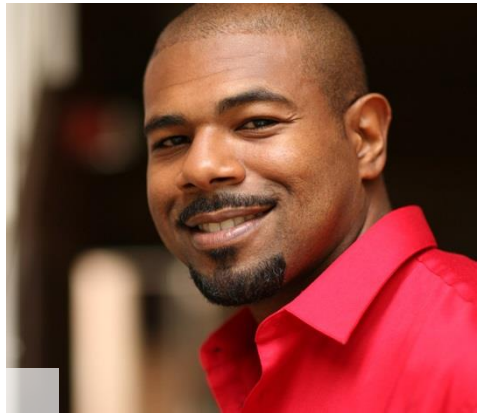
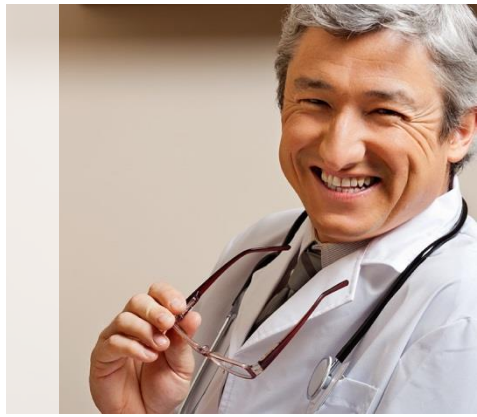



Medical Necessity

Ronald Hirsch, MD
Accretive Health





What is Medical Necessity?

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 and commercial plans are "defined benefit" health plans. They only pay for certain services as defined, not for everything that a patient wants or doctor orders.

Reasonable and Necessary

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
  - http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pim83c13.pdf

Commercial Insurers add Cost

Clinical evidence- Credible, published, scientific evidence supported by controlled clinical trials or observational studies

Rigorous and consistent clinical management of:

Clinical effectiveness - Treatment of illness, injury, disease or symptom must be proven to be clinically effective.

Clinical appropriateness - Type, frequency, extent and duration of services must be appropriate for the individual member.

Cost effectiveness - Services must not be more costly than alternative services that are at least as likely to produce equivalent therapeutic and diagnostic results.

- http://consultant.uhc.com/assets/medical-necessity-overview-presentation.pdf

Medical Necessity- Two Types

Medically necessary of the setting- Does the patient require care that can only safely be provided in the hospital/rehab/LTACH/SNF/home?

The 2 MN Rule- "The crux of the medical decision is the choice to keep the beneficiary at the hospital in order to receive services **or** reduce risk, or discharge the beneficiary home because they may be safely treated through intermittent outpatient visits or some other care."

2014 IPPS Final Rule, p. 50945

Home Care

Confined to the Home

1) because of illness or injury, need the aid of supportive devices such as crutches, canes, wheelchairs, and walkers; the use of special transportation; or assistance of another person in order leave their place of residence, ***or*** *have a condition such that leaving his or her home is medically contraindicated.*

and

2) there must exist a normal inability to leave the home and if the patient does leave home, it requires a considerable and taxing effort.

Require Skilled Services

Medical necessity to provide the care itself- Does the patient have medical necessity to have the service that is being planned for them?

How is Medical Necessity Determined?

Medicare

- National Coverage Determinations (NCD)
  - From CMS, apply everywhere, cannot be ignored
- Local Coverage Determinations (LCD)
  - From each Medicare Administrative Contractor (MAC)
  - Apply to area specified by the MAC
  - Exceptions allowed, can be overruled by an ALJ
- Clinical Judgment of the Medical Reviewer
  - Published medical literature, consensus of expert medical opinion, and consultations with their medical staff, medical associations, including local medical societies, and other health experts

What about the FDA?

510 (K) Process

- Product substantially equivalent to existing technology; no additional testing needed
- FDA cleared does not mean insurance approved or even safe

What is your hospital's new product/ service evaluation procedure?

Do you look at…

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

Left Atrial Appendage Occlusion

Press Releases

Boston Scientific Receives FDA Approval for WATCHMAN™ Left Atrial Appendage Closure Device

First-Of-Its-Kind Alternative to Long-Term Warfarin Therapy for Stroke Risk Reduction in Patients with Non-Valvular Atrial Fibrillation

Mar 13, 2015

Approved but no one will pay for it

Cahaba, NGS draft LCDs- Left atrial appendage closure or occlusion by any technique for any indication is not safe and effective based on review of available literature using standard strength of evidence guidelines.

Cigna, Aetna, BC of NC, MS, etc.- The use of percutaneous left-atrial appendage closure devices for the prevention of stroke in atrial fibrillation is considered **investigational.**

What Exactly was Approved???

Device Information:

Trade Name:	LARIAT Loop Applicator
Classification:	Class II
Classification Name:	Suture, Non-absorbable, Synthetic

Physical Description:

The LARIAT Loop Applicator is a one piece, single-use suture delivery and deployment device with a pre-tied polyester suture loop that is pre-loaded on the device. A central lumen within the LARIAT Loop Applicator is designed for aspiration and stabilization of tissue during the delivery of the LARIAT Suture Loop.

The suture is itself a cleared medical device as a part of Pre-Market Notification K021019.

Intended Use:

The LARIAT Loop Applicator facilitates suture placement and knot tying for use in surgical applications where soft tissue are being approximated and/or ligated with a pre-tied polyester suture.

Equivalent Device:

The subject device is substantially equivalent in intended use and/or method of operation to the Ethicon Endosuture System (K963329), the Genzyme Saph-Loop Ligating Loop (K022410), and the HysteRx Liga-Loop Suture Applicator (K993695).

Purpose: The FDA is alerting health care providers and patients of reports of patient deaths and other serious adverse events associated with the use of the LARIAT Suture Delivery Device and its associated devices to close the left atrial appendage, a pouch-like region of the left atrium in the heart, in patients with irregular heart rhythm (atrial fibrillation) to prevent stroke.

We identified 45 adverse events through June 30, 2015 that occurred in patients undergoing LAA closure procedures with the LARIAT Suture Delivery Device and/or its associated devices. These reports describe 6 patient deaths and other serious medical complications including laceration and/or perforation of the heart, complete LAA detachment from the heart, bleeding (hemorrhage), low blood pressure (hypotension), fluid collection around the heart (pericardial effusion), fluid collection around the heart that causes low blood pressure and decreased heart function leading to shock (cardiac tamponade), and fluid collection around the lung (pleural effusion). Of the 45 adverse events reported to the FDA, 34 (approximately 75%) resulted in the need to perform emergency heart surgery.

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm454501.htm

Gaming the system

So 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

51 Back Pain Procedures Not Covered by Aetna

AccuraScope procedure;
Annulus repair devices (Xclose Tissue Repair System, Barricaid, Disc Annular Repair Technology (DART) System)
BacFast HD for isolated facet fusion;
Chemical ablation (including but not limited to alcohol, phenol or sodium morrhuate) of facet joints;
Coccygeal ganglion (ganglion impar) block for coccydynia, pelvic pain, and all other indications;
Cryoablation (cryoanesthesia, cryodenervation, cryoneurolysis, or cryosurgery) for the treatment of lumbar facet joint pain;
Deuk Laser Disc Repair;
Devices for annular repair (e.g., Inclose Surgical Mesh System);
Dynamic (intervertebral) stabilization (e.g., BioFlex, CD Horizon Agile Dynamic Stabilization Device, DSS Dynamic Soft Stabilization System, Dynabolt Dynamic Stabilization System, Dynesys Spinal System, Graf ligamentoplasty/Graf artificial ligament, Isobar Spinal System, NFix, Satellite Spinal System, Stabilimax NZ Dynamic Spine Stabilization System, and the Zodiak DynaMo 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;
Epidural steroid injections for the treatment of non-radicular low back pain;
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 allograft implants (NuFix facet fusion, TruFuse facet fusion)
Facet joint implantation (Total Posterior-element System (TOPS) (Premia Spine), Total Facet Arthroplasty System (TFAS) (Archus Orthopedics), ACADIA Facet Replacement System (Facet Solutions/Globus Medical);
Far lateral microendoscopic diskectomy (FLMED) for extra-foraminal lumbar disc herniations or other indications;
Intercostal nerve blocks for intercostal neuritis;
Interlaminar lumbar instrumented fusion (ILIF);
Interspinous and interlaminar distraction devices (see Appendix);
Interspinous fixation devices (CD HORIZON SPIRE Plate, PrimaLOK SP, SP-Fix Spinous Process Fixation Plate, and Stabilink interspinous fixation device) for spinal stenosis or other indications (see Appendix)
Intradiscal, paravertebral, or epidural oxygen or ozone injections;
Intradiscal steroid injections;
Intravenous administration of corticosteroids, lidocaine, magnesium, Toradol or vitamin B12 (cyanocobalamin) as a treatment for back pain;
Khan kinetic treatment (KKT);
Laser facet denervation;
Least invasive lumbar decompression interbody fusion (LINDIF);
Microendoscopic discectomy (MED; same as lumbar endoscopic discectomy utilizing microscope) 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/endoscopic 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 canall stenosis or other indications;
Minimally invasive thoracic discectomy for the treatment of back pain;
Minimally invasive (endoscopic) transforaminal lumbar interbody fusion (MIT LIF; same as MAST fusion) for lumbar disc degeneration and instability or other indications;
OptiMesh grafting system;
Percutaneous cervical diskectomy;
Percutaneous endoscopic diskectomy with or without laser (PELD) (also known as arthroscopic microdiskectomy or Yeung Endoscopic Spinal Surgery System [Y.E.S.S.]);
Piriformis muscle resection and other surgery for piriformis syndrome;
Psoas compartment block for lumbar radiculopathy or myositis ossification;
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 joint infection, tumor involving the sacrum, and 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 SImmetry Sacroiliac Joint Fusion System);
Sacroplasty for osteoporotic sacral insufficiency fractures and other indications;
Total Facet Arthroplasty System (TFAS) for the treatment of spinal stenosis;
Vesselplasty (e.g., Vessel-X

New procedure run amok

The local coverage determination (LCD) for low density lipoprotein (LDL) apheresis became effective on February 4, 2013.

Medicare Part B data analysis obtained for the second half of 2013 indicated a significant increase in Carrier to Nation Ratio at nearly 800 percent above the national average. Due to the risk for a high dollar claim payment error, this LCD has been revised to address the limited indications for this service and establish frequency parameters in the utilization guidelines section for LDL apheresis.

LCD 33000- First Coast Services

In order to initiate LDL apheresis, patients must have refractory familial hypercholesterolemia (FH), have failed at least a six-month continuous trial of maximum-tolerated drug therapy (defined as a trial of drugs from at least three separate classes of hypolipidemic agents such as bile acid sequestrants, HMG-COA reductase inhibitors, fibric acid derivatives, or niacin/nicotinic acids) and diet therapy and have met the following criteria:

Group A. Functional Homozygous FH with LDL-C > 500 mg/dl; or

Group B. Functional heterozygous (or homozygous) FH with LDL-C > 190 mg/dl with CHD (as defined below) or with a CHD risk equivalent (as defined below):

http://goo.gl/KlB4Nf

New Technology Will be Scrutinized

If yes, evaluate each service for medical necessity- New technology add-on payments, blood clotting elements, outlier payments

Argus- artificial retina- $72,028.75

Kcentra- reversal of warfarin bleeding- $1,587.50

CardioMEMS monitor- $8,875

MitraClip valve- $15,000

Responsive Neurostimulator System - $18,475

Blinatumomab- $27,018

LUTONIX® and IN.PACT™ Admiral™- $1,036

The Big Money

ICD- Defibrillators

NCD 20.4

Get the NCD, develop a check list

New HRS guidelines adopted in 2014 expand indications- NCD not yet changed. Lots of money at risk http://goo.gl/lfEMQ3

A Little Bit Less Money

Pacemakers

NCD 20.8

Revised August 13, 2013

Documented non-reversible symptomatic bradycardia

- Need a rhythm strip
- Need symptoms
- Need no meds that slow HR or note that meds cannot be stopped

Does it need fixing?

Hundreds sue Ky. hospital over heart procedures

Andrew Wolfson, The (Louisville, Ky.) Courier-Journal 10 a.m. EST February 17, 2013

The hospital and 11 cardiologists are accused of conspiring to perform unnecessary procedures to unjustly enrich themselves.

(Photo: James Crisp, The (Louisville, Ky.) Courier-Journal)

727 CONNECT | 141 TWEET | 10 LINKEDIN | 43 COMMENT | EMAIL | MORE

LONDON, Ky. -- After enduring at least two-dozen heart procedures over two decades, disabled former meat cutter Edward Marshall decided in September 2010 that he'd been treated long enough by cardiologists at St. Joseph London hospital.

So he saw a specialist in Lexington, who told him some disturbing news: An artery treated just months earlier was barely blocked, and there had been no need for Dr. Sandesh "Sam" Patil to enlarge it with a balloon angioplasty, then prop it open with a stent.

"I would have not carried out this procedure," the Lexington cardiologist, Dr. Michael R. Jones, told Marshall in a letter that is included in the court record.

STORY HIGHLIGHTS

- Suit claims two patients died, others at risk for potentially fatal complications
- St. Joseph London hospital, physicians deny allegations
- U.S. attorney's office in

http://www.usatoday.com/story/news/nation/2013/02/16/hundreds-sue-hospital-over-heart-procedures/1925245/

Total Joints- The start of Denial Frenzy

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 …there is an exception

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.

No NCD but CMS stepped in

CMS publication MLN Matters SE 1236

Documenting Medical Necessity for Major Joint Replacement (Hip and Knee)

CMS recognizes that joint replacement surgery is reserved for patients whose symptoms have not responded to other treatments. To avoid denial of claims for major joint replacement surgery, the medical records should contain enough **detailed** information to support the determination that major joint replacement surgery was reasonable and necessary for the patient. **Progress notes consisting of only conclusive statements should be avoided.**

Why are they 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.

Reviewed	$1,421,327.76	123
Denied	$459,511.03	41
Charge Denial Rate	32.3%	

Nuclear Stress Tests

Patient calls hospital to schedule test.

Do you have a written order from MD?

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Patient calls hospital to schedule test.

Do you have a written order from MD?

What is the ICD-9 code? 786.50

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Does anyone check to see if the patient actually needs a nuclear stress test?

Noridian LCD L33660

The patient has an abnormal ECG with a high likelihood of coronary artery disease (CAD) based on multiple risk factors or strongly suggestive symptoms

The patient takes medication that would make interpretation of a standard exercise test inaccurate

The patient had an abnormal standard stress test and further evaluation is medically necessary

The patient has a condition which would likely result in a nondiagnostic or inaccurate standard stress test

CT scanner- the “tunnel of truth”

From 1995 to 2007, the number of ED visits that included a CT examination increased from 2.7 million to 16.2 million, constituting a 5.9-fold increase and a compound annual growth rate of 16.0%. The percentage of visits associated with CT increased from 2.8% to 13.9%, constituting a 4.9-fold increase and a compound annual growth rate of 14.2%.

Radiology. 2011 Jan;258(1):164-73.

A CT scan is ordered…

Patient calls hospital to schedule CT

Do you have a written order from MD?

Does the ICD-9 code support it?

Is the order signed and dated by doctor?

Does anyone check to see if a CT scan

Is actually medically necessary?

Provider Compliance Tips for CT Scans

If you receive a documentation request from a Medicare review contractor, submit:

1. The order from the ordering practitioner-

If you forgot to keep a copy of the order, contact the ordering practitioner and request that they send you a copy of the order.

If the ordering practitioner can't find a copy of the order in the patient's medical record, ask them to send you the progress notes, plan of care or any other medical record entry from PRIOR to the day of the CT scan that documents the intent to order the CT scan.

2. **The ordering practitioner's progress notes** or other medical record entries (e.g. medical history, physical exam) documenting why the CT scan is needed

Medicare Learning Network ICN907793 April 2014

NCD 220.1- CT scans

There is no general rule that requires other diagnostic tests to be tried before CT scanning is used. However, in an individual case the Medicare Administrative Contractor (MAC) medical staff may determine that use of a CT scan as the initial diagnostic test was not reasonable and necessary because it was not supported by the patient's symptoms or complaints stated on the claim form; e.g., "periodic headaches."

So, is it appropriate?

American College of Radiology Appropriateness Criteria

Clinical Condition: **Headache**

Variant 1: **Chronic headache. No new features. Normal neurologic examination.**

Radiologic Procedure	Rating	Comments	RRL*
MRI head without and with contrast	4	See statement regarding contrast in text under "Anticipated Exceptions."	O
MRI head without contrast	4		O
CT head without contrast	3		☢☢☢
CT head without and with contrast	3		☢☢☢
CT head with contrast	3		☢☢☢
MRA head without and with contrast	2		O
MRA head without contrast	2		O
Arteriography cervicocerebral	2		☢☢☢
CTA head with contrast	2		☢☢☢
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

Follow up Testing- Is it Indicated?

Nodule Type	Management Recommendations	Additional Remarks
Solitary pure GGNs		
≤5 mm	No CT follow-up required	Obtain contiguous 1-mm-thick sections to confirm that nodule is truly a pure GGN
>5 mm	Initial follow-up CT at 3 months to confirm persistence then annual surveillance CT for a minimum of 3 years	FDG PET is of limited value, potentially misleading, and therefore not recommended
Solitary part-solid nodules	Initial follow-up CT at 3 months to confirm persistence. If persistent and solid component <5 mm, then yearly surveillance CT for a minimum of 3 years. If persistent and solid component ≥5 mm, then biopsy or surgical resection	Consider PET/CT for part-solid nodules >10 mm
Multiple subsolid nodules		
Pure GGNs ≤5 mm	Obtain follow-up CT at 2 and 4 years	Consider alternate causes for multiple GGNs ≤5 mm
Pure GGNs >5 mm without a dominant lesion(s)	Initial follow-up CT at 3 months to confirm persistence and then annual surveillance CT for a minimum of 3 years	FDG PET is of limited value, potentially misleading, and therefore not recommended
Dominant nodule(s) with part-solid or solid component	Initial follow-up CT at 3 months to confirm persistence. If persistent, biopsy or surgical resection is recommended, especially for lesions with >5 mm solid component	Consider lung-sparing surgery for patients with dominant lesion(s) suspicious for lung cancer

Recommendations for the Management of Subsolid Pulmonary Nodules Detected at CT: A Statement from the Fleischner Society-- http://dx.doi.org/10.1148/radiol.12120628

Let's "see" what else is at Risk

Cataract Extraction 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

Palmetto Audit March to May 2014

A total of 785 claims were reviewed, with 308 of the claims either completely or partially denied. The total dollars reviewed was $2,659,398.06 out of which $913,119.92 was denied, resulting in a charge denial rate of 34.3 percent.

Denial Code	Denial Description	Specific 'Granular' Error Findings	Number of Occurrences
5D164/5H164	Documentation Submitted Does Not Support Medical Necessity	No Evidence of Patient's Best Corrected Snellen Visual Acuity (BCVA) Present in the Record.	187
5D164/5H164	Documentation Submitted Does Not Support Medical Necessity	No Evidence of Patient Reported Impairment of Visual Function Resulting in Restriction of Activities of Daily Living.	163
5D164/5H164	Documentation Submitted Does Not Support Medical Necessity	No Evidence/Documentation That Comprehensive Eye Examination and a Single Diagnostic A-Scan Was Done.	29
5D169/5H169	Services Not Documented	The Documentation Submitted Does Not Support Operative Eye Billed.	28
5D169/5H169	Services Not Documented	A Signed Operative Note/Report is Not Present.	26

Will chemo denials metastasize?

Ixabepilone (Ixempra ™), 1mg (J9207) Breast Cancer (174.0-175.9)

Ixabepilone is indicated in combination with capecitabine for the treatment of patients with metastatic or locally advanced breast cancer resistant to treatment with an anthracycline and a taxane, or whose cancer is taxane resistant and for whom further anthracycline therapy is contraindicated.

Anthracycline resistance is defined as progression while on therapy or within 6 months in the adjuvant setting or 3 months in the metastatic setting. Taxane resistance is defined as progression while on therapy or within 12 months in the adjuvant setting or 4 months in the metastatic setting.

Ixabepilone is indicated as monotherapy for the treatment of metastatic or locally advanced breast cancer in patients whose tumors are resistant or refractory to anthracyclines, taxanes, and capecitabine.

What is the Medicare Regulation?

Coverage for medication is based on the patient's condition, the appropriateness of the dose and route of administration, based on the clinical condition and the standard of medical practice regarding the effectiveness of the drug for the diagnosis and condition. The drug must be used according to the indication and protocol listed in the accepted compendia ratings listed below.

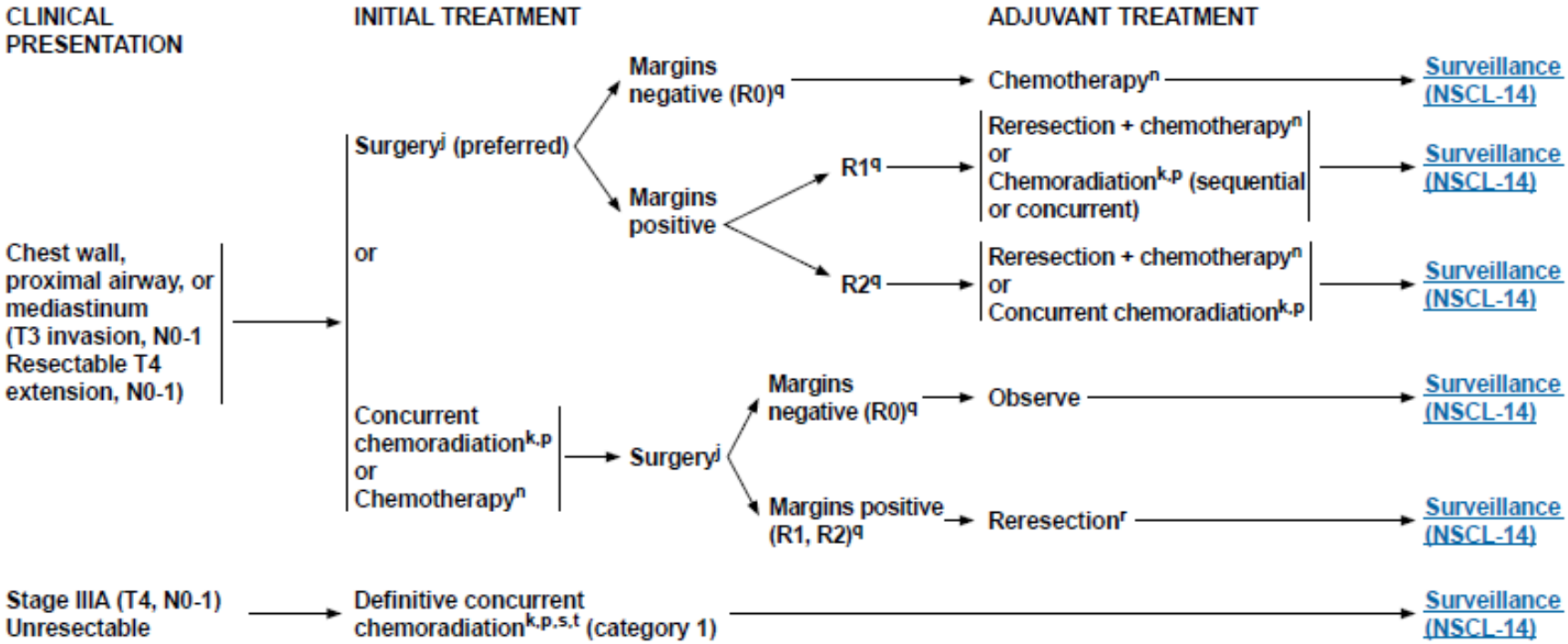
-National Comprehensive Cancer Network (NCCN) Drugs and Biologies Compendium
-Thomson Micromedex DrugDex
-American Hospital Formulary Service-Drug Information (AHFS-DI)
-Clinical Pharmacology

and

-Peer Reviewed Literature

NCCN Guidelines Version 5.2015
Non-Small Cell Lung Cancer

NCCN Guidelines Index
NSCLC Table of Contents
Discussion



[j] See Principles of Surgical Therapy (NSCL-B).
[k] See Principles of Radiation Therapy (NSCL-C).
[n] See Chemotherapy Regimens for Neoadjuvant and Adjuvant Therapy (NSCL-D).
[p] See Chemotherapy Regimens Used with Radiation Therapy (NSCL-E).
[q] R0 = no residual tumor, R1 = microscopic residual tumor, R2 = macroscopic residual tumor.
[s] RT should continue to definitive dose without interruption if patient is not a surgical candidate.
[t] If full-dose chemotherapy is not given concurrently with RT as initial treatment, give additional 2 cycles of full-dose chemotherapy.
[u] Consider RT boost if chemoradiation is given as initial treatment.

Note: All recommendations are category 2A unless otherwise indicated.
Clinical Trials: NCCN believes that the best management of any cancer patient is in a clinical trial. Participation in clinical trials is especially encouraged.

Can you afford $5,000 per denial?

South Carolina Results

A total of 97 claims were reviewed, with 81 of the claims either completely or partially denied. The total dollars reviewed was $677,251.37 of which $431,708.53 was denied, resulting in a charge denial rate of 63.7%.

- There was no physician certified diagnosis submitted in the medical record that would substantiate the medical need for use of bevacizumab.
- For the diagnosis of non-squamous non-small cell lung cancer (unresectable, locally advanced, recurrent or metastatic), the recommended dose for bevacizumab of less than or equal to 15 mg/kg intravenously every 3 weeks in combination with carboplatin and pacilitaxel was not ordered or followed.

http://goo.gl/KObpwM

Noridian aiming to stamp out Cancer

Recent Announcements Published to "Latest Updates"

- **Outpatient Drug J0897 - California Service Specific Probe Review Notification**
  Noridian Healthcare Solutions (Noridian) is initiating a service specific probe review for outpatient drug services. Read the complete update
- **Outpatient Drug J0178 - California Service Specific Probe Review Notification**
  Noridian Healthcare Solutions (Noridian) is initiating a service specific probe review for outpatient drug services. Read the complete update
- **Outpatient Drug J9041 - California, Service Specific Probe Review Notification**
  Noridian Healthcare Solutions (Noridian) is initiating a service specific probe review for Outpatient Drug Services. Read the complete update
- **Outpatient Drug J2505 - California Service Specific Probe Review Notification**
  Noridian Healthcare Solutions (Noridian) is initiating a service specific probe review for outpatient drug services. Read the complete update
- **Outpatient Drug J9310 - California Service Specific Probe Review Notification**
  Noridian Healthcare Solutions (Noridian) is initiating a service specific probe review for outpatient drug services. Read the complete update
- **Outpatient Drug J9055 - California Service Specific Probe Review Notification**
  Noridian Healthcare Solutions (Noridian) is initiating a service specific probe review for Outpatient Drug Services. Read the complete update

Neulasta

Glowing with the Risk of Denial- IMRT

IMRT is considered reasonable and necessary in instances where sparing the surrounding normal tissue is of added benefit and *at least one* of the following conditions is met:

-The target volume is in close proximity to critical structures that must be protected.
-The volume of interest must be covered with narrow margins to adequately protect immediately adjacent structures.

-An immediately adjacent area has been previously irradiated and abutting portals must be established with high precision.

-The target volume is concave or convex, and critical normal tissues are within or around that convexity or concavity.

-Dose escalation is planned to deliver radiation doses in excess of those commonly utilized for similar tumors with conventional treatment.

What cancers are those?

Primary, metastatic or benign tumors of the central nervous system including the brain, brain stem and spinal cord;

Primary, metastatic tumors of the spine where the spinal cord tolerance may be exceeded with conventional treatment

Primary, metastatic, or benign lesions to the head and neck area including: Orbits, Sinuses, Skull base, Aero-digestive tract, Salivary glands;

Carcinoma of the prostate;

Selected cases of thoracic and abdominal malignancies;

Selected cases (i.e. not routine) of breast cancers with close proximity to critical structures;

Other pelvic and retroperitoneal tumors that meet the requirements for medical necessity; and

Re-irradiation that meets the requirements for medical necessity

WPS LCD L30316

Do your doctors document “IMRT because…”?

Although IMRT is not indicated as the routine management for other cancers, IMRT is often reasonable and necessary treatment for other sites. There is no definitive list of "approved sites" nor is it possible to preclude some cancers solely on the basis of primary site of origin. The radiation oncologist must consider the five criteria detailed above (proximity to critical structures, narrow margins, previous radiation, target shape, and dose escalation requirement) and then determine if IMRT is indicated. For example, IMRT may be indicated in the treatment of lung cancers and intra-abdominal and pelvic malignancies where the effect of organ motion must be considered. In the case of breast cancer, while not routine, IMRT may be indicated when the tumor is in proximity to the heart. For all instances, the physician should document the indications for IMRT. It may be used as the primary/sole modality or as a boost to conventional therapy.

We've tried everything; time to cut

12/11/2013 Per CERT Physician, disagree with the procedure of bilateral laminectomy, facetectomy and foraminotomy and thus admission as being reasonable and necessary. Beneficiary had "intractable low back and leg pain" and opted to proceed to surgery. There however was no documentation of conservative treatments or even any reports of radiologic imaging submitted. Without more data on how it affects his daily activities or what treatment have been tried, cannot approve the surgery option.

Joint replacements, spine surgery are top targets

Spinal Fusion

DRG 460 – North Carolina Results

A total of 137 claims were reviewed, with 90 of the claims either completely or partially denied. The total dollars reviewed was $3,436,774.63, out of which $2,246,323.73 was denied, resulting in a charge denial rate of 65%. The denial reasons identified, based on dollars denied, were:

98.6%- Need for Services Not Medically and Reasonably Necessary

You don't want this denial!

"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."

Observation leads to Outlier Pay

For 22 of the 73 sampled claims, the Hospital incorrectly billed Medicare for observation hours resulting in incorrect outlier payments. Specifically, the Hospital included observation time for services that were part of another Part B service including postoperative monitoring or standard recovery care (10 errors), for time the patients remained in the hospital after treatment was finished (3 errors), or the medical record did not contain an order for the observation services (1 error). For the remaining 8 errors, the patient's condition did not warrant observation services.

– OIG audit of Northwestern Memorial Hospital

Take Aways

Look at your high volume/high dollar services

Are there medical necessity coverage guidelines?

- Medicare
- Commercial insurers, including MA plans

Does the patient meet those guidelines?

Look at your new procedures

How much care can you afford to give away?

2016 OPPS Proposed Rule

Observation

Currently APC 8009

-ED visit or direct admit plus 8 or more hrs Observation = $1,234

-Eligible part B services billed separately

-imaging, diagnostic and therapeutic procedures

-No 8009 if status T procedure day of or day prior

Proposed C-APC 8011

-ED visit or direct admit plus 8 or more hrs Observation = $2,111

No other services can be billed- same as cv, surgery, gyne

2016 OPPS Proposed Rule

While we have been clear that the 2-midnight benchmark does not override the clinical judgment of the physician regarding the need to keep the beneficiary at the hospital, to order specific services, or to determine appropriate levels of nursing care or physical locations within the hospital, some stakeholders have argued that the 2-midnight benchmark removes physician judgment from the decision to admit a patient for inpatient hospital services. We disagree….but

2016 OPPS Proposed Rule

but…we are proposing to modify our existing "rare and unusual" exceptions policy to allow for Medicare Part A payment on a case-by-case basis for inpatient admissions that do not satisfy the 2-midnight benchmark, if the documentation in the medical record supports the admitting physician's determination that the patient requires inpatient hospital care despite an expected length of stay that is less than 2 midnights.

What does that mean?

CMS says there is no difference between inpatient and outpatient care for patients who are expected to need under two midnights of care except when physician judgment says there is a difference.

Utter Nonsense!

What is the 2 MN Rule?

Two and a half step process

1- Does the patient require care that can only be safely provided in the hospital?

2- How many midnights is the patient expected to require in the hospital until able to safely move to a lower level of care (regardless of who is going to pay for that care)?

2.5- Always admit if second midnight is necessary.

Two Midnight Audits

The audit moratorium is over Sept 30, 2015

BFCC-QIO to take over short stay review admissions as of October 1, 2015

20 per small hospital, 50 per large hospital per year, audited every 6 months

QIO will discuss cases with provider prior to denying

High denial hospitals to be referred to the RACs for further auditing; no idea what is a high error rate

Comprehensive Care for Joint Replacement

71 cities, all total joint patients included

All A and B costs for 90 days from surgery

Savings can be shared – hospital, MD, SNF, HHA, PT

Year 2- overruns must be paid back, 3 day SNF rule can be waived for 3+ star SNF

Medicare Care Choices

141 hospices chosen- 4 in NJ- VNA of Engelwood, Compassionate Care Marlton, RWJ VN, Meridan in Neptune

Can provide palliative care to hospice-eligible patients who want cont'd curative treatment- CA, HF, COPD, HIV

$400 per patient per month

Home Care Certification Documentation

Transmittal 602, Change Request 9189

No face-to-face form required

Physician orders home care on eligible patient

HHA documents homebound status and skilled needs in plan of care

HHA sends plan to physician, reviews and signs it

Physician keeps copy in office chart

see my RACMonitor.com article

A Moment of Silence

For ICD-9. Your simplicity, familiarity and brevity will be missed.

Questions?

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