Medical Necessity – The Sequel – Beyond Observation and Inpatient

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Objectives

- Familiarize you with the regulatory authority governing coverage determinations
- Review the criteria of several common coverage decisions
- Discuss methods to improve compliance by physicians
A 67 year old female presents with an MI, confirmed by EKG and troponin and goes to cath lab from ED where an LAD stent is placed. She is admitted and monitored. She has a 40 second run of VT that self-terminates. The cardiologist calls the EP doc who sees patient and schedules ICD. Do you…

- Allow procedure to proceed because you never question your doctor’s medical decisions?
- Stop the procedure from being scheduled?
- Discuss with the doctor and if insists then present an ABN?
- Discuss with the doctor and I insists then present a HINN 11?
Why audit at all?

- EMH Regional Medical Center And North Ohio Heart Center To Pay $4.4 Million To Resolve False Claims Act Allegations

-the United States alleged that EMH and NOHC performed angioplasty and stent placement procedures on patients who had heart disease but whose blood vessels were not sufficiently occluded to require the particular procedures at issue

The whistleblower in this matter, Kenny Loughner, was the former manager of EMH’s catheterization and electrophysiology laboratory. As a result of today’s settlement, Mr. Loughner will receive $660,859 of the United States’ recovery.
– Physician kickbacks- rent, employee salaries, student supervision
– Direct admit SNF patients from distant SNF, bypass closer hospitals
– Admit patients without acute medical needs
– Pulmonologist oversedates patients so trach needed and hospital gets DRG 003- weight- 17.8 (joint replacement- 2.87) and MD gets more visits

Variation not due to sicker patients

- Redding: 11.4
- Modesto: 5.9
- Los Angeles: 5.1
- San Francisco: 4.1

CABG per 1,000 Medicare enrollees (1998–2001)
Hospital Audits - The Beginning

● Books 1-3 – Inpatient or Observation
  – Intensity of Service and Severity of Illness
  – Comorbidities and Risk
  – 24 hours time warps into 48 hours and approached 72 hours

● Book 4 - A New World – released October 1, 2013

● Books 5-7 – The Two Midnight Rule
  – Counting Midnights
  – Intensity of Service or Severity of Illness
  – Certification of all Admissions
The Next Series- Medical Necessity

“Does the patient even need the care they are being provided, no matter what level of care was designated?”

Differentiation between:

patient/doctor wants care

v.

patient needs care
The First Chapter of the Medical Necessity Series

- **MS-DRG 470 -- Major joint replacement or reattachment of lower extremity w/o MCC**
  - Applicable NCD/LCD: LCD L32078

- FCSO CERT error findings:
  
  In 92 percent of these cases, the documentation did not support that the procedure was reasonable and necessary
How dare they tell me what is necessary!

- Section 1862(a)(1)(A) of the Social Security Act states that Medicare payments may not be made for items and services that “are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”

- Medicare is a “defined benefit” health plan. It only pays for certain things as defined by the SSA, not for everything that a patient wants or doctor orders.
Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:

- Safe and effective
- Appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is:
  - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member
    - Furnished in a setting appropriate to the patient's medical needs and condition
    - Ordered and furnished by qualified personnel
    - One that meets, but does not exceed, the patient's medical need
    - At least as beneficial as an existing and available medically appropriate alternative
Guidelines from CMS

- **NCD- National Coverage Determination**
  - Applies to all CMS jurisdictions

- **LCD- Local Coverage Determination**
  - Issued by MAC (Medicare Administrative Contractor)
What about Medicaid? Here’s IL

The department reimburses hospitals for medically necessary inpatient and outpatient diagnostic and treatment services that are provided to participants covered under the department’s medical programs. These services must be provided in compliance with hospital licensing standards.

Services Not Covered

- Items or services for which medical necessity is not clearly established
- Services provided only, or primarily, for the convenience of patients or their families
- Deceased people are not eligible for services

State of IL Handbook for Hospital Services, ch. 100 and ch. H-230
Did 92% of people get an unnecessary surgery?

- “Was the procedure truly not medically necessary or was the procedure appropriately done and it was the documentation that did not support medical necessity?”
  - My question to FCSO Medical Director, July 18, 2012 Webinar on Pre-payment reviews

- “We believe the care was appropriate in the majority of cases but strongly believe that good documentation is necessary for good care to be provided.”
  - Citation: *Outstanding medical records create superior patient outcomes* from: http://medicare.fcso.com/CERT/237256.asp
The Medical Record

When the contribution of rigorously structured medical records was studied in a critical-care setting (acute coronary syndrome) in an extensive cross-section of U.S. hospitals (more than 200), the results were dramatic: "substantial incremental differences in survival and discharge health status were observed when high standards of clinical records were maintained"

NCD’s

The NCDs are developed by CMS to describe the circumstances for Medicare coverage nationwide for a specific medical service procedure or device. NCDs generally outline the conditions for which a service is considered to be covered (or not covered) under §1862(a)(1) of the Act …NCDs are usually issued as a program instruction. Once published in a CMS program instruction, an NCD is binding on all Medicare carriers/DMERCS, FIs, QIOs, Program Safeguard Contractors (PSCs) and Medicare+Choice organizations.
And an LCD?

- An LCD is a decision by a Medicare administrative contractor (MAC), fiscal intermediary or carrier whether to cover a particular service on a MAC-wide, intermediary wide or carrier-wide basis in accordance with Section 1862(a)(1)(A) of the Social Security Act (i.e., a determination as to whether the service is reasonable and necessary).

» Chapter 13.1.3 Program Integrity Manual
The LCDs specify under what clinical circumstances a service is considered to be reasonable and necessary. They are administrative and educational tools to assist providers in submitting correct claims for payment. Contractors publish LCDs to provide guidance to the public and medical community within their jurisdictions.
Case Study

Your hospital has a busy urology service. The urologists perform TURP’s regularly. Post-op CBI is continued for two days and patients go home after 2 midnights on POD #3.

Do you...

– Advise the doctor to admit the patient pre-op since the stay will surpass 2 midnights?
– Advise the doctor to perform the surgery as outpatient and admit them prior to the second midnight?
– Advise the doctor to perform the surgery as outpatient and place them on observation if they need a third midnight?
– Advise the doctor to perform the surgery as outpatient and admit them only if they need a third midnight?
– Let them do what they want; they bring in lots of patients?
Acceptance by individual health care providers, or even a limited group of health care providers, normally does not indicate general acceptance by the medical community. Testimonials indicating such limited acceptance, and limited case studies distributed by sponsors with interest in the outcome, are not sufficient evidence of general acceptance by the medical community.

The broad range of available evidence must be considered and its quality shall be evaluated before a conclusion is reached.
So back to our TURP case

- TURP is not on Medicare’s Inpatient Only list
  - Most TURP’s should be performed as outpatient unless specific circumstances warrant inpatient status
  - The generally recognized standard for TURP’s is an overnight stay then home on POD#1
  - This group’s standard of keeping patients two overnights represents “acceptance by a limited group of health care providers”
  - Patient should be kept outpatient and admitted only if they require a third midnight in the hospital
What Is Not Included in Medical Necessity?

- I’ve always done it this way.
- But the patient insists I do it.
- The sales person said that it works well for this.
- But I have to do something.
One Big, Big, Big Caveat

- Medicare coverage and FDA approval are not the same!!!

- FDA approval = required for medication/device to be used in US- specifies FDA-approved indications

- Medicare coverage = Medicare will pay for use if fits their accepted NCD/LCD

- Pilot project- Joint FDA/CMS evaluation of new technology
  
For Example…

DEVICE: VERTOS MEDICAL MILD® DEVICE KIT

510(k) NO: K093062 (TRADITIONAL)
DECISION MADE: 04-FEB-10

St. Francis Hospital Offers a New, Mild® Procedure for Treating Chronic Back Pain

Roslyn, NY - It may be hard for some of us to imagine being able to walk only a half a block without feeling chronic pain. But it’s an ordeal patients who suffer from spinal stenosis experience every day. The debilitating condition is caused by an abnormal narrowing of the spine that can make every step a nightmare. Now St. Francis Hospital is offering a new procedure called Minimally Invasive Lumbar Decompression or MILD, that's anything but, when it comes to relieving the pain.

Patrick Anello, M.D., recently performed the first MILD procedures at St. Francis, with amazing results. The procedure is performed under a mild local anesthetic with light sedation. Using an image-guided probe the size of a pen, doctors can locate and remove small portion of tissue and bone that pinch your spinal cord and cause pain.

“Traditional back surgery can involve a three to four hour procedure with a lot of blood loss,” says Dr. Anello, a Board Certified Anesthesiologist and Pain Management physician. “A MILD procedure takes about an hour, requires no sutures, and patients can often be released from the hospital the very same day.”

Dr. Anello says patients typically have a 50-50 chance of feeling relief following the procedure.
Any LCD’s on this?

- NGS - not covered
- NHIC - covered
- Palmetto - covered
- CGS - covered
- Novitas - not covered
- WPS - covered
- FCSO - not covered
- Noridian - not covered
NGS June 2012

Percutaneous Laminotomy/Laminectomy (Intralaminar Approach) (CPT-0275T) – Related to LCD L25275

The mild® procedure is performed percutaneously with image guidance. The literature is interesting and summarized above for this procedure performed with a device that has received a 501k clearance from the Federal Drug Administration (FDA). However, the literature thus far is not considered sufficiently mature or robust to establish efficacy and coverage. Further patient outcome studies with blinding, controls and randomization with larger numbers of patients followed over a longer period time to determine efficacy are felt to be needed prior to allowing coverage.
Recently Released by CMS

Subject: Proposed Decision Memo for CAG #00433N
Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS)
Date: October 17, 2013

I. Proposed Decision
The Centers for Medicare & Medicaid Services (CMS) proposes that PILD for LSS is not reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act. Therefore, CMS proposes that PILD for LSS is non-covered by Medicare.
What does commercial insurers say?

- Image-guided minimally invasive lumbar decompression is considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.

- UHC - The following spinal procedures are unproven:
  - B. Spinal Decompression
    1. Interspinous process decompression (IPD) systems, such as the X-STOP for the treatment of spinal stenosis
    2. Minimally invasive lumbar decompression (MILD)

- Cigna does not cover a percutaneous or endoscopic laminectomy or disc decompression procedure, including but not limited to the following, because it is considered experimental, investigational or unproven
Aetna’s list of non-covered treatment for back pain

- BacFast HD for isolated facet fusion;
- Coccygeal ganglioneuroma (ganglion impar) block for coccydynia, pelvic pain, and all other indications;
- Devices for annular repair (e.g., Inclose Surgical Mesh System);
- Dynamic stabilization (e.g., Dynesys Spinal System, Graf ligamentoplasty/Graf artificial ligament, and the Stabilimex NZ Dynamic Spine Stabilization System);
- Endoscopic disc decompression, ablation, or annular modulation using the DiscFX System;
- Endoscopic laser foraminoplasty, endoscopic foraminotomy, laminotomy, and rhizotomy (endoscopic radiofrequency ablation);
- Endoscopic transforaminal diskectomy;
- Epidural fat grafting during lumbar decompression laminectomy/discectomy;
- Epidural injections of lytic agents (e.g., hyaluronidase, hypertonic saline) or mechanical lysis in the treatment of adhesive arachnoiditis, epidural fibrosis, failed back syndrome, or other indications;
- Epiduroscopy (also known as epidural myeloscopy, epidural spinal endoscopy, myeloscopy, and spinal endoscopy) for the diagnosis and treatment of intractable LBP or other indications;
- Facet chemodenervation/chemical facet neurolysis;
- Facet joint implantation;
- Far lateral microendoscopic diskectomy (FLMED) for extra-foraminal lumbar disc herniations or other indications;
- Intercoastal nerve blocks for intercostal neuritis;
- Interlaminar lumbar instrumented fusion (ILIF);
- Inter-spinous and interlaminar distraction (e.g., the Aspen spinous process fixation system, the Coflex interlaminar stabilization spinal implant, the Coflex-F implant for minimally invasive lumbar fusion, Eclipse inter-spinous distraction device, ExtenSure bone allograft inter-spinous spacer, X-Stop device, and the TOPS System) for spinal stenosis or other indications;
- Intradiscal and/or paravertebral oxygen/ozone injection;
- Intradiscal steroid injections;
- Khan kinetic treatment (KKT);
- Laser facet denervation;
- Microendoscopic discectomy (MED) procedure for decompression of lumbar spine stenosis, lumbar disc herniation, or other indications;
- Microsurgical anterior foraminotomy for cervical spondylotic myelopathy or other indications;
- Minimally invasive/endooscopic cervical laminoforaminotomy for cervical radiculopathy/lateral and foraminal cervical disc herniations or other indications;
- Minimally invasive lumbar decompression (MILD) procedure (percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements under indirect image guidance) for lumbar canal stenosis or other indications;
- Minimally invasive (endoscopic) transforaminal lumbar interbody fusion (MITLIF) for lumbar disc degeneration and instability or other indications;
- NuFix facet fusion;
- OptiMesh grafting system;
- Percutaneous cervical diskectomy;
- Percutaneous endoscopic discectomy with or without laser (PELD) (also known as arthroscopic microdiscectomy or Yeung Endoscopic Spinal Surgery System [Y.E.S.S.]);
- Piriformis muscle resection and other surgery for piriformis syndrome;
- Piriformis compartment block for lumbar radiculopathy or myositis ossificans;
- Racz procedure (epidural adhesiolysis with the Racz catheter) for the treatment of members with adhesive arachnoiditis, epidural adhesions, failed back syndrome from multiple previous surgeries for herniated lumbar disk, or other indications;
- Radiofrequency denervation for sacroiliac joint pain;
- Radiofrequency lesioning of dorsal root ganglia for back pain;
- Radiofrequency lesioning of terminal (peripheral) nerve endings for back pain;
- Radiofrequency/pulsed radiofrequency ablation of trigger point pain;
- Sacroiliac fusion or pinning for the treatment of LBP due to sacroiliac joint syndrome; **Note:** Sacroiliac fusion may be medically necessary for sacroiliac pain due to severe traumatic injury, where a trial of an external fixator is successful in providing pain relief;
- Sacroiliac joint fusion (e.g., by means of the iFuse System and the Simmons Sacroiliac Joint Fusion System);
- Sacroplasty for osteoporotic sacral insufficiency fractures and other indications;
- TruFuse facet fusion;
- Vesselplasty (e.g., Vessel-X);
- Xclose Tissue Repair System.
Gaming the system

How does a doctor avoid a non-coverage rule? “Stretch the truth”

The bait and switch for mild® procedure
- Doctor schedules as 63030- traditional diskectomy
- Vertos rep shows up in OR with mild® equipment
- Doctor performs 0275T
- Doctor bills 63030, gets paid
- Hospital must bill actual procedure- 0275T, gets denied
- Vertos still sends bill to hospital for hardware
When do insurers care about coverage?

When they pay for it!

- Was stay medically necessary? If yes, pay DRG or per diem, hospital may do “anything” to patient they feel is indicated for patient

- Did any service change the DRG/rate? If yes, evaluate medical necessity of that service

- Were any services billed separately (carved out)? If yes, evaluate each service for medical necessity- New technology add-on payments, blood clotting elements, outlier payments
Example of carve add-on denial

Section 1886(a)(4) of the Soc Sec Act provides that Prospective Payment System (PPS) hospitals receive an additional payment for the costs of administering blood-clotting factor to Medicare hemophiliacs who are hospital inpatients.

OIG Audit of Inpatient Claims for Blood Clotting Factor Drugs

OIG review- the Hospital submitted a claim to Medicare with incorrect charges, that resulted in an incorrect outlier payment. Specifically, the Hospital billed for off-label use of medication that was not covered by Medicare. (NovoSeven $10,000 per vial)

Effective January 1, 1994, off-label, medically accepted indications of Food and Drug Administration-(FDA) approved drugs and biologicals used in an anti-cancer chemotherapeutic regimen are identified under the conditions described below.

- Off-label, medically accepted indications are supported in either one or more of the compendia (4) or in peer-reviewed medical literature (26 journals).

» Medicare Benefit Policy Manual, Chapter 15, 50.4.5
The Approved Compedia

- American Hospital Formulary Service-Drug Information (AHFS-DI)
- National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
- Thomson Micromedex DrugDex
- Clinical Pharmacology
The Approved Journals

- American Journal of Medicine;
- Annals of Internal Medicine;
- Annals of Oncology;
- Annals of Surgical Oncology;
- Biology of Blood and Marrow Transplantation;
- Blood;
- Bone Marrow Transplantation;
- British Journal of Cancer;
- British Journal of Hematology;
- British Medical Journal;
- Cancer;
- Clinical Cancer Research;
- Drugs;
- European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology);
- Gynecologic Oncology;
- International Journal of Radiation, Oncology, Biology, and Physics;
- The Journal of the American Medical Association;
- Journal of Clinical Oncology;
- Journal of the National Cancer Institute;
- Journal of the National Comprehensive Cancer Network (NCCN);
- Journal of Urology;
- Lancet;
- Lancet Oncology;
- Leukemia;
- The New England Journal of Medicine; or
- Radiation Oncology
Use medications in order!

- Kyprolis™ (carfilzomib) is approved for the treatment of patients with multiple myeloma who have received at least two prior therapies, including bortezomib and an immunomodulatory agent, and have demonstrated disease progression on or within 60 days of completion of the last therapy.

- The medical record must clearly document the patient’s prior chemotherapy regimens, disease progression and body surface area.

- Documentation must include verification of the administration of dexamethasone 4 mg orally or intravenously prior to all doses of during Cycle 1 and prior to all doses during the first cycle of dose escalation to reduce the incidence and severity of infusion reactions.

- $9,550 for a typical cycle of six vials, cycle every 28 days

- Currently, no data are available that demonstrate an improvement in progression-free survival or overall survival.
**Provenge - prostate cancer**

- $33,000 per dose, 3 doses 2 weeks apart
- Documentation regarding means of castration (e.g., surgically by bilateral orchiectomy or documentation of 3 or more months of chemical castration and agent used or the medical documentation from the treating physician includes a clear statement of failure of chemical castration)
- Medical records should specifically address evidence of progressive disease after surgical or chemical castration (examples may include: changes in size of lymph nodes or parenchymal masses on physical examination or radiographic studies, bone scan progression, PSA progression, etc.)
- Evidence that the patient is asymptomatic or minimally symptomatic (should include a note about the patient’s level of activity)
- Each claim must stand alone, meaning the documentation in the submitted record must support the medical necessity of the service(s) billed on each individual claim.
Is this all about the money?

- Adherence to NCCN guidelines for treatment of ovarian cancer is correlated with overall survival and may be a useful process measure of quality cancer care. High-volume providers are significantly more likely to provide NCCN guideline-adherent care and are associated with improved survival outcomes. Ovarian cancer case volume may be a useful structural measure of quality cancer care. Increased efforts to concentrate ovarian cancer care are warranted.

Take Home Message:

Anyone at your hospital looking at outpatient chemo?
  - Can’t ask for the drug back when claim is denied.
The Other Caveat

• Just because it is not covered does not mean it cannot be offered to the patient

• ABN for outpatient services

• HINN 11- Non-covered item in covered stay
Where do I find NCD/LCD’s?

www.cms.gov/mcd
  – (Medicare Coverage decisions)
● LCD 32081- Total Joint Replacements
  – First Coast Services

● Unsuccessful history of appropriate conservative therapy (non-surgical medical management) that is clearly addressed in the pre procedure medical record. Non-surgical medical management is usually implemented for 3 months or more to assess effectiveness.
But …

- If certain conservative measures are not necessary for a given patient, it should be directly noted in the pre-procedure documentation. The clinical judgment of the treating physician is always a consideration if clearly addressed in the pre-procedure record and if consistent with the episode of care for the patient as documented in patient records and claim history.
Who Did They Consult?

- InterQual® 2011 Procedures Adult Criteria, Total Joint Replacement, Knee and Hip & Removal and Replacement, Total Joint Replacement Knee and Hip. McKesson Corporation.


A denied claim

- Mrs. Smith is a female, age 70, with chronic right knee pain. She states she is unable to walk without pain and pain meds do not work. Therefore, she needs a total right knee replacement.
An acceptable History

- Mrs. Smith is a 70-year-old female who is suffering from end-stage Osteoarthritis (OA) of her right knee, worsening gradually over the past 10 years. Treatment has included NSAIDs which have not effectively relieved her pain/inflammation and which have recently begun to cause her gastric distress. She has also participated in an exercise program/physical therapy for the past 3 months without functional improvement. Sometimes the pain keeps her awake at night. She is using a cane and is no longer able to climb the five steps to her front door. Personal safety is compromised as she had falls x 3 in attempting the stairs to her home entrance. Her knee pain and stiffness limit her ability to perform ADLs. She cannot walk from her bedroom to her kitchen without stopping to rest.
Physical Examination:

- Vital Signs: 140/90, Heart rate 78, RR 18.
- Physical exam: Bilateral varus knee deformity consistent with severe osteoarthritis. Right knee extension reduced to minus 15 degrees and flexion to less than 100 degrees. Unable to rise from chair unassisted. Full motion of the right hip, no calf tenderness or ankle edema. Antalgic gait noted.
- X-ray (7/2/11): right knee shows joint space narrowing along with marginal osteophytes.

Impression:

- Total Knee Arthroplasty (TKA) indicated.
Why are they (we) not listening?

- The J15 Part A Medical Review department performed a service-specific probe review on claims submitted for Major Joint Replacement (DRG 470) in Ohio from March through May 2013. Based on the results summarized below, the probe edit review will be advanced to a complex edit review in Ohio.

<table>
<thead>
<tr>
<th>Reviewed</th>
<th>$1,421,327.76</th>
<th>123</th>
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<tbody>
<tr>
<td>Denied</td>
<td>$459,511.03</td>
<td>41</td>
</tr>
<tr>
<td>Charge Denial Rate</td>
<td>32.3%</td>
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What about Rebilling?

Part B rebilling of denied admissions is only available for denials related to level of care, not medical necessity of the procedure itself.

Inpatient pacemaker denial for LOC- rebill as Part B, get APC and at least cost of pacemaker covered

Denial of pacemaker placement for failure to meet NCD-zero payment, you still owe Medtronic for the device
Can You See Me Now?

- Palmetto – CERT review of Cataract Extraction
  - 88% deemed not medically necessary!

- Established LCD 30889- Cataract surgery in Adults
  - Defines indications for surgery and documentation requirements

- Denials rampant in California
Indications

- Cataract causing symptomatic impairment of vision not correctable by a change in glasses or contact lenses resulting in activity limitations
- Retinopathy that cannot be monitored due to presence of cataract
Documentation

- A statement indicating that specific symptomatic impairment of visual function resulting in specific activity limitations.
- A statement or measurements indicating that the patient’s impairment of visual function is believed not to be correctable with a tolerable change in glasses or contact lenses.
- An appropriate preop ophthalmologic examination
- Ancillary testing as appropriate to establish medical necessity, such as Snellen testing, Glare testing
Cardiac Catheterization

- WPS LCD L30719, NGS L26880
- Cardiac catheterization/coronary angiography is considered the standard for evaluating ventricular function, assessing valvular heart disease and coronary artery anatomy for patient management. While other methods are available, and are important in the overall evaluation, cardiac catheterization combined with coronary angiography is typically considered the key in clinical decision-making in the surgical or percutaneous candidates.
Approved Indications

- Patients without symptoms or with atypical symptoms, who have had *documented evidence* of CAD on specified noninvasive cardiac testing
Approved Indications (cont.)

- Rest or exercise-induced electrocardiography (ECG) abnormalities suggesting myocardial *ischemia associated with other risk factors*. Abnormal exercise ECG including ST segment depression, exercise-induced ST elevation in leads other than aVr, blunted systolic blood pressure response during progressive exercise, or exercise-induced ventricular tachycardia.
Approved Indications (cont.)

- Abnormal myocardial perfusion scintigraphy includes radiopharmaceutical distribution that is compatible with coronary ischemia
Approved indications (cont.)

- Abnormal radionuclide ventriculography where the left ventricular ejection fraction falls during exercise or rest, and the findings are suggestive of CAD
- After successful resuscitation from cardiac arrest when a reasonable suspicion of coronary artery disease exists
- Prior to a high risk surgery
- Angina that has proven inadequately responsive to medical treatment or prior intervention
- Acute Coronary Syndrome
• Angina associated with abnormal results of non-invasive cardiac testing that are suggestive of CAD
Approved Indications (cont.)

- When the presence of atypical chest pain due to coronary spasm is suspected, or there are signs and symptoms of abnormal left ventricular function.
Complicated MI

- Complicated myocardial infarction
  - The patient experiences an episode(s) of ischemic chest pain, particularly when accompanied with ECG changes.
  - Mitral regurgitation or ruptured interventricular septum is suspected, particularly when accompanied with heart failure or shock.
  - Sub acute cardiac rupture (pseudo aneurysm) is suspected.
  - Hemodynamic compromise or clinical heart failure exists.
  - After non-Q-wave myocardial infarction, particularly when there is suspicion of ischemia post-MI.
More Complicated MI Indications

- Recurrent, potentially malignant ventricular arrhythmias.
- Evidence of myocardial ischemia (e.g., abnormal blood pressure response or ventricular tachycardia on predischarge exercise stress testing, abnormal laboratory testing or non-invasive cardiac tests).
- Heart failure or left ventricular ejection fraction is significantly decreased and is associated with manifestations of recurrent myocardial ischemia, or is associated with significant ventricular arrhythmias.
- Evaluation for multivessel disease for prognosis and management.
- No note about uncomplicated MI- like the old days.
What Does That All Mean?

- “Chest pain, take to cath lab” may not get paid

- Unclear if high risk patients without documented ischemia will be covered, even with a good note

(We have yet to see denials, but it’s only a matter of time.)
What About Intervention?

- WPS LCD 32791- Percutaneous Coronary Intervention
- Patients with acute coronary syndrome (e.g., acute myocardial infarction, unstable angina)
- Patients with a history of significant obstructive atherosclerotic disease
- Patients with restenosis of a coronary artery previously treated with intracoronary stent or other revascularization procedure
- Patients with chronic angina or silent ischemia

- WPS is revising the LCD now- comments welcome
“Performance of a diagnostic cardiac catheterization and interventional procedure on the same day is increasingly the standard of practice. While there may be reasons for delaying the interventional procedure (e.g., transfer from a community hospital to a tertiary center, excessive dye load, further treatment planning or evaluation of angiography, etc.), it is recommended that both procedures be performed during the same encounter when medically appropriate. Separation of these procedures for the purpose of circumventing the multiple surgery pricing, or for the convenience of physician or hospital scheduling, is considered an inappropriate practice and may subject the services to review and denial for medical necessity.”

- LCD L32791 – WPS Medicare
On the Other Hand

- Putting Ad Hoc PCI on Pause
  - Brahmajee K. Nallamothu, MD, MPH; Harlan M. Krumholz, MD, SM

- “At the other extreme are ongoing concerns about how frequently PCI is performed when medical therapy appears suitable. Part of this results from the well-described “oculo-stenotic” reflex, i.e. the tendency to treat blockages, even when clinically silent, based on benefits attributed to PCI that are not supported by the literature.”
"Stenting belongs to one of the bleakest chapters in the history of Western medicine," Nortin Hadler, a professor of medicine at the University of North Carolina at Chapel Hill, told Bloomberg. Cardiologists he said, continue to conduct these procedures because the "interventional cardiology industry has a cash flow comparable to the GDP [gross domestic product] of many countries" and doesn't want to lose it.

Ad Hoc Percutaneous Coronary Intervention: A Consensus Statement From the Society for Cardiovascular Angiography and Interventions; CCI Journal November 29, 2012
Stenting non-culprit lesions in ACS

Previous thinking- stent culprit, stage non-culprit

New study- stent all lesions > 50%

After a mean follow-up of 23 months, the primary end point, defined as death from cardiac causes, nonfatal MI, or refractory angina, occurred in 21 patients treated with preventive PCI and 53 patients treated with PCI of the culprit lesion only. This translated into a 65% relative reduction in risk and 14% absolute reduction in the primary end point. There was also an observed 68% relative reduction in the risk of nonfatal MI and a 65% reduction in the risk of refractory angina.

PRAMI- http://www.theheart.org/article/1575917.do

• Take home- Medicine changes, do your doctors change their clinical practices?
Non-Coronary Stenting

- Renal Artery
  - Uncontrolled malignant hypertension despite multidrug therapy who have been found to have unilateral or bilateral renal artery stenosis equal to or greater than 50%.
  - Progressive renal insufficiency due to atherosclerotic stenosis of > 70%.
  - Recurrent congestive heart failure, pulmonary edema, or coronary ischemia in the setting of stenosis of the renal artery(s) of > 60%.
  - Renal artery stenosis of > 50% in a transplanted kidney.

- Late breaker- Stenting does not work- watch for changes to guidelines
  
Lower Extremity

- Lifestyle limiting claudication, ischemic rest pain, nonhealing tissue ulceration, focal gangrene, dissection, impending failure of a lower extremity bypass graft.
Defibrillators ICD’s

- NCD 20.4

- Well established criteria
- Consistent with Heart Rhythm Society recommendations

- Primary prevention- patient must be able to sign own informed consent- no surrogate!

- Take Home: Use a checklist!!!- too expensive to mess around
- 32,000 ICD’s placed per year in US

- Nationally, 22.5% for non-evidence-based indications (hospital range 0-60%)

- $250,000,000 spent per year in US for ineffective device

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Non–Evidence-Based ICD Implantations in the United States Sana M. Al-Khatib, MD et al. JAMA. 2011;305(1):43-49
ICD indication #2

- Documented sustained ventricular tachyarrhythmia (VT), either spontaneous or induced by an electrophysiology (EP) study, not associated with an acute myocardial infarction (within 40 days) and not due to a transient or reversible cause.

- Our case- HINN-11- non-covered service during a covered inpatient stay
BiV pacers

- New York Heart Association (NYHA) classification of heart failure III or IV; \textit{and}
- Sinus rhythm, or chronic atrial fibrillation (AF), or frequent dependence on ventricular pacing; \textit{and}
- left ventricular ejection fraction (LVEF) less than or equal to 35 \%; \textit{and}
- QRS duration greater than or equal to 120 msec; \textit{and}
- beneficiary is on a stable pharmacologic regimen before implantation, which may include any of the following, unless contraindicated: angiotensin-converting enzyme inhibitor, angiotensin receptor blocker, beta blocker, digoxin, or diuretics
or

• NYHA classification of heart failure II; and
• sinus rhythm; and
• no evidence of atrial arrhythmia; and
• left ventricular ejection fraction (LVEF) less than or equal to 30%; and
• left bundle branch block with QRS duration greater than or equal to 130 msec; and
• beneficiary is on a stable pharmacologic regimen before implantation, which may include any of the following, unless contraindicated: angiotensin-converting enzyme inhibitor, angiotensin receptor blocker; beta blocker; digoxin, or diuretics
Cardiac-Resynchronization Therapy in Heart Failure with a Narrow QRS Complex
New England Journal of Medicine, Sept. 3, 2013

In patients with systolic heart failure and a QRS duration of less than 130 msec, CRT does not reduce the rate of death or hospitalization for heart failure and may increase mortality.
Pacemakers

- NCD 20.8
- Aug. 13, 2013 - NCD changed - single and dual covered equally
  1. Documented non-reversible symptomatic bradycardia due to sinus node dysfunction.
  2. Documented non-reversible symptomatic bradycardia due to second degree and/or third degree AV block.

- No retroactive effective date; denials will continue for 3 years based on ...
Dual Chamber Pacer criteria- for “old” pacers

- Patients in whom single-chamber (ventricular pacing) at the time of pacemaker insertion elicits a definite drop in blood pressure, retrograde conduction, or discomfort.
- Patients in whom the pacemaker syndrome (atrial ventricular asynchrony), with significant symptoms, has already been experienced with a pacemaker that is being replaced.
- Patients in whom even a relatively small increase in cardiac efficiency will importantly improve the quality of life, e.g., patients with congestive heart failure despite adequate other medical measures.
- Patients in whom the pacemaker syndrome can be anticipated, e.g., in young and active people, etc.
Old NCD Caveat

- Dual-chamber pacemakers may also be covered for the conditions (defined as Group I.A. in the Medicare NCD Manual), 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 is 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.

- Take Home: If denied, get letter from cardiologist explaining why dual chamber was indicated for this patient; also point out that studies in new NCD date from pre-2010 so standard of care has been dual chamber.
A patient is scheduled for elective a dual chamber pacemaker replacement as outpatient. The notes indicate “dual chamber pacer originally placed 1987 after syncopal episode. No old records available.” Do you…

- Allow the placement to proceed?
- Present an ABN?
- Tell the doctor to turn off the pacer and wait until she has another qualifying episode?

This could also apply to replacement ICD’s where EF has improved.
What about replacement devices?

- In this instance I don't believe the NCD would apply. The NCD applies when making the initial determination to insert a permanent cardiac pacemaker. In this situation the decision has already been made. The patient has, and has had, a pacemaker for 5 years.
- The replacement dual chamber pacemaker must meet the NCD requirements as indicated in the CMS Pub. 100-03, Chapter 1, Part 1, section 20.8.
- The critical question is whether the patient’s current clinical needs are best addressed by use of a dual chamber pacemaker or alternatively some other therapy. While certain events (e.g. syncope) may support the need for a pacemaker, the NCD does not require all beneficiaries to experience an event. There is also no NCD requirement to turn off the pacemaker and await some event.
- Given all this information, the bottom line is that reasonable clinicians should make reasonable decisions. If there is a replacement need, then some supporting documentation (to the extent of practical expectations) should be available to support the ongoing need for dual pacing at the time of replacement. The concept of reasonable & necessary is not a one-time, "static" event, but a long-term perspective for managing all Medicare beneficiaries.
Nuclear Stress tests

- NGS LCD 26859
- Diagnostic evaluation of patients with chest pain and uninterpretable or equivocal ECG changes caused by drugs, bundle branch block, or left ventricular hypertrophy
- Preoperative assessment for non-cardiac surgery, when used to determine risk for surgery and/or perioperative management in:
  - patients with minor or intermediate clinical risk predictors and poor functional capacity or patients with intermediate or high likelihood of coronary heart disease, or patients with poor functional capacity undergoing high risk non-cardiac surgery: aortic and peripheral vascular surgery
MAC ADR received by Hospital

ADR was for 35 non-emergent stress tests with SPECT. Again the reason for good cause was a “significant increase in 2012 for billing and payment”. The ADR requests;

- Copy of claim/bill
- Physician order
- Test report
- Documentation of diagnosis/ indication for test
- “All documentation that supports payment of this claim”
Question

- The patient is a 52 yr old female (on Medicare) with 3-4 months of back pain, and had difficulty walking and a limp. She had a MRI which was reported as “abnormal.” She had a history of two previous back surgeries of unknown type. Her exam showed the following: “she can walk upright, does not have to bend as much as previously, is having less pain, and does not limp.” There was no documentation of any conservative measures in the record. The surgeon has scheduled the patient for outpatient spinal fusion. Do you…
  - Allow the surgery to proceed?
  - Discuss with surgeon then present a pre-admission HINN?
  - Discuss with surgeon then present an ABN?
  - Don’t do anything because your hospital does not review cases pre-op?
Spinal Fusion for Lumbar Stenosis

- LCD 32074 First Coast Services

- Lumbar instability
- Spinal Stenosis, failed 3 months conservative treatment
- Spondylolisthesis, failed 3 months therapy
- Degenerative Disc disease, failed 6 months therapy
● This hospital allowed surgery to proceed and was denied.

● “Per CERT Physician Specialist, disagree with procedure of lumbar laminectomy and admission as being reasonable and necessary. She had multiple post-operative complications including hypotension and respiratory failure which would have been avoided if she had not had surgery.”
Another case

65 yr old female sees surgeon for gastric bypass. BMI 34, no comorbid conditions. Meets with surgeon, agrees to pay for surgery out of pocket. No discussion with hospital. Surgery performed.

Patient ends up in ICU with complications; on vent, husband brings in patient’s Medicare card, presents to hospital staff.

Who pays the bill?
The hospital is stuck with the bill

Services "related to" noncovered services (e.g., cosmetic surgery, noncovered organ transplants, noncovered artificial organ implants, etc.), including services related to follow-up care and complications of noncovered services which require treatment during a hospital stay in which the noncovered service was performed, are not covered services under Medicare.” -MBPM, Chapter 1, Section 120

Take Home: Patient should have been screened and asked to sign a HINN for surgery even if “self pay.” No HINN, no bill patient.
Stretta Procedure  CPT 43257

- NGS LCD L26863
- The Stretta procedure delivers radiofrequency thermal energy to the lower esophagus as a treatment for gastroesophageal reflux disease (GERD). National Government Services considers the Stretta procedure to be investigational and therefore non-covered.
  - efficacy based on objective physiologic measurements has not been shown;
  - a clear mechanism of action has not been determined, and;
  - significant long-term studies confirming efficacy and safety have not been carried out.
You are a general internist. Your long time patient, a healthy 70 year old female, is sent to you for medical clearance for cataract extraction. The ophthalmologist sends a form and requests you “clear the patient” and perform an EKG, CXR, CBC, CMP, PT/PTT, HCG and UA with culture. Do you…

- Clear the patient and do everything requested?
- Clear the patient and do none of the tests?
- Evaluate the patient’s suitability for surgery and indicate that there is no medical indication for the tests?
- Send the patient to another ophthalmologist?
Pre-op tests

- WPS LCD 32779- Non-covered Preoperative services
  - The use of diagnostic testing as part of a pre-operative examination, where there is an absence of signs or symptoms indicating a need for the test, is not covered under the Medicare benefit.
  - Electrocardiograms performed pre-operatively, when there are no indications for this test;
  - Radiologic examination of the chest performed pre-operatively, when there are no indications for this test;
  - PT and/or PTT performed prior to medical intervention when there are no signs or symptoms of bleeding or thrombotic abnormality or a personal history of bleeding, thrombosis conditions associated with coagulopathy.
Want to get your anesthesiologists up in arms?

- Novitas LCD DL27489- Monitored Anesthesia Care (MAC)
  - The anesthesia procedures listed in the "CPT/HCPCS Codes" section of this policy are usually provided by the attending surgeon, are included in the global fee, and are not usually separately reimbursable. However, in certain instances, MAC provided by anesthesia personnel may be necessary for these procedures, if the patients' diagnosis or pertinent medical history is reflective of one or more of the conditions found in the "ICD-9 Codes That Support Medical Necessity"
The MAC service rendered must be reasonable, appropriate and medically necessary. The presence of an underlying condition alone, as reported by an ICD-9 code, may not be sufficient evidence that MAC is necessary. The medical condition must be significant enough to impact on the need to provide MAC such as the patient being on medication or being symptomatic, etc. The presence of a stable, treated condition in and of itself is not necessarily sufficient.
So What?

- Current trend is to do colonoscopies with propofol and MAC

- Pros:
  - Faster recovery
  - Less work for GI doc- can concentrate on scope
  - Easy work for anesthesiologist
  - Really a doctor payment issue so does not affect hospital

- Cons:
  - Adds costs- insurer, Medicare, patient
    - Patient can’t pick anesthesiologist- out of network nightmares
  - GI doc fee includes payment for sedation
Is Propofol really preferred?

- 451 GI docs, 460 Endo RN’s surveyed
  - Prefer propofol- 53% GI docs, 70% RN’s
  - Prefer Versed/Fentanyl- 34% GI docs, 26% RN’s
  - Prefer no sedation- 13% GI docs, 14% RN’s
  
  - Willing to pay over $100 out of pocket for propofol
    - 15% GI docs, 24% RN’s
  
  - One doctor comment- “I am willing to fly first class as long as I don’t have to pay for it.”
190.31 PSA testing

PSA is of proven value in differentiating benign from malignant disease in men with lower urinary tract signs and symptoms (e.g., hematuria, slow urine stream, hesitancy, urgency, frequency, nocturia and incontinence) as well as with patients with palpably abnormal prostate glands on physician exam, and in patients with other laboratory or imaging studies that suggest the possibility of a malignant prostate disorder. PSA is also a marker used to follow the progress of prostate cancer once a diagnosis has been established, such as in detecting metastatic or persistent disease in patients who may require additional treatment. PSA testing may also be useful in the differential diagnosis of men presenting with as yet undiagnosed disseminated metastatic disease.

Generally, for patients with lower urinary tract signs or symptoms, the test is performed only once per year unless there is a change in the patient's medical condition.
Another one

**201.2- Pap smear**

A screening pap smear and related medically necessary services provided to a woman for the early detection of cervical cancer (including collection of the sample of cells and a physician's interpretation of the test results) and pelvic examination (including clinical breast examination) are covered under Medicare Part B when ordered by a physician (or authorized practitioner) under one of the following conditions:

- She has not had such a test during the preceding two years or is a woman of childbearing age (§1861(nn) of the Act).
- There is evidence (on the basis of her medical history or other findings) that she is at high risk of developing cervical cancer and her physician (or authorized practitioner) recommends that she have the test performed more frequently than every two years.
Looking to the Future- Potential NCD Topics

- CMS invited the public’s input concerning any items and services that may be inappropriately used (i.e., underused, overused, or misused) or provide minimal benefit in hospitals, clinics, emergency departments, doctors’ offices, or in other healthcare settings. CMS also expressed interest in public input on items or services that might improve health outcomes and are not currently covered.
- Abdominal CT
- Back surgery for recurring low back pain
- Knee MRI for likely arthritic condition
- Misuse and overuse of the hospital outpatient settings for IV infusions and injectables
- Neuroimaging for headaches
- Nonemergent percutaneous transluminal coronary angioplasty (PTCA) and stents
- Nuclear stress tests for cardiac related symptoms
- Intraaortic balloon pump and percutaneous ventricular assist device for cardiogenic shock, high risk PCI and acute MI
- Proton beam therapy for prostate cancer
- Surgery for low risk prostate cancers
- Underuse of physical therapy and other non-invasive therapy for back pain
- Vertebroplasty and kyphoplasty
- Wound center debridement vs. active wound management and frequent non-medically necessary debridement for very small wounds

But that’s not our MAC!

Contractors may review claims on either a prepayment or postpayment basis regardless of whether a NCD, coverage provision in an interpretive manual, or LCD exists for that item or service. However, automated denials can be made only when clear policy or certain other conditions (see chapter 3, §3.5.1) exist. When making individual claim determinations, the contractor shall determine whether the item or service in question is covered based on an LCD or the clinical judgment of the medical reviewer.

--Medicare Program Integrity Manual, Chapter 13 – Local Coverage Determinations, section 13.3
What Can You Do?

Educate your doctors
Create check off forms
Get office records
Educate your doctor’s office staff
Provide resources
If it is elective, review it before it happens - no notes, no criteria met, either no schedule or get patient ABN/HINN
Preadmission Physician Orders for Surgery

FAX to 1-224-783-3084 - Pre-Admission Testing when reservation made
If Inpatient or Ext. Recovery bed needed, also fax to 1-224-783-8169 - bed control
Call 1-224-783-8790 for reservations

Patient Name: __________________________ Phone: ________________
Birth Date: ____________________________
Surgery Date: ________________________ Surgery Time: ________________
Time of Arrival: _______________________
Consent to Read: (please spell out complete surgery with no abbreviations, specify left and right)

__________________________________________________________________________
__________________________________________________________________________

Diagnosis: __________________________ ICD Code: ________________

CPT Code(s) of procedure: ____________, ____________, ____________

Insurance: ___________________________ Pre-auth Number: ________________

Patient Status: (check one): ___Inpatient ___Day Surgery ___Extended Recovery
Note: OPO can only be chosen after procedure if there is a medical reason to monitor patient.
Extended Recovery should be chosen for non-medical stays for patient/physician convenience.
Refer to www.shermandocs.com for list of surgeries that must be done as Inpatient.
Take Home: What is your hospital’s new service evaluation procedure?

- Do you look at…
  - FDA/CMS/Insurance approvals?
  - Medical Necessity Guidelines?
  - Equipment costs- fixed and per procedure?
  - Staff training?
  - Reimbursement- DRG / APC?
  - Precertification requirements?
  - Expertise of physicians?

- Just because you can offer a new service does not mean that you have to offer it. (Gotta wonder…who is going to be patient #1 and do they know it?)
10 things plastic surgeons won’t tell you
What to know before you and your wallet go under the knife

By Elizabeth O’Brien and Jim Rendon

1. “I trained a whole weekend to learn this procedure.”

Dentists, gynecologists, barely trained spa technicians — it seems like everyone’s offering anti-aging treatments these days. And no wonder: Cosmetic treatments are a lucrative business, with $11 billion spent (on 14.6 million procedures) in the U.S. in 2012, up 5.5% from 2011, according to the American Society of Plastic Surgeons. That’s appealing not only to physicians hoping to offset the costs of higher malpractice premiums and lower reimbursements from

A jury ordered the hospital to pay plaintiff Clay Chandler $168 million in damages for brain damage he suffered as a result of uncorrected leakage in his abdomen after a weight loss procedure in 2007 performed by surgeon John DePeri.

Although pamphlets and other advertising materials claimed the Memorial Hospital program was accredited with the American Society of Bariatric Surgery's Center of Excellence seal, a jury found the hospital allowed a surgeon who did not meet the ASB's standards to perform surgery.

In accredited programs, providers must have performed at least 50 bariatric surgeries and completed at least 20 hours of bariatric education courses. However, DePeri performed only 21 bariatric surgeries and took one class prior to operating on Chandler.

www.fiercehealthcare.com/story/hospital-pays-178m-false-advertising-inexperienced-doc/2012-02-15#ixzz2ebqMY91C
Questions?

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