DEPARTMENT: Regulatory Compliance Support	**POLICY DESCRIPTION:** Billing for Investigational Devices in Clinical Trials
PAGE: 1 of 7	**REPLACES POLICY DATED:** 1/1/04, 4/30/05 (GOS.BILL.007); 3/6/06; 7/1/09, 5/15/10, 1/1/2016
EFFECTIVE DATE: August 7, 2024	**REFERENCE NUMBER:** REGS.BILL.007
APPROVED BY: Ethics and Compliance Policy Committee	

SCOPE: All Company-affiliated hospitals procuring, utilizing and/or billing Medicare Fee-for-Service for investigational devices. Specifically, the following departments:

Administration
Billing Integrity
Charge Integrity
Case Management
Finance
Health Information Management
Materials Management
Medical Staff
Operating Room Director
Quality Management
Registration/Admitting
Reimbursement
Research Coordinators
Revenue Integrity
Shared Services Centers
Supply Chain

PURPOSE: To establish guidelines for billing investigational devices and the routine costs associated with the provision of investigational devices.

POLICY: Investigational devices must be billed in accordance with the Centers for Medicare and Medicaid Services (CMS) regulations. CMS will determine coverage of investigational devices based on the Food and Drug Administration's (FDA) categorization (Category A or Category B) of the device.

The hospital may accept an investigational device from a manufacturer or research sponsor at no charge for use in a clinical trial. However, in such cases, the hospital must not charge the patient or Medicare for the device. When the hospital receives a device at no charge, the hospital may bill Medicare for the routine costs of the clinical trial involving the use of the device so long as the services meet all other Medicare coverage requirements. Also, the hospital must not accept a free device as a condition of doing business with a manufacturer.

PROCEDURE:

1. Each hospital assigns an Institutional Review Board (IRB) that is responsible for approving the use of all investigational devices within the hospital. This IRB may be an internally run IRB or an externally run IRB. The IRB is not to be confused with the hospital's operational and financial review committees and/or functions. For more information about the use of internal or external IRBs, see https://hcahealthcare.sharepoint.com/sites/CORP-ClinicalResearchComplianceandIntegrity/SitePages/Non-IRB-Oversight-Obligations.aspx

2. Verification of CMS approval of the IDE study as a qualifying study should be provided to or obtained by the Service Center. Verification can be in the form of (a) a copy of the CMS approval letter provided to the sponsor of the study or (b) a printout of the study page from the CMS Approved IDE Studies website at https://www.cms.gov/medicare/coverage/investigational-device-exemption-ide-studies/approved.

3. The hospital must review the contract related to the clinical trial to determine which services are the responsibility of the sponsor (or their designee) and which services may be billed to Medicare. Items/services provided solely to satisfy data collection and analysis needs and that are not used in direct clinical management of the patient are not covered by Medicare and are generally the responsibility of the sponsor (or their designee). Items/services reimbursed by the sponsor (or their designee) of the clinical trial must not be billed to Medicare.

4. If the hospital anticipates filing a Medicare claim which involves services related to a Category A or Category B device, the facility must review the CMS coverage website for Medicare reimbursement status for all Category A and B IDE studies approved by the FDA on or after January 1, 2015 at the following web address: https://www.cms.gov/medicare/coverage/investigational-device-exemption-ide-studies/approved. Hospitals must contact the Medicare Administrative Contractor for further guidance if an IDE study is not listed as approved on the CMS coverage website. IDE studies where the facility received coverage approval from the Medicare Administrative Contractor prior to January 1, 2015 should continue to follow the processes established by the Medicare Administrative Contractor for any required subsequent reporting.

   Note: IDE studies approved by Medicare Administrative Contractors prior to January 1, 2015 will continue to be administered by the Medicare Administrative Contractor and processes established by the Medicare Contractor for any renewals, site additions, or protocol changes must be followed.

5. Claims involving investigational devices and the associated routine costs must not be billed and claims should be placed on hold until notification has been received from the Medicare Contractor indicating the coverage status of the device for IDE studies prior to January 1, 2015 or verification of CMS approval has been provided from the CMS Coverage Website for IDE studies seeking approval on or after January 1, 2015.

6. The hospital must develop a process to store and maintain documentation that the IDE study was reviewed during the study planning phase and was listed as approved on the CMS Coverage Website, including the date of verification, prior to enrolling a Medicare patient,

7. Once approval has been verified with Medicare and all other coverage requirements have been met, it is appropriate to bill routine care items and services in Category A IDE studies or the Category B device (when the device is not received free-of-charge) and routine care items and services in Category B IDE studies to Medicare.

BILLING FOR INVESTIGATIONAL DEVICES AND ROUTINE COSTS:

1. A copy of the beneficiary's signed informed consent to participate in a clinical trial must be present in the medical record.

2. Hospital personnel must verify that all investigational devices utilized in the hospital chargemaster are assigned to "Revenue code 624 – Investigational Device," regardless of Medicare coverage.

3. Category A Devices:
   - The Category A device is not reported on the UB.
   - For covered routine cost of clinical trials, the UB must include the following:
     - Condition code 30 (Qualifying Clinical Trials).
     - ICD-10-CM diagnosis code Z00.6 (Encounter for examination for normal comparison and control in clinical research program) as an Other Diagnosis code. Note: ICD-10-CM codes may only be assigned by an individual designated as a coder; billers may not perform this function.
     - Value code D4 and the 8 digit Clinical Trial Number on the paper/DDE claim UB-04 or the 8-digit Clinical Trial Number in the electronic claim equivalent, 837I (Loop 2300 REF02 (REF01=P4)) for an 837I claim.
     - For outpatient claims only: Include modifier "Q1" (Routine clinical service provided in a clinical research study that is in an approved clinical research study) only on line items for services related to the clinical trial.

4. Category B Devices:
   - For inpatient claims, the device must be reported on the UB with the FDA approved IDE number on the line item including revenue code 624. If the device is received at no cost, the device is not reported on the claim.
   - For outpatient claims, the device must be reported on the UB with the applicable HCPCS/CPT code and the FDA approved IDE number on the line item including revenue code 624.
     - If the Category B IDE device is received at no cost, the device must be reported on the claim with a token charge in the covered charge field along with condition code "53" (Initial placement of a medical device provided as part of a clinical trial or a free sample) and Value Code "FD" along with the usual cost of the device in the amount field associated with value code FD.

   - For covered routine cost of clinical trials the UB must include the following:
     - Condition code 30 (Qualifying Clinical Trial)
     - ICD-10-CM diagnosis code Z00.6 (Encounter for examination for normal comparison and control in clinical research program) as an Other Diagnosis code. Note: ICD-10-CM codes may only be assigned by an individual designated as a coder; billers may not perform this function.
     - Value code D4 and the 8 digit Clinical Trial Number on the paper/DDE claim UB-04 or the 8-digit Clinical Trial Number in the electronic claim equivalent, 837I (Loop 2300 REF02 (REF01=P4)) for an 837I claim.
     - For outpatient claims only, the following must be included:

- Modifier “Q1” (Routine clinical service provided in a clinical research study that is in an approved clinical research study) only on line items related to the clinical trial.
- Modifier “Q0” (Investigational clinical service provided in a clinical research study that is in an approved clinical research study) on the line item for the device.

SPECIAL CONSIDERATIONS:

- Edits have been established in the electronic billing system to identify claims for Medicare beneficiaries which include revenue code 624 and/or /ICD-10-CM diagnosis code Z00.6.
- If it is anticipated that the beneficiary may be responsible for a device or associated routine costs then the appropriate notice of noncoverage must be provided prior to providing the item/service. For inpatient noncovered services a Hospital Issued Notice of Noncoverage (HINN) should be issued and for outpatient services an Advance Beneficiary Notice of Noncoverage (ABN) should be issued. For additional information regarding the HINN, refer to the company policy – Hospital Issued Notice of Noncoverage (REGS.GEN.010), and regarding the ABN refer to the company policy – Advance Beneficiary Notice of Noncoverage (REGS.GEN.003).
- Category A or B IDE studies may be subject to additional coverage requirements when provided under a Medicare National Coverage Determination (NCD). Hospitals that provide such services (e.g., intracranial PTA stenting, TAVR) must review the NCD requirements and ensure they are in compliance with all applicable regulations.
- Hospital and Service Center personnel must establish a process regarding whether or not investigational devices and associated routine costs should be billed to Medicare or to a sponsor.
- There are no CMS rules regarding the non-research use of Humanitarian Use Devices (HUD). It is recommended that the facility work with their Medicare Administrative Contractor to determine how to bill for HUDs.
- For beneficiaries who are enrolled in a Medicare Advantage plan, the billing guidelines outlined in the Medicare Claims Processing Manual, Chapter 32, Section 69.9, should be followed.

EDUCATION:
All staff associates involved in the delivery of services or in the preparation or submission of claims involving investigational devices and/or the routine costs associated with clinical trials must be educated on the contents of this policy.

The Facility Ethics and Compliance Committee is responsible for implementation of this policy within the hospital.

DEFINITIONS:

Category A device: An innovative/experimental device for which "absolute risk" of the device type has not been established (that is, initial questions of safety and effectiveness have not been

resolved and the FDA is unsure whether the device type can be safe and effective). There is no Medicare coverage, under any circumstances, for a Category A device. This categorization is made by the FDA.

Category B device: A device for which the underlying questions of safety and effectiveness of that device type have been resolved, or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type. Medicare will determine coverage for Category B devices. This categorization is made by the FDA.

Clinical Trial Number: A unique identification code is given to each clinical study registered on www.ClinicalTrials.gov. Because the format is the letters "NCT" followed by an 8-digit number (for example, NCT00000419), this identifier is also known as the NCT Number. This number is only derived at the https://clinicaltrials.gov website (preceded by “NCT”) and must not be confused with other clinical study identifiers such as the Sponsor’s protocol number or the IRB’s protocol number.

Humanitarian use device (HUD): A device that is intended to benefit patients by treating or diagnosing a disease or condition that affects or is manifested in fewer than 8,000 individuals in the United States per year. FDA approval of an HUD is obtained through a humanitarian device exemption.

Investigational device: A medical device which is used in a clinical investigation or research using one or more subjects to determine the safety and/or effectiveness of a device for a specific application or intended use.

- Non-significant risk device: A device which does not meet the FDA definition for a Significant Risk Device Study and does not require an FDA-approved IDE. Clinical trials for non-significant risk devices are the responsibility of the hospital’s IRB.
- Significant risk device: An investigational device that is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject; is purported or represented to be for use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject; is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

Investigational device exemption (IDE): An application which, when approved by the FDA, permits an investigational device (Category A or B), which would otherwise be subject to marketing clearance, to be shipped lawfully for the purpose of conducting a clinical trial in accordance with federal regulations.

Medical Device: For purposes of the FDA process, refers to an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is (a) recognized in the official National Formulary, or the U.S. Pharmacopoeia, or any supplement to them; (b) 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 (c) intended to affect the structure or any function of the body of man or other animals; and which does not achieve 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 its primary intended purposes. Of note, to the extent that software meets the above definition, it may be considered a Medical Device by the FDA.

Medical Device Clinical Trial: A formal study, which, once approved by the FDA, permits a sponsor to utilize an investigational medical device for investigation or research purposes using one or more human subjects to determine the safety and/or effectiveness of the device for a certain intended use.

Routine Costs/Services: Items and services that are otherwise generally available to Medicare beneficiaries that are provided in either the experimental or the control arm of a clinical trial except for the investigational item/service itself, unless otherwise covered outside the clinical trial, items/services provided solely to satisfy data collection and analysis needs and that are not used in direct clinical management and items/services provided by the research sponsor free of charge. Routine costs may include items/services that are typically provided absent a clinical trial (conventional care), items/services required solely for the provision of the investigational item/service, the clinically appropriate monitoring of the effects of the item/service, or the prevention of complications and items/services needed for reasonable and necessary care arising from the provision of an investigational device or service, in particular, the diagnosis or treatment of complications.

COVERAGE:

Medicare coverage of Category A and B devices and the routine costs of clinical trials involving a Category A or B device are as follows:

1. Category A devices are considered experimental and are not covered by Medicare. Category A devices must not be billed to Medicare.
2. A Category B device is eligible for Medicare coverage if the device has been granted an FDA approved Investigational Device Exemption (IDE) with Category B status.
3. The routine costs of clinical trials involving a Category A or B device and Category B devices in Category B IDE studies may be billed to the Medicare program when all of the following conditions have been met:
    a. The clinical trial has been approved by an Institutional Review Board (IRB) approved by the hospital;
    b. The services are furnished to a patient who is participating in an FDA-approved clinical trial;
    c. For IDE studies where a facility received coverage approval from a Medicare Contractor prior to January 1, 2015, the hospital Medicare Contractor has been notified and advises the hospital that the routine costs may be billed. Please note: the hospital must receive confirmation from the Medicare contractor prior to billing; or
    d. For IDE studies where a facility is seeking a new approval on or after January 1,

2015, the hospital has verified the clinical trial is listed on the CMS Coverage website as approved for Medicare reimbursement at the following address: http://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies.html. Hospitals must contact the Medicare Contractor for further guidance if an IDE study is not listed as approved on the CMS coverage website.

Note: Medicare may cover services related to a condition or complication that arises as a result of the use of a non-covered Category A or Category B device.

Note: Facilities should work with their local Medicare Administrative Contractor for coverage determinations on Non-Significant Risk devices.

REFERENCES:

1. 42 CFR Parts 405 and 411
2. 42 CFR §412.42
3. Medicare Benefit Policy Manual (CMS Pub. 100-2), Chapter 14 – Medical Devices
4. FDA (www.fda.gov) “Device Advice”
5. FDA Guidance for Institutional Review Boards and Clinical Investigators 1998 Update, Medical Devices
6. FDA Guidance for Institutional Review Boards and Clinical Investigators 1998 Update, “Off-Label” Use of Marketed Drugs, Biologicals and Medical Devices
7. Medicare Coverage Related to Investigational Device Exemption (IDE) Studies. http://www.cms.gov/Medicare/Coverage/IDE/index.html.
8. Medicare – Hospital Issued Notice of Non-Coverage, REGS.GEN.010
9. Advance Beneficiary Notice of Noncoverage, REGS.GEN.003
10. HCA Quality Management Institutional Review Board Policies
11. Medicare National Coverage Determinations Manual, Chapter 1, Part 4, Section 310
12. Medicare Claims Processing Manual, Chapter 32, Sections 68, 69, 160 and 161
13. Transmittal 2955 (CR 8401) Mandatory Reporting of an 8-Digit Clinical Trial Number on Claims, effective January 6, 2014.
14. Transmittal 3105 (CR 8921) Medicare Coverage of Items and Services in Category A and B Investigational Device Exemption (IDE) Studies, effective January 5, 2015.
15. Transmittal 198 (CR 8921) Medicare Coverage of Items and Services in Category A and B Investigational Device Exemption (IDE) Studies, effective January 5, 2015.
16. Transmittal 3181 (CR 8961) Implementation of New NUBC Condition Code “53” “Initial placement of a medical device provided as part of a clinical trial or a free sample,” effective July 1, 2015.