The reimbursement information provided in this presentation is gathered from third-party sources and is presented for illustrative purposes only. This information does not constitute reimbursement or legal advice. The presenter makes no representation or warranty regarding this information or its completeness, accuracy, timeliness, or applicability with a particular patient. Further, the presenter disclaims liability or responsibility for the results or consequences of any actions taken in reliance on information in this presentation.
IDE REIMBURSEMENT TRAINING

Goal

- Understand the fundamentals of Medicare Category B IDE regulations including the site requirements of submitting for coverage and identifying claims
- Awareness of available sponsor provided site tools and materials for Category B IDE studies

Desired Outcome

- Minimize reimbursement barriers to timely study enrollments in IDE device studies

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FDA designates an IDE as either Category A or B

Category A “Experimental”
(absolute risk of the device type has not been established)
• Eligible for coverage at local CMS contractor(s) discretion of “Routine Costs” only (not the device) for immediate life-threatening conditions

Category B “Non-Experimental/Investigational”
(underlying questions of safety & effectiveness of device type have been resolved)
• Eligible for coverage at local CMS contractor(s) discretion including the IDE device and the related services
  • Policy does not provide coverage for any devices that would otherwise not be covered by Medicare

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FDA Criteria for CMS Categorization of Investigational Devices

Category A
Experimental

A1: Device type for which no marketing application has been PMA-approved for any indication for use.

A2: Devices that would otherwise be in Category B but have undergone significant modification for a new indication or use.

Category B
Non-experimental/Investigational

B1: Devices under investigation to establish substantial equivalence to a predicate device.

B2: Technological characteristics and indications for use are comparable to a PMA approved device.

B3: Technological advances compared to a PMA approved device (Generational Changes).

B4: Comparable to approved device. Under investigation for a new indication. No significant device modifications.

B5: Pre-amendments Class III devices that become the subject of an IDE after FDA requires premarket approval.

B6: Non-significant risk device investigations for which FDA required the submission of an IDE.

IDE REIMBURSEMENT CATEGORIES

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Submit for coverage / Identify claims

1. **Submit for coverage** to the Medicare Part A and Part B contractor(s) before submitting individual patient claims\(^4\)
   - Written CMS study coverage approval is required to submit Medicare claims for payment

2. **Identify claims** to Medicare with the study’s IDE # *plus* a Revenue Code “624” and/or a “Q0” procedure modifier\(^4\)
   - “Routine Costs” must also be appropriately identified (e.g., Dx code V70.7, Q1 modifier, Condition code 30)
The Feasibility System
Pivotol Device Study

CLINICAL STUDY
REIMBURSEMENT GUIDE

IDE# G123456
Providers that participate in an IDE trial and anticipate filing Medicare claims must notify the Medicare contractor. The following information must be furnished prior to submission of a claim for payment:

1. A copy of the FDA approval letter provided to the sponsor
   • Enclose the FDA IDE approval letter w/ Category Bx designation
2. The name of the device (trade, common, and classification)
3. Any action taken to conform to any applicable IDE special controls
4. A narrative description of the device
5. A statement indicating how the device is similar to and/or different from other comparable products
6. Indication of whether the device will be billed on an inpatient or outpatient claim
7. A brief summary of the study design or a copy of the actual trial protocol
   • Enclose a copy of IDE protocol document
8. The provider’s protocol for obtaining informed consent
   • Enclose a copy of study consent template
9. Other items as required by the local Medicare contractor(s)
   • Determine if local contractor(s) require copies of other items in addition to items #1-8:
     1. IRB approval letter
     2. Procedure codes
     3. Fee agreement
     4. Journal articles

Verify local CMS requirements before submitting individual coverage requests to avoid delays in receiving a decision.

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CMS-1500 Claim Form

Identify Medicare claims with the study’s IDE# and a “Q0” (Q “zero”) modifier

Modifier (Field 24.D)
- Enter “Q0” – “Investigational clinical service provided in a clinical research study that is in an approved clinical research study”

Prior Authorization Number (Field 23)
- Enter “IDE number” (e.g., “FDA IDE # G123456”)

Routine Costs: Follow the billing instructions (e.g., Dx V70.7, Q1 modifier) found in the Medicare Claims Processing Manual, Chapter 32, §69.6, Pp. 51-54: www.cms.hhs.gov/manuals/downloads/clm104c32.pdf
HOSPITAL BILLING REQUIREMENTS

UB-04 Claim Form (CMS-1450)

Identify Medicare claims with the study’s IDE # and report under hospital revenue code “0624”

Revenue Code (Field 42)
- Revenue code “0624” is used to report IDE device charges
- Enter a “Q0” modifier (Outpatient hospital claims only)

Description (Field 43):
- The “IDE number” entered (e.g., “FDA IDE # G123456”)

Routine Costs: Follow the billing instructions (e.g., Dx V70.7, Q1 modifier, condition code 30) found in the Medicare Claims Processing Manual, Chapter 32, §69.6, Pp. 51-54: www.cms.hhs.gov/manuals/downloads/clm104c32.pdf

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MEDICARE PAYMENT

Medicare contractors determine payment on a case-by-case basis. The following criteria are used for Category B IDE trials:

- The use of the device must be part of an FDA-approved clinical trial;
- The device must be assigned to Category B as described by FDA regulations;
- The use of the device must be medically necessary for the patient for whom coverage is sought;
- The amount, duration, and frequency of the use of the device must be medically appropriate;
- The device must be used in a setting appropriate for the patient’s medical needs and condition.

“Payment for the device may not exceed the Medicare-approved amount for a comparable device that has been already FDA-approved” (e.g., Normal MS-DRG, APC, or MPFS payments)

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A medical device company needed to increase enrollments and reduce reimbursement coverage barriers in their Pivotal IDE study. Clinical sites were losing potential enrollees due to real and perceived reimbursement coverage and payment issues, which was negatively impacting enrollment rates and increasing budgetary costs for the sponsor manufacturer.

Sites were upset with the sponsor as eligible subjects were already difficult enough to screen and identify only to lose many potential enrollments due to reimbursement related issues. Mike Sanchez (MS) was hired on a contract basis as a reimbursement consultant to identify the reimbursement issues and formulate a plan to minimize enrollment barriers related to reimbursement.
CASE STUDY: ACTIONS

MS interviewed each site study coordinator to gather the data needed to understand the most relevant IDE reimbursement issues for study sites. It was identified that lack of site understanding and sponsor support of Category B IDE Medicare requirements was causing reimbursement related enrollment problems.

MS provided a training webinar for all site coordinators and the sponsor’s clinical staff members. MS developed protocol-specific reimbursement binders including electronic coverage request templates, coding summaries, and Medicare contractor IDE policy directories, which were distributed to all sites. Additional, MS was available to answer sponsor and site IDE reimbursement related questions on an as-needed basis.
Within approximately two months after site training and distribution of the tools and materials developed by MS, it was clear that site reimbursement coverage denials were significant reduced, which positively impacted study enrollment rates, helped reduce sponsor budget expenditures, and fostered improved relations with clinical sites.
1. Category B IDE studies are eligible for coverage at local CMS contractor discretion, but the process is not automatic

2. Site providers must submit for Category B IDE coverage approval(s) and identify individual claim submissions

3. Reimbursement barriers and timelines can be minimized by sponsor understanding Category B IDE requirements and providing sites with protocol-specific tools and materials
Committed to helping your company make intelligent, informed decisions that includes sound reimbursement advice

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REFERENCES

1. U.S. Food and Drug Administration: IDE Memorandum #D95-2 (09/15/95)

2. CMS MedLearn Matters Article: MM3548 (12/17/04)

3. Medicare Benefit Policy Manual: Chapter 14, Medical Devices (10/01/03)

4. Medicare Claims Processing Manual: Chapter 32, Billing Requirements for Special Services (01/01/09) (Pp. 45-50)

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