THE TYPES OF DEVICE TRIALS, BILLING AND REIMBURSEMENT

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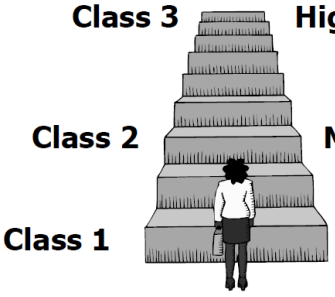
Devices are classified according to risk



Pacemakers, heart valves

Powered wheelchairs

Bandages, stethoscopes, dental floss

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CATEGORY A AND B / IDE

- Category A (Revolutionary)
  - Is a device for which the "absolute risk" of the device type has not been established and the FDA is unsure whether the device type can be safe and effective. Medicare covers routine care items and services furnished in an Category A IDE study if CMS determines that the Medicare coverage IDE study criteria are met.
- Category B (Evolutionary)
  - Is a device for which the initial questions of safety and effectiveness have been resolved, or it is known that the device can be safe and effective because other manufactures have obtained FDA pre-market approval or clearance of the device type. Medicare can make payment for a Category B IDE study if CMS determined prior to the submission of the first related claim that the CMS coverage IDE criteria are met.

CMS Benefit Policy Manual, Chapter 14, Section 20

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INVESTIGATIONAL DEVICES: COVERAGE PRINCIPLES SUMMARY

Category A	Category B	CEDs
• Trials involve immediately life-threatening condition (if trial was initiated before January 1, 2010)	• All CMS approved trials	• All CMS approved registries and trials
• Device NEVER covered	• Device covered if not provided free by sponsor or promised free • Reimbursement may not exceed amount for comparable marketed device	• Device covered if not provided free by sponsor or promised free • Reimbursement may not exceed amount for comparable marketed device
• Routine care services covered	• Routine care services covered	• Routine care services covered
• Medicare contractor approval required	• Medicare contractor approval required	• Medicare contractor approval required

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OTHER DEVICES

- Premarket Approval (**PMA**) - is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices
- **510(K)** or Pre-Market Notification - Parties who must submit their device should notify FDA of their intent to market a medical device at least 90 days in advance.

From:
https://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarketsubmissions/premarketapprovalpma/
https://www.fda.gov/medicaldevices/productsandmedicalprocedures/deviceapprovalsandclearances/510kclearances/

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OTHER DEVICES

- Humanitarian Use Device (**HUD**) - a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year
- Humanitarian Device Exemption (**HDE**) - a marketing application for an HUD. An HDE is exempt from the **effectiveness** requirements and is subject to certain profit and use restrictions.

https://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarketsubmissions/humanitariandeviceexemption/default.htm

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WHAT ABOUT CED'S?

- Coverage with Evidence Development (CED)
  - "CED is a paradigm whereby Medicare covers items and services on the condition that they are furnished in the context of approved clinical studies or with the collection of additional clinical data. In making coverage decisions involving CED, CMS decides after a formal review of the medical literature to cover an item or service only in the context of an approved clinical study or when additional clinical data are collected to assess the appropriateness of an item or service for use with a particular beneficiary."

https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development
https://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=27

CED EXAMPLE - TAVR

- Transcatheter Aortic Valve Replacement (TAVR)

Registry Approvals

STS/ACC Transcatheter Valve Therapy (TVT) Registry
ClinicalTrials.gov number: NCT01737528
https://www.ncdr.com/TVT/Home/Default.aspx

Clinical Study Approvals

Study Title: A Study to Assess Safety and Probable Benefit of the Transfemoral JenaValve Pericardial TAVR System in the Treatment of High Surgical Risk Patients with Symptomatic, Severe Aortic Regurgitation (AR)
Sponsor: JenaValve Technology, Inc.
Clinicaltrials.gov number: NCT04415047
Investigational Device Exemption (IDE) Number: G150035
CMS Approval Date: 02/16/2021

Study Title: Evaluation of the Portico NG Transcatheter Aortic Valve in High and Extreme Risk Patients with Symptomatic Severe Aortic Stenosis (Portico NG Approval Study)
Sponsor: Abbott
Clinicaltrials.gov number: NCT04011722
Investigational Device Exemption (IDE) Number: G120263
CMS Approval Date: 03/05/2020

https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/TAVR

DEVICE TRIAL QUALIFYING DOCUMENTATION

CED IDE Study Example				
CED IDE Study Example				
This Medicare coverage analysis is intended as a general guideline for use in determining which items and services are billable to Medicare based upon current benefit policies, coverage determinations, coverage decisions, and federal guidelines. All items and services that are billable to Medicare must be supported by medical necessity.				
Investigational Device Analysis				
Question	Yes	No	Not Applicable	Comments
Does the study have an IDE from the FDA?	X			
Is the Device assigned Category A status?		X		
Is the Device assigned Category B status?	X			
Is it listed as an Approved IDE Study per CMS? (http://www.cms.gov/Medicare/Coverage/IDE/) OR Is it listed as an approved CED Study Per CMS? https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-	X			https://www.cms.gov/medicarecoverageideapproved-ide-studies/ OR https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/TAVR
What is the IDE number?				G654231 (Per protocol)
If the trial does not have an IDE, has the device been			X	
If the trial does not have an IDE, is the trial involving FDA approved device approved during the PMA process or a 510K cleared device? If yes, What is the PMA/ 510K number?			X	
If the device is being used off-label?			X	
If off-label is the device IDE exempt and verified by the FDA or IRB?			X	
Does the trial qualify for coverage?	X			Yes - CMS Centrally Approved https://www.cms.gov/medicarecoverageideapproved-ide-studies/ OR https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/TAVR

CMS APPROVAL

- You must have CMS (or MAC) approval before you start billing CMS for the study.
- The following Medicare Contractors require notification prior to submitting the first claim: CGS J-5, FCSO J-N; Noridian J-E and J-F, Novitas J-H and J-L, Palmetto J-M.
- The sponsor should seek CMS approval for their Category A and B device trials.

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.

Showing 1-10 of 561 entries

Show entries: 10 per page | Filter On | Apply

Study Title	Sponsor Name	NCT Number	IDE Number	CMS Approval Date	Category
RNS® System Responsive Thalamic Stimulation for Primary Generalized Seizures (NAUTILUS) Study	NeuroPace	NCT05147571	G210286	2022-07-12	B
A Feasibility Evaluation of the Muse Magnetic Resonance Guided Focused Ultrasound System	University of Utah	NCT05291507	G210365	2022-07-12	A
A Prospective Multicenter Study of Transbronchial Microwave Ablation Using Robotic Assisted Bronchoscopy in Subjects with Oligometastatic Tumors in the Lung	Ethicon, Inc.	NCT05299606	G210303	2022-07-12	A

BILLING FOR IDE AND CEDS (DEVICE)

- These elements must appear on the claim as required by CMS and other payers:
  - NCT#
  - IDE# (or PMA, 510K, HUD/HDE)
    - if CED only, there will not be an IDE# (e.g. TAVR Registry)
  - Diagnosis code Z00.6 (secondary position)
  - Condition Code 30 (hospital only)
  - Modifiers (outpatient hospital and all professional fees)
    - Q1 – protocol directed routine care items
    - Q0 – investigational device (remember it may be provided and must be listed as a no charge item)

CMS Claims Manual, Chapter 32, Section 68.2

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NO COST ITEMS DUE TO RECALL, REPLACEMENT OR FREE SAMPLE

- Institutional Billing for No Cost Items due to Recall, Replacement or Free Sample
  - **Condition Code 53 (outpatient)**: Initial placement of a medical device provided as part of a clinical trial or free sample
  - **Value Code FD & Dollar Value of the Device (outpatient):** Credit Received from the Manufacturer for a Medical Device
  - **Modifier FB (outpatient):** only if a replacement
  - **Condition Code 49**: Product replacement within product lifecycle
  - **Condition Code 50**: Product replacement for known recall or a product

CMS Claims Manual, Chapter 4, Section 61 & Chapter 32, Section 67

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INSTITUTIONAL BILLING FOR CATEGORY B DEVICE

- Outpatient –
  - Institutional providers must bill the Category B IDE number on a 0624 revenue code line with charges in the covered charges (Total Charges) field.
    - Remember to add a HCPCS code when billing the device
    - Add modifier Q0
    - **Note: if device is provided free, report with a token charge in the "Non-Covered Charges" field
- Inpatient –
  - Free Device - Hospital inpatient providers should not bill for the Category B IDE device if receiving the device free-of-charge
  - Not a Free Device – Providers should bill the Category B device on a 0624 revenue code line with charges in the covered charges (Total Charges) field

CMS Claims Manual, Chapter 32, Section 68

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WHAT ABOUT MEDICARE ADVANTAGE?

Drug Clinical Trials

- Charges for qualifying clinical trials are billed to Medicare, NOT the MA plan
- The MA plan becomes secondary

CMS Managed Care Manual, Chapter 4, Section 10.7.1

Device Studies

- MA plan is responsible for claims related to Category A and B IDE studies and for routine care items and services in a CMS-approved Category A and B IDE studies
- The MA plan is also responsible for the Category B device, if not provided free

CMS Managed Care Manual, Chapter 4, Section 10.7.2

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AUDIT CHALLENGES

- You have an FDA approved Category B device but the Sponsor is providing the device at no cost.
  - What challenges would this present?
  - Would you ask the Sponsor not to provide the device?

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AUDIT CHALLENGES

- Sponsor does not want to apply to CMS for approval to bill, but will not cover the cost of the device or insertion of the device
  - What does your site do?
  - What are things that you have to consider?

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AUDIT CHALLENGES

- The study is a two arm study and the study is blinded. Sponsor only wants to cover the investigational device arm.
  - What are the challenges with this?

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COMMERCIAL PAYERS CHALLENGES FOR IDE STUDIES

- Not all private payers follow Medicare policy.
- Coverage varies even among payer plans.
- Prior authorization is usually required.
  (site should determine coverage before enrollment and always remember that the patient may end up being responsible for the balance bill)
- Know the policies of the top 3-5 payers in your region.
- Review denials.
- Use your coverage analysis and CMS approval as support.

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Thank You

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