Medicare National Coverage Determinations (NCD) for Clinical Trials

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Medicare NCD for Qualifying Trials

• Per Medicare National Coverage Determinations Manual, Section 310.1 Medicare covers "the routine costs of qualifying clinical trials, as such costs are defined below, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicare rules apply."

Coverage Based on Medical Necessity

• Section 1862 (a) (1) (A) of the Social Security Act states that no Medicare payment shall 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".
Coverage Based on Medical Necessity

• For an item or service to be considered medically necessary it must be:
  – Consistent with the symptoms or diagnosis of the illness or injury under treatment;
  – Ordered by the treating or consulting physician who uses the results in the medical management of the problem;
  – Consistent with generally accepted professional medical standards

Medicare NCD for Qualifying Trials

• A trial that meets the criteria for a qualifying trial can receive Medicare coverage of routine costs under these NCD requirements:
  – The item or service falls within a Medicare benefit category e.g., physicians services, hospital services, diagnostic testing
  – The item or service is not statutorily excluded from coverage e.g., cosmetic surgeries and hearing aids are never covered by Medicare
  – The item or service is deemed reasonable and necessary

Medicare NCD and LCD for Routine Costs

• The statement: “All other Medicare rules apply”. What exactly does this mean?
  – Routine items and services are subject to National Coverage Determinations (NCD) policies published by CMS Medicare
  – Medicare payment contractors may develop Local Coverage Determinations (LCDs) if an NCD for an item or service does not exist or if an NCD needs to be further defined
  – Medicare NCD and LCD policies restrict or limit coverage based on “medical necessity”
Medicare NCD and LCD Coverage

- NCD’s and LCD’s restrict coverage based on specific diagnosis codes for diagnostic tests, lab tests, drugs and procedures
- Coverage of an item or service is limited by:
  - Coverage may be limited to certain diagnoses
  - Frequency of testing may be limited by NCD, LCD or clinically accepted standard of practice
  - For lab tests, there are 23 national coverage determinations updated annually in the Medicare National Coverage Determinations (NCD) Coding Policy Manual and Change Report

- [Website](http://www.cms.gov/Medicare/Coverage/CoverageGenInfo/LabNCDs)

Example: NCD Policy Guidelines for Partial Thromboplastin Time (PTT)

- **Indication:** PTT is used to assess patients with signs and symptoms of abnormal bleeding, hemorrhage or thrombosis OR
- Personal history of a condition known to be associated with the risk of hemorrhage or thrombosis

- **Limitations:** “Hospital/clinic-specific policies, protocols, etc., in and of themselves cannot alone justify coverage.”

Example: NCD Policy Guidelines for Hemoglobin A1c

- **Indication:** Hemoglobin A1c is medically necessary to manage diabetes.
  - “It is not reasonable or medically necessary to perform this test more than every 3 months on a controlled diabetic.”
  - “Medical necessity documentation must support testing in excess of the stated guidelines.”
  - It is not sufficient to select an appropriate diagnosis code from the listing of covered diagnoses codes
  - Submitting a covered diagnosis code of diabetes when all of the policy criteria has not been met does not mean the test(s) should have been billed to or paid for by Medicare.
Medicare NCD Policies and Screening Tests

• Screening tests for Clinical Trials:
  – Medicare does not cover screening tests when no signs or symptoms or conditions are present
  – Medicare will not pay for clinical trial screening tests to rule out unknown conditions considered high risk by the trial’s protocol
  – Medicare recognizes that screening tests can have clinical value but are excluded from payment by the Medicare Program
  – Clinical Trial screening tests that do not meet Medicare coverage criteria will not be submitted to insurance

Medicare NCD Policies and Safety Tests

• Tests for Safety Monitoring
  – Tests for safety monitoring that do not meet the NCD or LCD guidelines will also not be billed to insurance.
  – “Routine” tests that do meet Medicare’s criteria for a covered diagnosis should have the correct diagnosis code linked to the service or item to avoid denial of payment
  – The revenue manager can order a report to review denial of lab tests based on inappropriate diagnoses codes

Medicare NCD and Non Qualifying Trials

Charges not covered by CMS:
- Items or services that are the subject of the non-qualifying clinical trial
- Required by the protocol, including standard of care items or service
- Not ordinarily covered by CMS
- Free by Sponsor or PI
- Data collection or analysis
- Investigated item or service

Charges covered:
- Prevention, diagnosis or treatment of complications
- Unrelated medically necessary items and services (not subject of protocol)
New Study Initiation Process by DOCR Includes Medicare NCD Review

- DOCR requires new study initiation meetings to include an evaluation of Medicare NCD policy coverage guidelines for clinical trials
- Each qualifying “routine” item and service will be evaluated through DOCR to determine if it meets coverage criteria under Medicare NCD and LCD policies for correct assignment on the calendar in Maestro Care for new studies
- Each item and service determined to be the subject of a non-qualifying trial will also be evaluated to ensure these items and services are included in the budget

Summary of Medicare NCD for Clinical Trials

- Documentation must support a determination that tests and procedures are “reasonable and necessary” to diagnose, treat or monitor treatment of clinical trial subjects
- All “routine” items and services of a qualifying trial must be evaluated for each Medicare subject to determine if a given symptom or condition is covered and therefore billable to Medicare per NCD/LCD guidelines
- Contract negotiations should ensure grant coverage for items and services not covered by Medicare NCD

DUHS Compliance

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