Clinical Trial Billing Compliance under Medicare
February 12-13, Pier 5 Hotel, Baltimore, MD

Medicare Coverage with Evidence Development and Potential Impact on Your Clinical Trial Policy

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Medicare Clinical Trial Policy

- Medicare Clinical Trial Policy, National Coverage Decision (NCD) 310.1
- Medicare Clinical Research Policy (pending)
Overview of Current Medicare Clinical Trial Policy

- Qualifying Clinical Trials
  - Evaluates Medicare Benefit
  - Therapeutic Intent (no exclusive test of toxicity or disease pathophysiology)
  - Enroll Beneficiaries Diagnosed with Disease
  - Principal purpose of trial is to test whether treatment will improve health outcomes
  - No duplication of existing studies
Overview of Current Medicare Clinical Trial Policy (cont’d)

- Sponsored by “credible” organization or individual
- Comply with 45 C.F.R. Part 46 HHS Human Subject Protection regulations
- Deemed Trials:
  - Supported by federal agency, e.g., CMS, NIH, CDC
  - Investigational New Drug (IND) exemption
Medicare Clinical Trial Policy

Trends
Recent Developments

- Coverage with Evidence Development (CED)
- Coverage with Study Participation (CSP)
- Medicare Evidence Development Coverage Advisory Committee (MedCAC)
- Revised Medicare Clinical Trial Policy: Medicare Clinical Research Policy (pending)
Coverage with Evidence Development and Coverage with Study Participation

- No guarantee of Medicare payment for clinical trial costs required by CSP
- Strategies to obtain Medicare payment:
  - Early informal contact with CMS, Office of Clinical Standards and Quality, to discuss Clinical Trial and potential NCD
  - Contact local Medicare contractor (Medical Director), if appropriate, to discuss coverage and reimbursement requirements
  - Ensure protocol and principal investigator meet CMS coverage requirements
  - Identify evidence on improvement of health outcomes and enhancement of body of medical evidence generalizable to Medicare population
  - Identify barriers to Medicare beneficiary access if no Medicare funding
CED Principles

Road Map
CED Principles

- National Coverage Determination (NCD) with CED will be transparent and public
- CED not used when Local Coverage Determination (LCD) or NCD are justified by current medical evidence
- Expand access to new treatments for beneficiaries
- Develop evidence complimentary to existing medical evidence
CED Principles (cont’d)

- Used infrequently
- No duplication or replacement for FDA’s authority assuring safety and efficacy
- Will not assume NIH’s role in supporting, managing, prioritizing clinical trials
- Compliance with federal laws, regulations, patient protections
Coverage with Study Participation

- One of two new concepts under CED:
  - Coverage with Study Participation (CSP)
- What’s the difference?
- CSP: CMS may require when insufficient clinical evidence to determine medical necessity, but there is some evidence that technology may improve health outcomes
When May CMS Require CSP?

- Current clinical evidence has not evaluated outcomes that are relevant or generalizable to Medicare beneficiaries.
- Current clinical research failed to adequately address the risks and benefits to Medicare beneficiaries for off-label or other anticipated uses of drug, biological or device.
- Current clinical research studies have not included specific patient subgroups or diseases characteristics prevalent in Medicare population.
- Coverage is being considered for new indications of items or services currently marketed but that lack sufficient evidence in peer-reviewed literature on effectiveness for Medicare population.
Current NCDs with CED

- Chemotherapy for Colorectal Cancer (Clinical Trial), NCD 110.17
- Positron Emission Tomography (Fluoro-D-Glucose) (PET (FDG)) for Dementia and Neurodegenerative Diseases (Clinical Trial), NCD 220.6.13
- Home Use of Oxygen in Approved Clinical Trials, NCD 240.2.1
- PET (FDG) for Brain, Cervical, Ovarian, Pancreatic, Small Cell Lung and Testicular Cancers (Registry), NCD 220.6.14
- Implantable Cardioverter Defibrillators (ICDs) (Registry or Clinical Trial), NCD 20.4
CED Impact
How May CED Affect Your Clinical Trial?

- NCD may limit (condition) Medicare coverage to use of item or service in approved clinical trial
- Medicare coverage of item or service outside clinical trial is not guaranteed
- Medicare payment is not guaranteed
- Medicare may require publication of study results
- Recruitment of Medicare beneficiary study subjects may be limited by ability and willingness to participate in clinical trial
“Case Study” of CSP

NCD/CSP requirements:

- Chemotherapy for Colorectal Cancer Clinical Trial, NCD 110.17
- Nine Trials identified by CMS and sponsored by National Cancer Institute
- Medicare coverage and payment for off-label use of specific anticancer drugs
- “Routine” costs covered under current Medicare policy
  - NCD 310.1 (Medicare policy on Routine Costs in Clinical Trials)
“Case Study” of CSP (cont’d)

- Use of “QR” modifier to identify non-routine costs that are payable in context of clinical trial (e.g., off-label use of anticancer drugs)
- Use of “QV” modifier to identify routine care costs that are payable
- Use of ICD-9-CM diagnosis code “V70.7” to identify clinical trial for claims processing
- Use of appropriate J-code to identify specific anticancer drugs administered during clinical trial for Medicare coverage and payment
Clarification of Medicare clinical trial coverage standards
- Qualified study exhibits therapeutic intent when major objective of study is diagnosis or treatment of disease including observation of benefit of the intervention studied
- Registration of clinical trial with www.ClinicalTrials.gov
- Outline plan in study protocol for publication of study results
- Investigational New Drug-exempt (IND-exempt) studies continue to have “deemed” status
December 2006 MedCAC Meeting (cont’d)

- “Routine costs” definition clarified
- Routine clinical services would include services that are: available to Medicare beneficiaries outside of a clinical study, excluding investigational clinical services; used for patient medical management required for provision of the investigational item or services (e.g., administration of otherwise non-covered drug); required for monitoring of an item or service or its effects; or for the prevention, diagnosis or treatment of complications
- Medicare Clinical Research Policy expected April 10, 2007
Medicare Coverage and Reimbursement Tips
Medicare Coverage and Reimbursement Tips

- Ensure that clinical trial and beneficiaries meet conditions of coverage in NCD
  - Deemed Clinical Trials: Funded by or in cooperation with NIH, CDC, AHRQ, CMS, DOD, VA
  - Deemed Clinical Trials: IND Exempt Trials
  - Enrolled beneficiaries must meet coverage criteria: e.g., diagnosed disease
  - Category B Investigational Device Exempt (IDE) Trials: Medicare coverage and payment for device and routine costs
  - Category A IDE Trials: Routine costs covered, but NOT device
Medicare Coverage and Reimbursement Tips (cont’d)

- Ensure that you follow claims processing guidance (Medicare Claims Processing Transmittals)
  - Report FDA-assigned IDE number for Category B (or Category A, if appropriate) device clinical trial
  - Use required modifiers, e.g., “QV” for routine care costs for qualified clinical trial; “QA” for routine care associated with qualified Category B device clinical trial
  - Use required ICD-9-CM codes, e.g., “V70.7” and “30”
  - Use required HCPCS Codes, e.g., “J Codes,” “E Codes,” “A Codes”
- When in doubt contact your Medicare contractor for guidance
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Source: Noridian Clinical Trial Billing Guidance
Medicare Coverage and Reimbursement Tips

- Comply with Medical Records Documentation Requirements (not required with claim, but make available on request)
  - Beneficiary records must include trial name
  - Sponsor; and
  - Sponsor-assigned protocol number
Medicare Coverage and Reimbursement Tips (cont’d)

- Comply with Medicare Clinical Trial application requirements:
  - Narrative description of device
  - Copy of FDA approvable letters
  - Copy of IRB approval letters
  - Describe Actions to conform to FDA/IRB requirements
  - Copy of Study Protocol
  - Copy of Protocol for Informed Consent
  - Sample patient consent form
  - Copy of all agreements, including financial
  - Facility billing procedures to avoid billing Medicare for non-clinical study costs, costs normally provided free of charge or costs reimbursed by other third parties (insurance)
Important Medicare Clinical Trial Billing Considerations

- Medicare Secondary Payor law (42 U.S.C. 1395y(b)(2)(A)(ii) (amended by MMA § 301(b)(1)):
  “business . . . professional entity ‘deemed’ to have a ‘self-insured plan’ if it carries its own risks, whether by failing to obtain insurance or otherwise”

- CMS interpretation: Statement by trial sponsor that it would “pay for medically necessary services” for complications related to clinical trial considered “insurance” for primary payment responsibility

- CMS may issue additional guidance in revised Clinical Trial Policy or in Frequently Asked Questions at www.CMS.hhs.gov
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Thank you!

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