that the results of NaF-18 PET imaging to identify bone metastases improve health outcomes of beneficiaries with cancer and is not reasonable and necessary under § 1862(a)(1)(A) of the Act unless it is to inform initial antitumor treatment strategy or to guide subsequent antitumor treatment strategy after completion of initial treatment, and then only under CED. All other uses and clinical indications of NaF-18 PET are nationally non-covered.

### D. Other

The only radiopharmaceutical diagnostic imaging agents covered by Medicare for PET cancer imaging are 2-[F-18] Fluoro-D-Glucose (FDG) and NaF-18 (sodium fluoride-18). All other PET radiopharmaceutical diagnostic imaging agents are non-covered for this indication.

## 240.1 - Lung Volume Reduction Surgery (Reduction Pneumoplasty)

### C. Nationally Non-Covered Indications

#### 1. LVRS is not covered in any of the following clinical circumstances:

a. Patient characteristics carry a high risk for perioperative morbidity and/or mortality;

b. The disease is unsuitable for LVRS;

c. Medical conditions or other circumstances make it likely that the patient will be unable to complete the preoperative and postoperative pulmonary diagnostic and therapeutic program required for surgery;

d. The patient presents with FEV1 <20% of predicted value, and either homogeneous distribution of emphysema on CT scan, or carbon monoxide diffusing capacity of <20% of predicted value (high-risk group identified October 2001 by the NETT); or

e. The patient satisfies the criteria outlined above in section B(1), and has severe, non-upper lobe emphysema with high exercise capacity. High exercise capacity is defined as a maximal workload at the completion of the preoperative diagnostic and therapeutic program that is above 25 w for women and 40 w for men (under the measurement conditions for cycle ergometry specified above)

#### 2. All other indications for LVRS not otherwise specified remain noncovered.

## 240.4.1 – Sleep Testing for Obstructive Sleep Apnea (OSA)

### C. Nationally Non-Covered Indications

Effective for claims with dates of services on and after March 3, 2009, other diagnostic sleep tests for the diagnosis of OSA, other than those noted above for prescribing CPAP, are not sufficient for the coverage of CPAP and are not covered.