I. **Policy Statement**
   a. To assure that all requirements are in place before the research proceeds and all persons responsible for the financial conduct of the study are notified prior to submission of any study-related claims.
   b. Services related to Category A, Category B, Non-Significant Risk (NSR) and Humanitarian Use Devices (HUD) in clinical trials must be prior approved by the payor including CMS/Medicare and commercial payers. Upon approval from Medicare or other payer as appropriate, enrollment can proceed. With each subject enrolled (regardless of payer involved), the investigator or research staff must notify the Office of Corporate Compliance (573-882-8957) and provide upcoming research visit dates.

II. **Definitions**
   a. Not Applicable.

III. **Process/Content**
   a. Clinical Trials with an Investigational Device Exemption (IDE) and Medicare Beneficiaries.
      i. Medicare may provide reimbursement for routine services in clinical trials involving FDA-approved investigational devices in protocols that have been approved by the IRB.
      ii. The Food and Drug Administration (FDA) assigns all approved IDEs to one of two categories.
         1. **Category A**: Experimental/investigational – an innovative device believed to be in Class III (require pre-market approval) 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). (per 42 CFR 405.201).
Medicare will reimburse for routine services related to Category A devices if the device is used in the trial for the diagnosis, monitoring, or treatment of an immediately life-threatening disease or condition. Medicare will not provide payment for the Category A device.

2. Category B: Non-experimental/investigational – a device believed to be in Class I (general FDA controls similar to those for general manufacturing are sufficient) or Class II (require special controls such as performance standards or post-market surveillance), or a device believed to be in Class III for which the incremental risk is the primary risk in question (that is, 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. (per 42 CFR 405.201).

Medicare will reimburse for routine services related to Category B device trials. Medicare may cover Category B devices if they are considered reasonable and necessary and if all other applicable Medicare coverage requirements are met. Medicare will never cover the cost of an item or service that is being provided free by the sponsor.

NSR (non-significant risk) devices that satisfy FDA criteria do not require an IDE. Medicare will reimburse for NSR devices subject to the same criteria used for Category B devices.

Medicare will also reimburse for HUD devices (a Humanitarian Use Device is a device that is intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect or are manifested in fewer than 4,000 individuals in the United States per year) using the same criteria as used for Category B devices.

Special Note about carotid studies: If the clinical trial is related to carotid artery stenting whether in an IDE or post-approval by the FDA (510K or PMA) study, approval must be obtained from CMS/Medicare.

b. Investigator Responsibility

Beginning January 1, 2015, approval for Medicare payment for IDEs will need to be requested directly from CMS/Medicare and not WPS. Attachment A provides a checklist and crosswalk table to guide completion of steps prior to or in conjunction with obtaining Medicare
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approval for the IDE. These require (a) confirmation of IRB approval (b) the FDA approval letter of the IDE, (c) the NCT number as assigned by Clinicaltrials.gov, and (d) a request letter and supporting materials. The Principal Investigator and research staff should proceed through the normal channels of FDA approval of the IDE, grant submission, IRB approval, and Clinicaltrials.gov registration utilizing existing MU Health Standard Operating Procedures (SOP) and policies.

ii. Attachment B provides an overview of the MU Health Care Value Analysis approval of an Investigational Device. If all five (5) criteria are NOT met, the IDE must be reviewed through the Value Analysis process and, the Principal Investigator (PI) must complete Attachment A. If all five (5) criteria are met, use of the IDE is considered a clinical trial and the PI should work directly with the OCC and the IRB, complete Attachment A, and the process will either require “Requesting Coverage of an IDE from CMS/Medicare” or will skip to d) below if there will be no charge incurred by the patient/participant for the investigational device.

iii. Once all internal approvals are granted and it is determined that the five (5) criteria for a clinical trial have NOT been met, the PI will seek approval from CMS/Medicare and Attachment A should be used as a guideline for completing the IDE request. For additional payers, the PI/research team should work directly with Managed Care Contracting to ensure appropriate contract terms are received for each commercial payer regarding investigational devices and clinical trials. For initial device set-up, proceed with initial review for the top five (5) common payers with subsequent reviews on a case by case basis for each new patient/participant. Please note the research unit will need to communicate with prior-authorization staff in Patient Admissions for each participant enrolled to determine insurance coverage and precertification prior to any billable procedures. Information provided by Managed Care Contracting will also need to be conveyed to Patient Admissions. Please note: Medicaid may not cover any charges related to “clinical studies, trials, testing and experimental medical procedures, drugs, equipment, etc.”

iv. The OCC will review the packet of information that is prepared for CMS/Medicare submission and will request completion of Attachment A (which includes completion of a request to the MU Health Value Analysis Team), however, submission to CMS/Medicare is the responsibility of the PI/research area.
c. Requesting Coverage of an IDE from CMS/Medicare
   
   i. Check the CMS website first to determine if the device is already approved for coverage at
      
      www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies.html
      
   ii. Interested parties with Food and Drug Administration (FDA) approval letters dated January 1, 2015 or later for IDE Category A or Category B studies that are seeking Medicare coverage for Category A or B IDE studies must submit a request packet to CMS that includes the following information:
       
      1. A request letter that describes the scope and nature of the IDE study. For your convenience we created a checklist and sample crosswalk to assist submitters in submitting a complete package. We encourage you to submit this crosswalk along with the request packet to facilitate CMS' review. The letter should focus on how the IDE study meets each of the regulatory Medicare coverage IDE study criteria, which are:
       
         a. The principal purpose of the study is to test whether the device improves health outcomes of appropriately selected patients.
         
         b. The rationale for the study is well supported by available scientific and medical information, or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
         
         c. The study results are not anticipated to unjustifiably duplicate existing knowledge.
         
         d. The study design is methodologically appropriate and the anticipated number of enrolled subjects is adequate to confidently answer the research question(s) being asked in the study.
         
         e. The study is sponsored by an organization or individual capable of successfully completing the study.
         
         f. The study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 21 CFR parts 50, 56, and 812, and 45 CFR part 46.
         
         g. Where appropriate, the study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Studies of all medical technologies measuring therapeutic outcomes as one of the objectives
may be exempt from this criterion only if the disease or condition being studied is life threatening and the patient has no other viable treatment options.

h. The study is registered with the National Institutes of Health (NIH) National Library of Medicine’s (NLM) ClinicalTrials.gov.

i. The study protocol describes the method and timing of release of results on all pre-specified outcomes, including release of negative outcomes and that the release should be hastened if the study is terminated early.

j. The study protocol must describe how Medicare beneficiaries may be affected by the device under investigation, and how the study results are or are not expected to be generalizable to the Medicare beneficiary population. Generalizability to populations eligible for Medicare due to age, disability, or other eligibility status must be explicitly described.

2. FDA approval letter of the Category A or Category B IDE. (CMS will review a submission with a conditional FDA approval letter; however, please submit the final FDA approval letter to CMS at clinicalstudynotification@cms.hhs.gov.)

3. IDE study protocol.

4. Institutional Review Board (IRB) approval letter (only submit one IRB approval letter per request).

5. National Clinical Trial (NCT) number (e.g., NCT00000123).

6. Supporting materials, as appropriate.

iii. Requests may be submitted either via email or hard copy. Please note that you do not need to submit both electronic and hard copies of requests to CMS. Emails and electronic documents are preferred over hardcopies.

1. Email: clinicalstudynotification@cms.hhs.gov
   a. In Subject line, please use the following format: [IDE#]-[NCT#]-[Company Name]-[Device Name]-[FDA Category] (e.g. “A112233-NCT12345678-Acme Co-TechTech-B”)
   b. For attached files, please use the following conventions:
      i. File names should clearly indicate the document type (e.g., "Request Letter", "IRB Approval Letter").
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ii. Each document type should be a separate file (i.e., the Request Letter should be separate from the IDE Study Protocol).

iii. Word, PDF, and Excel file types are preferred.

iv. Word-searchable PDF documents enable a more efficient review.

v. If needed, CMS may meet with and provide feedback to study sponsors or applicants during protocol development.

2. Hard Copy: mail to:
   a. Centers for Medicare and Medicaid Services
      Center for Clinical Standards and Quality
      Director, Coverage and Analysis Group
      ATTN: Clinical Study Certification
      Mail Stop: S3-02-01
      7500 Security Blvd.
      Baltimore, MD 21244

   d. Internal Notification
      i. Once it has been determined that the IDE is involved in a clinical trial (using the 5 criteria from Attachment A) OR the PI/research unit receives approval from CMS/Medicare for IED coverage, contact OCC with a copy of all final documents and the response from CMS/Medicare. OCC will communicate with the following areas to ensure all processes are in place to proceed forward with the IDE:

         1. Offices where notification only required:
            a. Manager, Hospital Patient Accounts
            b. OR Auditors
            c. Revenue Management / Chargemaster

         2. Offices where action required:
            a. IRB
            b. Clinical Resource Manager / MU Value Analysis Team (VAT)
            c. Manager, Patient Admissions (Registration Services, including prior authorization)
            d. Managed Care Contracting

      ii. Registration of subjects will proceed according to RC034 Billing for Services Provided for Research Activities which will require completion of a Data Dictionary Entry Form (DE) to establish a FSC 152 (or other
appropriate FSC for each payer with investigational or clinical trial contract terms) financial class to be utilized to note investigational utilization. The research area and the prior authorization staff within Patient Admissions will need to work jointly on a case by case basis for each research participant to verify insurance coverage and precertification requirements. If the enrolled subject is a Medicare beneficiary and approval was received from CMS for Medicare coverage, Patient Accounts will process the claim using the correct modifiers.

iii. The IRB will note if there is a requirement to work with the MU Health Value Analysis team and will also determine, in conjunction with VAT, if the device requires training of nursing or other support personnel, and will collaborate with VAT to assure that adequate training is provided.

iv. Product malfunctions and recalls will be handled in accordance with UHC policies EOC-3 Product/Equipment Recall and Alerts and EOC-548 Medical Devices – Reporting Malfunctions in addition to all procedures required by the protocol and contract related to the investigational device.

IV. Attachments
   a. See Attachments Tab.

V. References, Regulatory References, Related Documents, or Links
   b. FDA Device information: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm
   c. Health Sciences Institutional Review Board policy on Investigational or Unlicensed Test Articles: http://research.missouri.edu/hsirb/policies.htm
   d. National Coverage Provision/Medical Devices/PHYS-067
   e. Medicare Claims Processing Manual Chapter 32
   f. CMS National Coverage Determination (NCD) for Routine Costs in Clinical Trials Section 310.1
   g. Professional/Surgical Value Analysis Committee Process Guidelines
   h. UMHC Policy EOC-3 Product/Equipment Recall and Alerts
   i. UMHC Policy EOC-48 Medical Devices- Reporting Malfunctions
   j. Key Content Experts: Director of Academic Compliance, Clinical Resource Manager, and Chief Compliance Officer