Billing Medicare for Medical Devices

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Objectives

- Review Centers for Medicare & Medicaid Services (CMS) policies and procedures
- Describe the basics of research billing for devices
- Discuss submission requirements for device billing
- Identify keys to success
Who is CMS?

- Centers for Medicare and Medicaid Services is a federal agency within the United States Department of Health and Human Services (DHHS) that administers the Medicare program.
Who does Medicare cover?

- Medicare is health insurance for People 65 or older
- People under 65 with certain disabilities
- People of any age with End-Stage Renal Disease
Different Parts to Medicare

• Different parts of Medicare help cover specific services:

• **Medicare Part A - Hospital Insurance** covers hospital (facility) services

• **Medicare Part B - Medical Insurance** covers physician and outpatient care
• Medicare Part C also known as Medicare Advantage is a plan run by Medicare-approved private insurance companies

• Medicare Part D Medicare Prescription Drug Coverage helps cover the cost of prescription drugs
Local Contractors

- CMS Contracts with 15 “local” Medicare carriers to provide Medicare claims processing and payment services, in support of the Medicare FFS program.
- Contractors perform their responsibilities under the direction of CMS
• An executive memo from President Clinton on June 7, 2000 directing the secretary for HHS to authorize payment for:
  - Clinical trial “routine patient care costs…and costs due to complications associated with participation in clinical trials”
• September 9, 2000
  – CMS implemented a National Clinical Trial Policy NCD #310.1
• July 2007, the policy is revised to clarify that items or services covered outside the trial are also covered in the context of the trial.
Revision clarifies the general terms of the original policy and explains which costs are in fact eligible for reimbursement

Clinical Trial Policy #310.1

http://www.cms.gov/medicare-coverage-database/
What does the Clinical Trial Policy cover?

- Developed by CMS
  - Coverage for routine costs of ‘qualifying’ clinical trials
  - Coverage for reasonable and necessary items and services used to both diagnose and treat complications resulting from clinical trial participation
  - All other Medicare rules apply
What is a ‘qualifying’ clinical trial?

• The policy requires that the trial “qualify” for Medicare coverage.
• To qualify a trial must:
  • Evaluate an item or service that is included in a Medicare benefit category.
  • Have therapeutic intent for the patient.
  • Enroll patients with diagnosed disease rather than only healthy volunteers.
What is a “qualifying” trial?

• Must be deemed per the NCD OR

• Have the “desirable” characteristics needed for qualification
How do I qualify a device trial?

- Develop a process for determining that the trial meets the qualification requirements listed in NCD #310.1
- CMS has not published a standardized process for determination
- Institutions must develop their own internal process
Medicare Notification and Approval
• The Local Medicare Carrier for California is Palmetto
• After determining that the trial “qualifies” for Medicare coverage, notify your local Medicare carrier that your site is participating in an IDE trial
• How do I do that?
Notification and Approval:

- Medicare (Palmetto) website lists requirements for notification.
- After notification, Palmetto will send approval to provider that all required info has been received.
- Obtain approval for Parts A and B (hospital and physician services) when submitting the same packet of information.
- Indicate you need this information in your cover letter.
Jurisdiction 1 Part A
BILLING INSTRUCTIONS FOR INVESTIGATIONAL DEVICE EXEMPTIONS (IDES)

When requesting recognition as participants in investigational device exemptions (IDES), providers must adhere to the instructions in the CMS Manual System, Pub 100-04, Medicare Claims Processing Manual, Chapter 32 (Billing Requirements for Special Services), Section 68 (IDE).

The following information must be furnished to Palmetto GBA prior to submission of a claim for payment:

- Your Medicare provider number or NPI
- A copy of the Food and Drug Administration (FDA) - approval letter provided to the sponsor or manufacturer of the device. The approved IDE code number must be on the letter.
- The name of the device (both trade, common, or usual and classification name)
- Any action taken to conform to any applicable IDE special controls
- A narrative description of the device sufficient to make a payment determination
- A statement indicating how the device is similar to and/or different from other comparable products
- Indication of whether the device will be billed on an inpatient or outpatient claim
- A brief summary of the study design or a copy of the actual trial protocol
- The provider’s protocol for obtaining informed consents for beneficiaries participating in the clinical trial

This information should be forwarded to one of the addresses below:

<table>
<thead>
<tr>
<th>Part A</th>
<th>Part B</th>
<th>Overnight Mail</th>
</tr>
</thead>
<tbody>
<tr>
<td>Palmetto GBA</td>
<td>Palmetto GBA</td>
<td>Palmetto GBA</td>
</tr>
<tr>
<td>J1 Part A Medical Affairs</td>
<td>J1 Part B Medical Affairs</td>
<td>J1 Medical Affairs</td>
</tr>
<tr>
<td>P.O. Box 1437</td>
<td>P.O. Box 1476</td>
<td>2743 Perimeter Parkway</td>
</tr>
<tr>
<td>Augusta, GA 30903-1437</td>
<td>Augusta, GA 30903-1476</td>
<td>Building 200, 2nd Floor</td>
</tr>
</tbody>
</table>

If you need to request approval for both Part A and Part B you may do so within the same packet of information. Please indicate this request on your cover letter. You may mail this packet to one of the addresses above. There is no need to submit your request to both the Part A and Part B address if you indicate on your cover letter that you need approval for both.
Which Devices Are Covered?
Medicare Device Classifications

• Medicare classifies devices according to categories
  – Category A (Experimental)
    • Device not covered
  – Category B (Predicate Devices)
    • Device can be covered
• NSR devices (NSR-IDEs) are deemed to be in Category B
Category A Devices

- Category A devices are considered experimental and are NOT covered by Medicare. Their safety and effectiveness has NOT been established by the FDA.

- Medicare may cover the associated services of a Category A clinical trial if the trial meets the qualification requirements.
Category B Devices

- Medicare covers Category B devices under the IDE process if they are considered reasonable and necessary.
- A request for approval of a Category B device must be submitted to the local contractor (Palmetto) for review and determination of coverage eligibility.
Which device trials are covered?

1. Devices approved by the FDA through the Pre-Market Approval (PMA) process;
2. Devices cleared through the 510(k) process;
3. FDA-approved IDE Category B devices;
4. FDA-approved IDE Category A devices in an immediately life-threatening situation, disease, or condition (services only);
5. IRB-approved IDE devices.
• Medicare offers coverage for Part B devices
• Follow the notification and approval process from Palmetto for reimbursement of your device
• If your device is provided free of charge, notify Palmetto of participation in IDE trial
Claims Submission
Devices provided free of charge

• Providers are not required to submit items “free of charge” to Medicare
• If necessary, providers are instructed to submit such charges as non-covered or “0” charge at the time of entry, while assuring that the beneficiary is not held liable
Claims Coding

• Diagnosis code V70.7 (Examination of participant on clinical trial)
• Clinical Trial item or service code is reported with Q0/Q1 HCPCS modifier to identify clinical trial service
• HCPCS modifier used for outpatient claims
• Condition code 30 (indicates that a condition applies to the bill that affects processing and payment of the claim)
• When billed in conjunction with the V70.7 diagnosis code, the Q0/Q1 modifier will serve as the provider’s attestation that the service meets the Medicare coverage criteria
• Clinical trial name
• Sponsor of the clinical trial
• Protocol number
• This information should not be submitted with the claim itself but must be provided if requested for medical review.
Corrected Claims

• Claim is returned from carrier as a denial for a variety of reasons including:
  • Clinical trials indicators not on original claim
  • Failure to secure pre-authorization
  • Carrier request for medical records or other supporting documentation from provider but did not receive it
Submission of Corrected Claim

• Must type “corrected” in box 19 of CMS 1500 claim form – this tells Medicare the claim should be processed as new

• If errors or omissions are corrected but there is no indication of “corrected claim” the claim will be reprocessed as a “duplicate” and deny it again
Keys to success

- Understand the CMS’ policy on clinical research
- Early communication
  - Sponsor/CRO and site
  - Site’s research, clinical, and billing units
- Train the clinical and auxiliary teams
- Manage and review the billing process from study start-up to close-out
• CMS Manual System, Publication 100-03, Medicare NCD Manual, Chapter 1, Part 4, Section 310.1 (Routine Costs in Clinical Trials)

• Medicare Claims Processing Manual Chapter 32, Section 68.1-69.6

• Palmetto IDE submission
  http://www.palmettogba.com/palmetto/providers/Jurisdiction%201%20Part%20A~Articles~Investigational%20Device%20Exemptions%20(IDEs)~7QUQER5058?open&navmenu=%7C%7C
Thank you!