



# Medical Necessity

## CURRENT STATUS AND KEY BEST PRACTICES IN PREVENTION OF MEDICAL NECESSITY DENIALS AND RECOUPMENTS

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### Agenda

- A discussion of medical necessity – what it means and what it affects
- Details regarding the types of medical necessity determinations and the criteria for determining medical necessity
- An explanation of categorically excluded services
- Admission criteria [to include Skilled Nursing Facilities (SNF) and Inpatient Rehabilitation Facilities (IRF)]
- Recoupments and Self-Disclosure Protocol



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## What is Medical Necessity?

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### Types of Medical Necessity



#### **Clinical medical necessity<sup>1</sup>**

- Documentation by a physician or other practitioner (ordering practitioner) who is:
  - (a) licensed by the state to admit inpatients to hospitals
  - (b) granted privileges by the hospital to admit inpatients to that specific facility
  - (c) knowledgeable about the patient's hospital course, medical plan of care, and current condition at the time of admission

#### **Coding documentation for medical necessity**

- The admitting diagnosis code is the condition identified by the ordering practitioner at the time of the patient's admission to the hospital (this can include signs/symptoms on admission).

1: Hospital Inpatient Admission Order and Certification, CMS (January 30, 2014)

## Medical Necessity



### Definition

- Health care services or supplies needed to diagnose or treat an illness, injury, condition, disease, or its symptoms that meet accepted standards of medicine
- Safe, effective, not experimental, appropriate in terms of accepted standards of good medical practice, appropriate setting, furnished by qualified personnel<sup>2</sup>
  - FDA approval/clearance alone does not generally entitle a device to Medicare coverage.<sup>3</sup>
  - A type of molecular testing for cancer treatment found to be investigational where medical literature described testing as “promising”, or “randomized trial[s] would be preferable”, and that “limited case studies distributed by sponsors with financial interest in the outcome, are not sufficient evidence of general acceptance by the medical community”<sup>4</sup>
- Services that must meet criteria for National Coverage Determinations (NCD) and Local Coverage Determinations (LCD)
- “[C]omplex medical judgment which can be made only after the physician has considered a number of factors . . . .”<sup>5</sup>

2: PIM (CMS Pub. 100-08), ch. 3, § 3.3, 3.6.2.1, CMS Pub. 100-08, ch. 3, § 3.6.2.2  
3: 68 Fed. Reg. 55634, 55636 (Sept. 26, 2003)  
4: Caris MPI, Inc. Medicare Appeals Council Decision M-12-648 (2011)  
5: BPM (CMS Pub. 100-02), ch. 1, § 10 (2012)

## Medical Necessity (cont'd)



### Two-Midnight Standard

- Under the Two-Midnight Rule, other than for procedures that appear on the Medicare “inpatient only” list codified at 42 C.F.R. § 419.22(n), surgical procedures, diagnostic tests and other treatments are generally appropriate for inpatient payment under Part A only “when the physician expects the patient to require a stay that crosses at least 2 midnights and admits the patient to the hospital based on that expectation.”<sup>6</sup>
  - Conversely, if the physician does not expect the patient to stay across two midnights, then inpatient care would generally be inappropriate under Part A.
- This coverage standard has been codified in regulations at 42 C.F.R. § 412.3(e).

6: 78 Fed. Reg. at 50506

## Medical Necessity (cont'd)



### Two-Midnight Standard (cont'd)

- In making a decision as to whether a patient is expected to require a stay that crosses two midnights, physicians are to look at factors such as:
  - Patient history and comorbidities
  - Severity of signs and symptoms
  - Current medical needs and risk of adverse event
- The Two-Midnight Rule applies to all hospitals except IRFs.

## Two-Midnight Rule



### Exception to the Two-Midnight Rule

- “Rare and Unusual Circumstances”
  - Since adoption of the Two-Midnight Rule, CMS has stated in guidance that there may be “rare and unusual” circumstances in which an inpatient admission for a service not on the inpatient only list may be reasonable and necessary **in the absence of an expectation of a two-midnight stay.**
    - The rationale for such an exception is not stated, but the presumption is that certain “rare and unusual” cases may be severe enough to warrant the need for the type of medical care and services that can only be furnished safely and effectively on an inpatient basis regardless of how long those inpatient services are required.

## Two-Midnight Rule (cont'd)



### Exception to the Two-Midnight Rule (cont'd)

- CMS states that the following factors (among others) would be relevant to determining whether a patient requires inpatient admission under the expanded “rare and unusual” exception<sup>7</sup>:
  - The severity of the signs and symptoms exhibited by the patient
  - The medical predictability of something adverse happening to the patient
  - The need for diagnostic studies that appropriately are outpatient services (that is, their performance does not ordinarily require the patient to remain at the hospital for 24 hours or more)

7. 80 Fed. Reg. at 70541

## Physician Admission Orders



### Orders are entitled to no presumptive weight

- CMS has codified CMS Ruling 93-1 which rejects application of the “treating physician rule” to Medicare inpatient stays. In FY 2014, CMS adopted a regulation which states that “[n]o presumptive weight shall be assigned to the physician’s order . . . in determining the medical necessity of inpatient hospital services. . . .” The rule is codified at 42 C.F.R. § 412.46(b).

### Possible exception to the written order requirement and the ability to submit claims with missing or defective orders

- Despite this regulatory requirement, CMS has stated in guidance published in January 2014 that it will allow its contractors to consider the written order requirement to be fulfilled **in the case of defective or missing written orders** where it is clear in the medical record that the physician intended to admit the beneficiary as an inpatient.
- Hospitals with missing or defective written orders, therefore, should evaluate the circumstances of the affected inpatient admission to determine whether a claim for Part A reimbursement may still be submitted.

# Medicare Outpatient Observation Notice



## Medicare Outpatient Observation Notice (MOON)

- The development of MOON was to inform all Medicare beneficiaries when they are an outpatient receiving observation services, and are not an inpatient of the hospital or critical access hospital (CAH)
  - Must be delivered to Original Medicare (fee-for-service) and Medicare Advantage enrollees who receive observation services for more than 24 hours with delivery no later than 36 hours after observation begins
  - Oral notification as well as written notification must be provided so to confirm the beneficiary understands and is given opportunity for questions
  - The beneficiary or their representative must sign and date the MOON and a copy be given to the beneficiary as well as placed in the medical record.

# Criteria for Determining Medical Necessity



### InterQual and MCG (formerly Milliman)

- Evidence-based care guidelines for assessing the medical necessity appropriateness of admission and continued stay
- How does the Two-Midnight Rule change the use of these resources for Medicare inpatients?

### National Coverage Determinations (NCDs)

- An evidence-based process, with opportunities for public participation. In some cases, CMS' own research is supplemented by an outside technology assessment and/or consultation with the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC). In the absence of a national coverage policy, an item or service may be covered at the discretion of the Medicare contractors based on an LCD.
- Hyperbaric Oxygen Therapy (20.29), June 19, 2006
- Implantable Automatic Defibrillators (20.4), January 27, 2005

### Local Coverage Determinations (LCDs)

- A determination by a Medicare Administrative Contractor or a carrier under Part A or Part B, as applicable, respecting whether or not a particular item or service is covered on an intermediary- or carrier-wide basis under such parts, in accordance with section 1862(a)(1)(A).

## Medical Necessity Case Studies



- Harlan Appalachian Regional Hospital in 2011
  - The case involved whether the provider met medical necessity requirements for an injection subject to an LCD. The LCD required documentation of results of a bone marrow biopsy before Procrit could be covered as an injection; however, the provider did not provide proof of the bone marrow biopsy.
  - MAC recognized that while they are not bound by LCDs, they give substantial deference to the LCD's terms and found no reason to vary from the LCD in this case.
- UHC/AARP
  - The contractor's coverage policy imposed greater restrictions for gender reassignment surgery than Medicare.
  - MAC held: In the absence of an NCD, contractors and adjudicators should consider whether any Medicare claims for these services are reasonable and necessary under § 1862(a)(1)(A) of the [Act] consistent with the existing guidance for making such decisions when there is no NCD.

## Technical Denials



### **Denial of payment by Medicare for failure to meet coverage requirements, including:**

- Failure to meet a condition of payment required by the regulations such as:
  - Self-administered drugs
  - Ambulance services, such as transport from a hospital to a SNF when the patient is not bedridden
  - Air ambulance services when the medical record supports the patient could have been safely and effectively transported by ground transport
  - SNFs admission not preceded by the required three-day inpatient hospitalization
  - Payment for home health services because they were not ordered on a plan of care treatment or subsequent amendment
  - Services that do not meet all qualifying requirements for NCDs and LCDs
  - Incorrect code selection or insufficient documentation to support the code billed

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## Categorically Excluded Services

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## Categorically Excluded Services



**Medicare identifies the following four categories of items and services that are not covered under the Medicare Program:**

- 1) Services and supplies that are not medically reasonable and necessary
- 2) Non-covered items and services
- 3) Services and supplies denied as bundled or included in the basic allowance of another service
- 4) Items and services reimbursable by other organizations or furnished without charge



## Categorically Excluded Services (cont'd)



### Services and supplies that are not medically reasonable and necessary

- Services provided in a hospital that could have been furnished in a lower-cost setting/lower level of care
- Hospital services that exceed Medicare length of stay limitations
- Evaluation and management services that exceed those considered medically reasonable and necessary
- Therapy or diagnostic procedures that exceed Medicare usage limits
- Screening tests, examinations, and therapies for which the beneficiary has no symptoms or documented conditions (*The use of MRIs and CTs might fall into this category; some exceptions apply*)
- Services such as acupuncture, transcendental meditation, and assisted suicide

## Categorically Excluded Services (cont'd)



### Non-covered items and services

- This is a very large and general section which includes areas such as:
  - Items and services provided outside of the U.S.
  - Items and services required as a result of war
  - Personal comfort items and services; items and services furnished by the beneficiary's immediate relatives and members of the beneficiary's household; cosmetic surgery
  - Routine physical check-ups; eye exams; hearing aids and exams; and certain immunizations (not associated with an identified sign, symptom or complaint)
  - Custodial care
    - Custodial care is personal care that does not require the continuing attention of trained medical or paramedical personnel and services to assist an individual in activities of daily living such as:
      - Walking; getting in and out of bed; bathing; dressing; feeding; using the toilet; preparing special diets; and supervising the administration of self-administered medicines

## Categorically Excluded Services (cont'd)



### **Services and supplies denied as bundled or included in the basic allowance of another service**

- Fragmented services included in the basic allowance of the initial service
- Prolonged care (indirect)
- Case management services (e.g. phone calls to and from the beneficiary)
- Supplies included in the basic allowance of a procedure

## Categorically Excluded Services (cont'd)



### **Items and services reimbursable by other organizations or furnished without charge**

- Payment will not be made for items and services when a payment has been made or can reasonably be expected to be paid promptly under:
  - Automobile insurance
  - No-fault insurance
  - Liability insurance
  - Workers' Compensation law or plan of the U.S. or state
  - Defective equipment or medical devices covered under warranty

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## Admission Criteria

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## Admission Criteria



### Skilled Nursing Facilities (SNF)

- Three-day hospital stay to qualify for additional SNF care
  - A minimum of three consecutive, medically necessary inpatient days in an acute care setting
- Skilled services
  - Skilled nursing services, physical therapy and occupational therapy which are provided daily under the supervision of a professional
- Preadmission Screening and Resident Review (PASRR)
  - A federal requirement to help ensure that individuals are not inappropriately placed in nursing homes for long term care (LTAC). This is required prior to admission into a SNF or LTAC and services should not be provided or billed without this being submitted and placed on the patient chart.
- Practical matter
  - The physician must declare the need for skilled services, through physician certification and admission orders to skilled nursing. The physician provides the diagnoses and skilled services required. This must be on the patient chart upon admission and must take into consideration economy and efficiency, the daily skilled service can only be provided on an inpatient basis in a SNF.
- Minimum Data Set (MDS)<sup>8</sup>
  - "U.S. federally mandated process for clinical assessment of all residents in Medicare or Medicaid certified nursing homes. This process provides a comprehensive assessment of each resident's functional capabilities and helps nursing home staff identify health."

8: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/Minimum-Data-Set-3-0-Public-Reports/index.html>

## Admission criteria (cont'd)



### Inpatient Rehabilitation Facilities (IRF)

- Qualifying condition
  - At least 60% of the patient population in the IRF must have one of thirteen determined diagnoses
- Preadmission screening
  - Conducted immediately 48 hours preceding IRF admission
- Post-admission physician evaluation
  - Completed within the first 24 hours of admission
- Medical supervision by a physician with specialized training in rehabilitation services
  - Physician progress notes documented in the medical record at least every 2 to 3 days
- Individual overall Plan of Care (PoC)
  - Detail of the patient's medical prognosis, anticipated interventions, functional outcomes, and discharge destination
- Inpatient Rehabilitation Facility, Patient Assessment Instrument (IRF-PAI)
- Intensive level of rehabilitation services
  - To begin within 36 hours from midnight of the day of admission to IRF
  - Intensive level of therapy 3 hours/day at least 5 days/week or 15 hours/week in a 7-consecutive day period

## Admission Criteria (cont'd)



### Inpatient Rehabilitation Facilities (IRF)

- Multidisciplinary team approach to delivery of program
  - Minimum requirement includes: physician, rehabilitation nurse, social worker or case manager and licensed or certified therapist
- Coordinated PoC/team conference
  - Documentation supports team conference held at least once a week
  - Documentation indicates assessment of progress or problems impeding progress, consideration of possible resolutions and reassessment of rehab goals
- Expectation of significant practical improvement
  - Documentation of reasonable expectation of significant practical improvement
  - Beneficiary must classify into one of the Case Mix Groups payable by Medicare under the IRF Prospective Payment System (PPS)
- Realistic goals
  - Documentation of rehabilitation goals to support the patient's return to a maximum level of function based on the patient's overall condition and previous level of independence

## Billing Decisions for Medically Unnecessary Services

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### **Condition Code 44 (CC-44)**

- When a patient is admitted to a hospital as an inpatient but, upon internal review, the hospital determines the services did not meet inpatient criteria and the admission is changed to observation. This rule has become informally known as condition code 44. After meeting a series of specific and rigid requirements the patient stay can be billed as observation.

### **Provider liability**

- When Medicare Part A payment cannot be made because an inpatient admission is found to be not reasonable and necessary and the beneficiary should have been treated as a hospital outpatient rather than a hospital inpatient, Medicare will allow payment under Part B of all hospital services that were furnished and would have been reasonable and necessary if the beneficiary had been treated as a hospital outpatient, rather than admitted to the hospital as an inpatient, except for those services that specifically require an outpatient status, provided the beneficiary is enrolled in Medicare Part B and provided the allowed timeframe for submitting claims is not expired. The policy applies to all hospitals and CAHs participating in Medicare.

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## **Recoupments and Self-Disclosure Protocol**

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## Recoupments and Self-Disclosure Protocol



### Self-Disclosure

- A process for health care providers to voluntarily identify, disclose, and resolve instances of potential fraud involving the Federal health care programs (as defined in section 1128B(f) of the Social Security Act (the Act), 42 U.S.C. 1320a-7b(f))
- Good faith disclosure of potential fraud and cooperation with the OIG's review and resolution process are typically indications of a robust and effective compliance program
- Have instituted a presumption against requiring integrity agreement obligations in exchange for a release of the OIG's permissive exclusion authorities in resolving an SDP matter
- Entities that use the SDP and cooperate with the OIG during the SDP process deserve to pay a lower multiplier on single damages than would normally be required in resolving a Government-initiated investigation
- Settlements of SDP matters generally require a minimum multiplier of 1.5 times the single damages
- Requires that a Medicare or Medicaid overpayment be reported and returned by the latter of (1) the date that is 60 days after the date on which the overpayment was identified or (2) the date any corresponding cost report is due, if applicable
- All health care providers, suppliers, or other individuals or entities who are subject to the OIG's CMP authorities found at 42 C.F.R. Part 1003 are eligible to use the SDP
- The OIG expects disclosing parties to disclose with a good faith willingness to resolve all liability within the Civil Monetary Penalties Law's (CMPL's) six year statute of limitations as described in section 1128A(c)(1) of the Act

## Recoupments and Self-Disclosure Protocol (cont'd)



### Sample determination

- Estimation of damages must consist of a review of either: (1) all the claims affected by the disclosed matter or (2) a statistically valid random sample of the claims that can be projected to the population of claims affected by the matter.
- When using a sample to estimate damages, the disclosing party must use a sample of at least 100 items and use the mean point estimate to calculate damages. If a probe sample was used, those claims may be included in the 100-item sample if statistically appropriate.
- To avoid an unreasonably large sample size, the disclosing party may select an appropriate sample size to estimate damages as long as the sample size is at least 100 items. As a general rule, smaller sample sizes (closer to 100) will suffice where the population has a high level of homogeneity, and larger sample sizes will be necessary where the population contains a more diverse mixture of claim types.

### Extrapolation of error rate

- After review of sample, calculate a correct payment for the claims requiring adjustment
- Extrapolation is a sampling methodology which uses a mathematical formula to take the audit results from a random sample of Medicare or Medicaid paid claims in order to project those results over a much larger universe of claims often producing overpayments.
- The error rate shall be the percentage of net overpayments identified in the sample. The net overpayments shall be calculated by subtracting all underpayments identified in the sample from all gross overpayments identified in the sample. The error rate is calculated by dividing the net overpayment identified in the sample by the total dollar amount associated with the paid claims in the sample.

## Resources and References



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- Medicare Benefit Policy Manual, Chapter 1 – Inpatient Hospital Services Covered Under Part A (Rev. 232, 12-22-16); 110-Inpatient Rehabilitation Facility (IRF) Services
- Medicare Benefit Policy Manual, Chapter 8, Coverage of Extended Care (SNF) Services Under Hospital Insurance (Rev. 228, 10-13-16); 10-Requirements -General: 20 -Prior Hospitalizations and Transfer Requirements; 30 -Skilled Nursing Facility Level of Care-General; 40 -Physician Certification and Recertification for Extended Care Services; 50 -Covered Extended Care Services
- Medicare Claims Processing Manual, Chapter 30, Financial Liability Protections; 400.2 Scope, (Rev. 3695, Issued: 01-20-17, Effective 02-21-17, Implementation: 02-21-17)
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- State Operations Manual, Appendix A – Survey Protocol, Regulations and Interpretive Guidelines for Hospitals; (Rev. 151, 11-20-15); §482.30 Condition of Participation: Utilization Review
- U.S. Department of Health and Human Services, Office of the Inspector General; OIG's Provider Self-Disclosure Protocol, issued April 17, 2013 (updated Provider Self-Disclosure Protocol)
- U.S. Department of Health and Human Services; U.S. Food & Drug Administration, CPG Sec. 460.100 Hospital Pharmacies – Status as Drug Manufacturer, Issued 10/1/80; Page last updated: 03/20/2015
- U.S. Department of Health and Human Services; U.S. Food & Drug Administration, Investigational New Drug (IND) Application

## Questions



## Contact Information

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