Discussion Overview

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Medical Device - FDA Definition

- An instrument, apparatus, implement, machine, contrivance, implant, in-vitro reagent, or other similar or related article, including any component, part, or accessory, which is:
  - recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them;
  - 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 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 (21 U.S.C. 321(h)).
Code of Federal Regulations - Good Clinical Practices (GCP)

- Applies to manufacturers, sponsors, clinical investigators, IRB’s, and medical device itself.

- 21 CFR 812, *Investigational Device Exemptions*, covers the procedures for the conduct of clinical studies with medical devices including application, responsibilities of sponsors and investigators, labeling, records, and reports.

- 21 CFR 50, *Protection of Human Subjects*, provides the requirements and general elements of informed consent;

- 21 CFR 56, *Institutional Review Boards*, covers the procedures and responsibilities for institutional review boards (IRBs) that approve clinical investigations protocols;

- 21 CFR 54, *Financial Disclosure by Clinical Investigators*, covers the disclosure of financial compensation to clinical investigators which is part of FDA’s assessment of the reliability of the clinical data.

- 21 CFR 820 Subpart C, *Design Controls of the Quality System Regulation*, provides the requirement for procedures to control the design of the device in order to ensure that the specified design requirements are met.
Steps required for IDE Device Study

- FDA application/Approval of IDE
- IRB submission/approval (significant vs. non-significant risk)
- Central CMS submission/approval ----> Local MAC (Noridian) submission/approval
- Coverage Analysis (including coding) & Clinical Trial Contract execution
- Value Analysis Committee (and Purchasing) ----> EMPAC/EAP set-up ----> Device Storage/handling determination
FDA Classification of Medical Devices

- Class I devices are deemed to be low risk and are therefore subject to the least regulatory controls (e.g. dental floss, enema kits, elastic bandages).

- Class II devices are higher risk devices than Class I and require greater regulatory controls to provide reasonable assurance of the device’s safety and effectiveness (e.g. powered wheelchairs, pregnancy kits).

- Class III devices are generally the highest risk devices and are therefore subject to the highest level of regulatory control. Class III devices must typically be approved by FDA before they are marketed (e.g. replacement heart valves, implantable pacemakers, breast implants).

- ***Exempt - Devices that fall into a generic category of exempted Class I devices, do not require a premarket notification application and FDA clearance, before marketing the device in the U.S. However, the manufacturer is required to register their establishment and list their generic product with FDA (e.g. manual stethoscopes, mercury thermometers and bedpans).
**Category A IDE Studies**

- Experimental device
- The “absolute risk” of the device type has not been established
- Device **never** covered by Medicare
- Medicare covers routine care items and services provided in an FDA-approved Category A IDE study, if CMS determines that Medicare coverage IDE study criteria are met

**Category B IDE Studies**

- Non-Experimental Device
- Incremental risk is the primary risk in question
- May be covered by Medicare
- Medicare may make payment for Category B IDE device and routine care items and services furnished in an FDA-approved Category B IDE Study.
The Food and Drug Administration (FDA) has reviewed the supplement to your investigational device exemptions (IDE) application. You have corrected the deficiencies cited in our March 26, 2002 conditional approval letter. Therefore, your application is approved and you may continue your investigation at the institution enrolled in accordance with the investigational site waiver granted in our March 26, 2002 letter. Your investigation is limited to a institution and Washington.
IRB Approval -
Significant Risk vs. Non-Significant Risk Devices

- Devices studies that pose a significant risk (sutures, cardiac pacemakers, intracerebral shunts, orthopedic implants) require both FDA and an Institutional Review Board (IRB) approval prior to initiation of a clinical study. FDA approval is obtained by submitting an IDE application to FDA.

- Non-significant risk device (daily wear contact lenses, Foley urinary catheters) studies require only IRB approval prior to initiation of a clinical study. Sponsors of studies involving non-significant risk devices are not required to submit an IDE application to the FDA for approval. Submissions for non-significant device investigations are made directly to the IRB of each participating institution.
Types of Devices that may be covered by Medicare

- **FDA-approved IDE Category B Devices**
  - Allows the investigational device to be used in a clinical study to collect safety and effectiveness data.
  - Approved IDE permits a device to be shipped lawfully for the purpose of conducting investigations of the device without complying with other requirements of the FDA.
  - Sponsors are not required to submit a PMA or Premarket Notification (510(k)), register their establishment, or list the device while it is under investigation.

- **Humanitarian Device Exemption (HUD)**
  - Intended to benefit patients by treating or diagnosing a disease/condition that affects or is manifested in fewer than 4,000 individuals in the US per year.
  - For approval an humanitarian device exemption (HDE) application is submitted to FDA. Similar to a premarket approval (PMA) application, but exempt from effectiveness requirements of a PMA.

- **FDA approved through the Pre-Market Approval Process**

- **Cleared by FDA through the 510(k) Process**

- **Institutional Review Board approved devices**

- **Post-Market carotid artery stenting studies (as part of IDE study or Post-Market FDA approved Protocol)**
Step 1 - Sponsor’s submission for Central CMS Approval

Requesting Coverage

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:

A. 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:

1. The principal purpose of the study is to test whether the device improves health outcomes of appropriately selected patients.
2. 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.
3. The study results are not anticipated to unjustifiably duplicate existing knowledge.
4. 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.
5. The study is sponsored by an organization or individual capable of successfully completing the study.
6. 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.
7. 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.
8. The study is registered with the National Institutes of Health (NIH) National Library of Medicine’s (NLM) ClinicalTrials.gov.
9. 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.
CMS Approved IDE Studies

Approved IDE Studies

The following IDE studies have met CMS standards for coverage. Studies with the Category A are approved for coverage of routine services only. Studies with the Category B are approved for coverage of the Category B device and related services, and routine services.

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<th>Study Title</th>
<th>Sponsor Name</th>
<th>NCT Number</th>
<th>IDE Number</th>
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<td>GDS Accuchek Ventriculoplasty System</td>
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<td>Minimally Invasive Access to the Vascular Access Site</td>
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<td>Evaluation of the TULSA-PRO MRI-guided Transradial Ultrasound Prostate Ablation Device in Patients With Localized Prostate Cancer</td>
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<td>A Pilot Prospective, Randomized, Controlled, Multicenter Technical Feasibility Clinical Study Comparing Standard Anatomical Closure Technique to Standard Closure Techniques Plus Sympathetic Surgical Sealed</td>
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<td>NCT02641091</td>
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Step 2a - UCLA’s submission to Local MAC Noridian

Investigational Device Exemption (IDE)

IDE Documentation Requirements for Studies with an FDA Approval dated January 01, 2015 or later

Effective January 01, 2015, CMS Coverage Analysis Group began reviewing all IDE trials for approval. Once CMS approves the trial they list the trial on their web site as approved. This process is streamlining the approval process for all parties involved.

Noridian has reviewed our requirements for such studies. For IDE trials with an FDA approval letter on or after January 01, 2015 that have been approved by CMS Noridian will only require:

1. Notice of participation in the trial,
2. IDE designator assigned by the FDA
3. Clinical trial number as listed on [www.clinicaltrials.gov](http://www.clinicaltrials.gov)

A letter including the three above stated requirements along with the PTAN of the facility, the names of the principal investigator, study doctors and their NPIs is to be submitted at time of request to Noridian.

Such notice is necessary to input into the Noridian claims payment systems to assure proper processing of our provider’s claims related to such trial. For further information on this process, visit the CMS website: [http://www.cms.gov/Medicare/Coverage/IDE/index.html](http://www.cms.gov/Medicare/Coverage/IDE/index.html)
Step 2b - Submission to Local MAC Noridian

- For the purposes of an IDE approval the following financial disclosures **shall** be included in the informed consent and be clearly marked as such therein:
  - Funding source(s) for the project;
  - Funding for the facility
  - Funding for the investigators and if that funding is direct to the provider or if the facility is provided funds to offset his/her salary
  - Any relationship that the provider has with the sponsor. These include but are not limited to being a speaker for the sponsor, receiving other gratuities from the sponsor and/or being a paid consultant for the sponsor.
  - Other financial interests in the sponsor(s) such as stocks or other investments
  - Any other potential conflict of interest as it regards the respective study;
  - Any such interest as disclosed to the Institutional Review Board.

The informed consent does not necessarily need to include the extent of such potential conflict (e.g. how many stocks the institution/ primary investigator (PI)/ secondary or other investigators (SI) has from the sponsor or the actual monies paid directly to the institution/PI/SI) only that one exits. Noridian does reserve the right to request a budgetary review of IDE trials/studies but the latter does not need to be submitted with the application.

Failure to provide such information either in the affirmative with a listing of such items or in the negative (no known conflicts) will result in a denial of the request. The provision of fraudulent information will be referred to Medicare enforcement agencies.
Sample Approval Letter - Local MAC Noridian

May 31, 2016

Felicia Rue, Reimbursement Director
UCLA Hospital System
10920 Wilshire Boulevard Suite 1700
Los Angeles, California 90024

RE: [Redacted]

Dear Ms. Rue:

We are in receipt of your request to participate in the CMS approved Clinical Trial # [Redacted]. The University of California Los Angeles PTAN [Redacted] and [Redacted] NPI: [Redacted] will be entered into the Medicare claims system for Medicare Part A and B effective May 31, 2016.

If you have any additional questions, please feel free to contact me.

Sincerely,

[Signature]

Gary Oakes, MD
Contractor Medical Director
Noridian Healthcare Solutions, LLC
Device acquisition considerations

- Is the vendor (device manufacturer/study sponsor) an approved vendor for the health system?
- The end-user will need to submit a vendor-add request (The exception to this is if the device is distributed by another vendor).
- Certificate of Insurance, INCLUDING worker’s comp
- Business Information Form
- W-9
- Submission of an EMPAC add-request, referencing the IDE# and associated $0.00 cost. (Copy of the study contract required to verify the $0.00 cost and terms of the price protection).
- Once the vendor meets all University of California insurance requirements, the EMPAC and add request can be processed and an ordering number can be assigned.
- The EMPAC add information will automatically forward to the EAP team for assignment.
Medical documentation to support claim for device procedure

When your study involves an implantable device, it is very important that the physician dictating the note document:

- Study Participation
  - Study name
  - Sponsor
  - Sponsor-assigned protocol number

- Exact device name
- Manufacturer,
- Device ID,
- Surgical approach and name of procedure (to help the coders understand the type of procedure and device used and code accordingly.)

***If it is not documented, it never happened.
Record retention requirements

- Sponsors and investigators must maintain the required records for a period of two years after the date the investigation is completed or terminated or the records are no longer required to support a PMA or PDP, whichever date is later.

- An investigator or sponsor may withdraw from the responsibility to maintain records for the time required by transferring custody to another person who will accept responsibility for them. If an investigator or sponsor transfers custody of the records to another person, FDA must be notified within 10 working days after the transfer occurs.

- Sponsors, IRBs, and investigators are required to permit authorized FDA employees reasonable access at reasonable times to inspect and copy all records of an investigation. Upon notice, FDA may inspect and copy records that identify subjects.

- FDA has authority to inspect facilities at which investigational devices are being held including any establishments where devices are manufactured, packed, installed, used, or implanted.
Special billing rules for routine services rendered on an approved device study

- **NCT# (professional claim & hospital claim)**
- **Diagnosis** (professional claim & hospital claim; secondary position for diseased patient & primary position for healthy volunteer)
  - Z00.6
- **Modifiers** (professional claim)
  - Q0 Modifier - Investigational item/service, (e.g. Investigational drug J9999 Q0)
  - Q1 Modifier - Routine item/service, e.g. (Physical Exam 99211 Q1)
- **Revenue Code 0624** (hospital claim)
  - Medicare accepts revenue code 0624 for IDEs, but many other payers allow for this to be billed using revenue code 0278, Other Implants
- **Condition Code** (hospital claim)
  - CC 30 - “Qualified clinical trial.” Must appear on the hospital claim for items/services related to a Qualified Clinical Trial regardless of whether all services are related to the clinical trial or not.
  - CC 53 - used to identify and track medical devices that are provided by a manufacturer at no cost or with full credit to the hospital due a clinical trial or a free sample.
Case Studies

- **Device manufactured and paid for by the patient** - payment made by patient to be recorded on patients financial account; coding team needs to be aware that device is covered by patient but routine procedure (during which the device is implanted) may still be billable as routine.

- **Device becomes FDA approved, but not set-up in the CDM as such** - need to advise purchasing team and CDM team

- **Independent observer required by study sponsor** - need to include special clause in clinical trial contract

- **Deep Brain stimulator study** - Per study contract and budget - Sponsor agreed to cover the costs of the Device (Deep Brain Stimulator, and components thereof), initial implantation procedure and associated in-patient hospitalization fees, anesthesia, surgeon’s professional fees, and any required surgical revisions, explantation and associated in-patient hospitalization. - make sure that all charges are directed to the study grant account and not to insurance/patient.
Case Studies (cont’d)

- MAP Enrollee receiving a device while participating on an approved device study (IDE) conducted at UCLA -

The Medicare Advantage Plan is responsible for payment of claims related to enrollees’ participation in both Category A and B IDE studies that are covered by the Medicare Administrative Contractor (MAC) with jurisdiction over the MA plan’s service area.

The MAO (Medicare Advantage Organization) is responsible for payment of routine care items and services in CMS-approved Category A and Category B IDE studies. The MAO is also responsible for CMS-approved Category B devices. CMS will not approve Category A devices because they are statutorily excluded from coverage.
Resources


2) CMS Approved IDE studies - [https://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies.html](https://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies.html)


3) CMS guidance on investigational device approval - [https://www.cms.gov/Medicare/Coverage/IDE/](https://www.cms.gov/Medicare/Coverage/IDE/)

4) UCLA Purchasing - [http://purchasing.uclahealth.org/default.cfm](http://purchasing.uclahealth.org/default.cfm)