BILLING COMPLIANCE FOR DEVICE STUDIES

Training Objectives

• Understand device classifications and regulatory implications
• Define Investigational (IDE) and Humanitarian (HDE) device billing rules for the FDA and CMS (Centers for Medicare and Medicaid Services)
• Discuss impact of UPMC policy on the Research community and UPMC staff
• Review procedures to minimize risk of billing noncompliance

Why is Device Training Useful?

• Increased volume of investigational devices utilized in UPMC facilities
• Dynamic institution with a large network of departments involved to conduct one study
• Multiple guidance documents from regulatory authorities provide a patchwork for compliance
• Greater reliance by sponsors on the results of routine tests to analyze outcomes for the investigational item
• More complex billing processes due to mixed costs

Who Must Complete Training?

• Principle investigator, all co-investigators and research coordinators associated with consenting of potential research participant into IDE trial.
• Those who precertify the participant for device related procedure.
• Those who are involved in billing of device/procedure.

FDA DEVICE DEFINITION

• An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:
  • intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
  • intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.
• recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them.

FDA DEVICE CLASSIFICATION

• Non-Significant Risk (NSR)
  • exempt from FDA submission
  • requires IRB approval of NSR determination when used in a clinical trial
• Significant Risk
  • class I least regulated, general controls only
  • class II general controls and special controls such as performance standards or post-market surveillance
  • class III insufficient information exists to determine that either special or general controls, would provide reasonable assurance of safety and effectiveness and requires pre-market approval
HUMANITARIAN USE DEVICES

FDA definition:

A device that is intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect or is manifested in fewer than 4,000 individuals in the United States per year.

BILLING A HUMANITARIAN USE DEVICE

- An approved HDE authorizes marketing of the HUD. However, an HUD may only be used after approval has been obtained for the use of the device for the FDA approved indication from the hospital’s IRB of record.

- Physicians may not bill Medicare for their services prior to receiving Medicare Part A approval. As such, OPSARS will work collaboratively with our CMS intermediary to ensure timely approval and use of HUD.

FDA DEVICE MARKETING APPLICATIONS

- Pre-market notification (510K)
  - Premarketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective (substantially equivalent) to a legally marketed device that is not subject to premarket approval
  - May require clinical data to establish safety and effectiveness
  - Mostly class II devices (most class I devices are exempt)

- Pre-market approval (PMA)
  - FDA process of scientific and regulatory review to evaluate the safety and effectiveness
  - Most stringent type of device marketing application
  - Requires clinical data to establish safety and effectiveness
  - Class III devices

POST-MARKET APPROVAL STUDIES

- A clinical study or other investigation usually conducted under a single protocol to gather specific information to address precise study objectives about an approved medical device
  - Usually included in the Pre-Market Approval notice from the FDA (but sometimes initiated by sponsor)
  - Post-Approval Extension Studies represent an extension of a post-market approval study
  - Avoid confusion with PMA designation (pre-market approval vs. post-market approval)

Investigational Device Exemption (IDE)

- An Investigational Device Exemption (IDE) allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a PMA application or a 510K submission to the FDA
  - Clinical studies are most often conducted to support a PMA
  - A small percentage of 510K’s also require clinical data to support the application

FDA DEVICE CATEGORIES

IDEs are placed in one of two categories by the FDA for Medicare coverage determination

- Category A
  - Experimental, innovative class III devices
  - Absolute risk has not been established (i.e. initial questions of safety and effectiveness have not been resolved)

- Category B
  - Non-experimental and investigational devices (class I, II and III)
  - Absolute risk established, incremental risk is primary question (i.e. underlying questions of safety and effectiveness are resolved)
MEDICARE COVERAGE REQUIREMENTS

Medicare contractors are responsible for making the coverage determinations on all NSR and FDA-approved Category B devices based on:

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

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13

UPMC POLICY AND PROCEDURE

HS-PS0500 Investigational and Humanitarian Use Devices

• IDE Devices must be used within the context of a research study approved by the University of Pittsburgh Institutional Review Board (IRB) or a central, nationally accredited IRB.
• HDE Devices may be used either within a research study or as a standard of care service, and in both cases must have prior approval for use by the University of Pittsburgh IRB or a UPMC OSPARS approved IRB.
• The clinical use of a HDE Device is limited to the indication specified in the FDA-approved product labeling for that device.
• Any proposed “off-label” use of a HDE device constitutes “research” and must be approved by the University IRB or by the UPMC OSPARS approved IRB.
• A clinical informed consent document must be used with an HDE Device, even if it is not part of a research study.
• All research studies or protocols involving devices are subject to UPMC Fiscal Review in accordance with UPMC Policy HS-PS0498

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14

DEVICE SUBMISSION PACKET

UPMC Policy HS-PS0500 and Highmark Medicare Services requires the following to determine coverage and payment:

• an unredacted copy of the most recent FDA approval letter provided to the sponsor or manufacturer of the device
• the name of the device (both trade, common or usual, and classification name)
• action taken to conform to any applicable FDA special controls
• a narrative description of the device sufficient to make a payment determination
• cost of device
• indication of whether the device will be billed on an inpatient or outpatient claim (we request both Part A & B approval and indicate NPI for both facility and physician group)
• a statement indicating how the device is similar to and/or different from other comparable products
• IRB approved protocol and informed consent
• 2 peer reviewed published manuscripts pertaining to the device

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15

MEDICARE PARTS A & B

• Facilities bill Medicare Part A
• Physicians/providers bill Medicare Part B
• Highmark Medicare Services is now our CMS intermediary for both Part A & B

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16

DEVICE USE

• UPMC Supply Chain Management is notified by OSPARS and they negotiate with sponsor to arrange purchasing and shipping of the device
• Each time an IDE or HDE device is to be used, the Researcher will inform the Clinical Billing Specialist of the patient name, social security number, name and number of device, and scheduled date of service as soon as the informed consent is signed
• Preauthorize and communicate costs to the subject (copays, deducts)
• Use Research Requisition appropriately to communicate procedures as designated on the Fiscal form

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17

MEDICAL RECORD DOCUMENTATION

Subject’s medical record must include at minimum:

• Study title
• Sponsor
• Sponsor-assigned protocol number
• Copy of signed informed consent
• Narrative note describing the informed consent process with date and time
• Standard clinical documentation requirements (diagnosis and care plan documented by physician, etc.)

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18
MEDICARE MANAGED CARE BENEFICIARIES

- Medicare HMO (Advantage) patients do not have copays/deducts so typically do not have secondary payer insurance
- When a Medicare managed care patient enters a clinical trial, the services are billed to traditional Medicare, not the HMO!
- Beneficiaries become liable for copays/deducts
- Must be noted in consent form, if copays/deducts apply, that the subject is responsible to pay
- Sponsor is not permitted to cover copays/deducts (Medicare may consider this fraud/abuse)

MEDICARE MANAGED CARE BENEFICIARIES

IMPORTANT NOTES

- Take financial counseling seriously as part of the informed consent process, typically this is done at the department level by an experienced billing/coding specialist
- UPMC Health Plan is no different than other insurance companies, copays/deducts may still apply if preauthorization is obtained
- Devices are billed slightly differently than non-device studies in that the device is billed by the FDA device # and all associated items are billed as routine costs

DEFINITION OF ROUTINE COSTS

Routine costs DO include (and therefore are covered):

- Items or services that are typically provided absent from a clinical trial (i.e., routine care)
- Items or services required solely for the provision of the investigational item or service, the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications
- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service including the diagnosis or treatment of complications

DEFINITION OF ROUTINE COSTS

Routine costs DO NOT include (and therefore are NOT covered):

- The investigational item or service, itself unless otherwise covered outside of the clinical trial
- Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan)
- Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial

REFERENCES

- U.S. Food and Drug Administration Medical Devices
  http://www.fda.gov/MedicalDevices/default.htm
- Medicare A/B Reference Manual: [Chapter 7 - Clinical Trials and IDE Requests]
  https://www.highmarkmedicareservices.com/refman/chapter-7.html
- Medicare Benefit Policy Manual, Chapter 14 - Medical Devices
- UPMC System wide Policy & Procedure Manual
  http://policymanuals.infonet.upmc.com

QUIZ

- Internet-Based Studies in Education and Research
  Powered by HSConnect https://cme.hs.pitt.edu/
- Responsible Conduct of Research Modules
- Title: Investigational Device Training
- 10 Multiple Choice Questions
- Required Pass Rate = 80%
- OSPARS verifies completion of training upon submission of a Clinical Trials Application