CMS Coverage Playbook: How to Secure IDE Clinical Trial Reimbursement

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Requesting reimbursement for investigational device exemption (IDE) clinical trials in the United States is nothing if not complicated. For some medical device companies, it is easier to assume that private payers won't reimburse hospitals and providers for services rendered, and that the sponsor of the study will be responsible for all patient costs. By contrast, others may assume that private payers or CMS will cover all standard-of-care costs. Both are inaccurate and potentially problematic for the advancement of new medical technology.

Although it does take time and understanding of the process to request reimbursement, it's worth the effort. Upon approval, the sponsor can offset a significant percentage of routine healthcare and/or device costs accrued during the clinical trial.

The Centers for Medicare and Medicaid Services (CMS) is the primary payer of concern for medical device manufacturers for three reasons: CMS' coverage determination is largely based on the FDA's device classification, commercial payers tend to follow their lead, and a number of clinical trial participants are Medicare beneficiaries. According to an FDA report on age and demographic data reporting, the mean age for study populations for all pre-market approvals (PMAs) that reported demographic data was about 40 to 75 years.[1]

Here, we walk you through the process of obtaining Medicare coverage for your IDE clinical trial, as well as how to factor reimbursement into your clinical trial project plan.

CMS Reimbursement: Background in Brief

The CMS and the FDA started working together on reimbursement for IDE devices and related healthcare services in 1995. Under an Interagency Agreement, the FDA began categorizing devices with an approved IDE into two categories based on level of risk.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) allowed Medicare payment of the routine costs of care provided to Medicare beneficiaries in certain categories of investigational device exemption (IDE) studies. Covering medical care and/or device costs "removed a financial barrier that could otherwise discourage beneficiaries from participating," according to CMS.[2]

CMS reimbursement also lowers the financial barrier for device clinical trial sponsors. Obtaining coverage for device and/or healthcare costs can save sponsors tens of thousands of dollars per patient participating in the trial over the course of an IDE study.

In 2015, CMS added coverage criteria and changed review and approval from local review and approval through Medicare Administrative Contractors (MACs) to a centralized review. The requirements for obtaining CMS reimbursement have changed very little since.

Why Apply for CMS Reimbursement?

Without payer reimbursement, the burden of medical care and device costs falls on either patients or sponsors. Paying for medical care and IDE devices is not feasible for most patients. To facilitate recruitment, the sponsor often assumes responsibility for these costs.

Without reimbursement support for standard-of-care procedures and healthcare costs, medical device manufacturers often decide to conduct studies outside the U.S. where healthcare costs are less expensive. They collect initial safety and efficacy data overseas before returning to the U.S. to conduct an IDE trial. This may give sponsors the data they need to move forward with the trial and obtain reimbursement for a clinical study in the U.S., but it comes at a cost — specifically, delayed market entry in the U.S. and potentially millions of dollars in additional clinical trial costs.

When CMS approves an IDE study for reimbursement, sponsors not only get financial relief, but they also simplify their reimbursement process upon FDA clearance or approval. Sponsors have a billing and claims history and study data from a qualified clinical trial (QCT), which gives them an edge when seeking long-term approval.

When to Start Planning for CMS Reimbursement

Think about CMS reimbursement requirements as you prepare your IDE application. When the FDA approves an IDE study (or approves one with conditions), the FDA assigns the device to Category A or B. The category determines the extent of CMS reimbursement.

Many times, sponsors don't consider category designation until after the FDA approves their study. Without an understanding of coverage, you won't realize the true extent of study costs until it's too late.

CMS Category: The Difference Between A and B

The FDA bases Category A and B assignments on whether available data show that initial questions of safety and effectiveness have been resolved. The criteria include the following:

The FDA's Decision-Making Process for Category Designation

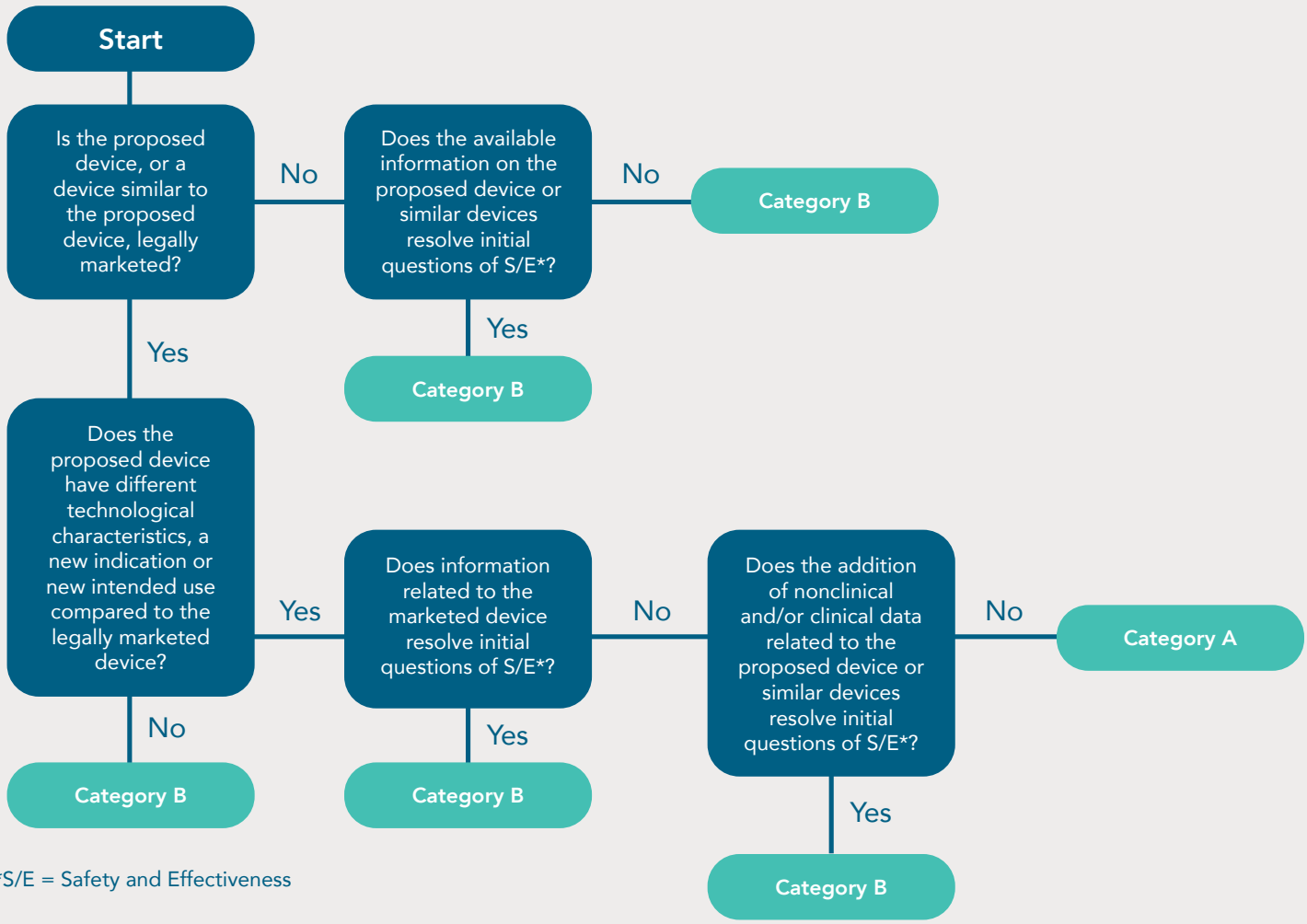

Image source: FDA

Category A — Experimental

Category A includes novel devices, devices with the new addition of a drug, devices being evaluated for a new intended use, and devices that raise initial safety and effectiveness questions.

If a device meets one or more of the following criteria, the FDA assigns Category A:[3]

- The FDA has not granted PMA, 510(k) clearance, or De Novo request for the proposed device or similar devices, and data on the proposed device or similar devices do not resolve initial questions of safety and effectiveness, and the FDA is unsure whether the device type can be safe and effective.
- The proposed device is being studied for a new indication, or new intended use, for which information from the proposed or a similar device related to the previous indication or intended use does not resolve initial questions of safety and effectiveness. Available nonclinical and/or clinical data on the proposed device or similar devices relative to the new indication or intended use also do not resolve these questions and the FDA is unsure whether the device type can be safe and effective.
- The proposed device has different technological characteristics compared to a legally marketed device, and information related to the marketed device does not resolve initial questions of safety and effectiveness for the proposed device. Available nonclinical and/or clinical data on the proposed device or similar devices also do not resolve these questions, and the FDA is unsure whether the device type can be safe and effective.

Category A Reimbursement

CMS only covers routine costs of care for Category A devices.[4] These costs include items and services otherwise available to Medicare beneficiaries. CMS does not cover the investigational item or service. For example, CMS may cover inpatient hospital services, but not the device itself, and possibly not the surgical procedure to use or implant the device.

CMS may deny all coverage for certain Category A device studies. A first-in-human study will likely get denied reimbursement by CMS. Because of the paucity of data to support safety and effectiveness, and because of the risk of harm to participants, CMS is less likely to cover these studies.

Recent Category A IDE clinical trials approved for CMS reimbursement include:			
A Prospective, Multicenter, Non-randomized, Single-arm, Open-label Clinical Study to Demonstrate the Safety and Performance of the Leaflex™ Performer			
Pi-cardia	NCT04636073	G200144	2021-03-04
The WhiteSwell System: WhiteSwell Bloodline, WhiteSwell Console, WhiteSwell Catheter			
Boston Biomedical Associates, LLC.	NCT02863796	G160083	2016-10-03
CytoSorb® Reduction of FREee Hemoglobin/Acute Kidney Injury (AKI) During Cardiac Surgery (REFRESH II Trial)			
CytoSorbents, Inc	NCT03384875	G140256	2018-02-02

Category B — Nonexperimental/Investigational

Category B devices pose less risk. They include novel and approved devices with proven safety and effectiveness. If a device meets one or more of the following criteria, FDA assigns Category B:[5]

- No PMA, 510(k) clearance, or De Novo request has been granted for the proposed device or similar devices; however, available information (e.g., feasibility study data) from the proposed device or a similar device resolve the initial questions of safety and effectiveness.
- The proposed device is being studied for a new indication or new intended use; however, information from the proposed or a similar device related to the previous indication or intended use resolves the initial questions of safety and effectiveness. In some cases, additional nonclinical and/or clinical data on the proposed device may also have been used to resolve these questions.

- The proposed device has similar technological characteristics compared to a legally marketed device, and information related to the marketed device resolves the initial questions of safety and effectiveness for the proposed device. In some cases, additional nonclinical and/or clinical data on the proposed device may also have been used to resolve these questions.

Category B Reimbursement

CMS may cover both routine care and the investigational device for Category B devices. For example, if a sponsor launches an IDE study for a new lumbar disc implant, and CMS covers lumbar disc replacement surgery, it will cover the procedure, care associated with the procedure, and the implant itself.

While Category B designation increases the odds of reimbursement, it's no guarantee. CMS may deny services provided during the study that it deems not medically necessary.

Recent Category B IDE clinical trials approved for CMS reimbursement include:[6]			
Evaluation of the Safety and Efficacy of the Carag Bioresorbable Septal Occluder (CBSO) to Treat Patients With Clinically Significant Secundum Atrial Septal Defect Carag AG			
Carag AG	NCT04591392	G170213	2021-02-11
Endovascular Ablation of the Right Greater Splanchnic Nerve in Subjects Having HFpEF: Feasibility Study: Randomized Controlled Feasibility Trial Rebalance HF Study			
Axon Therapies, Inc.	NCT04592445	G200219	2020-12-10
A Prospective Multicenter Randomized Controlled Clinical Study to Investigate the Safety and Effectiveness of the RECELL® System Combined With Meshed Autograft for Reduction of Donor Skin Harvesting in Soft Tissue Reconstruction			
Avita Medical	NCT04091672	BB13053	2019-12-03

What Are Routine Costs?

Routine costs include products and services normally available to Medicare beneficiaries. For example: a hospital stay, imaging, blood work, and medical care to monitor a participant's health or to prevent complications.

Routine costs do not include:

- Products and services used solely to collect data that aren't necessary for direct clinical care management (e.g., monthly CT scans for a condition that normally requires one CT scan)
- Products and services usually provided by the sponsor free of charge
- The investigational device (for Category A devices)

How to Apply for IDE Clinical Trial Reimbursement

Sponsors interested in obtaining CMS coverage for an IDE clinical trial must submit the following information to CMS:

1. Request letter that describes the scope and nature of the study. We strongly recommend using the checklist and crosswalk table created by CMS to prepare this letter. It lists Medicare coverage IDE study criteria that should be included in either the protocol or IRB approval letter.
2. Complete FDA approval letter for your Category A or B IDE.
3. IDE study protocol that includes descriptions of the following:
    - Method and timing of release of results on all prespecified outcomes, including release of negative outcomes and that the release should be hastened if the study is terminated early
    - How Medicare beneficiaries may be affected by the device under investigation
    - How 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

4. Institutional Review Board (IRB) approval letter
5. The National Clinical Trial (NCT) number
6. Any supporting materials, including investigator agreement, anticipated diagnosis, procedure, product, and revenue codes for Medicare claims associated with the trial, and other applicable documents

How Do I Get Paid?

Once CMS approves your IDE study for reimbursement, the provider (e.g., the hospital or the investigator) contacts its regional MAC to start the notification process for clinical trial participation. The MAC will also detail the billing and coding requirements and any other requirements unique to that MAC.

With all notification processes complete and appropriate billing codes understood, the provider submits Medicare claims on behalf of the patients. Typically, the sponsor is responsible for any costs not covered by Medicare, not including copayment or coinsurance amounts.

The sponsor also covers any unforeseen expenses, such as additional care due to complications or adverse reactions. If Medicare rejects or denies a claim, it's the sponsor's responsibility to assist the provider in resolving the discrepancy.

Advice for Sponsors: How to Streamline the Reimbursement Process

- Factor reimbursement into protocol development. The information CMS wants to see should be included in the protocol. Don't wait until you start clinical trials to request reimbursement. If you do, you may have to revise your protocol to include CMS criteria or be unpleasantly surprised by a denial.
- Change categories, if possible. If you believe your Category A device qualifies for Category B, you can submit an IDE supplement to request a categorization change with the FDA. For example, you may receive data from a feasibility study that resolves initial safety and effectiveness questions. Or, if an IDE study receives an approval with conditions, the sponsor may be able to change to Category B when those conditions are resolved.
- Extend your timeline to include CMS reimbursement decisions. The agency reviews complete submissions in "about" 30 days. Budget time into your study to allow for CMS submission preparation, review, and potential re-review. Planning for reimbursement on the front end will help prevent enrollment delays later.
- Take advantage of the Payor Communication Task Force. To ease communication between sponsors and payors, as well as to help speed up coverage decisions, the FDA Center for Devices & Radiological Health (CDRH) established the Payor Communication Task Force. The task force provides input to sponsors on clinical trial design and other plans related to coverage decisions. Payer participants include CMS as well as commercial payers.
- Recruit a reimbursement expert. Successfully requesting Medicare coverage for an IDE clinical trial requires legal, regulatory, and coding expertise. A CRO that has those experts available can help ensure your protocol includes the information CMS wants to see for approval — submitting a complete, accurate package increases the odds of approval and helps prevent delays that could affect your enrollment timeline. A reimbursement expert can also walk you through a category change and help you factor reimbursement into your study budget.

Applying for IDE clinical trial reimbursement and navigating the claims process post-approval are both complicated, time-intensive processes. By planning early, and by obtaining the assistance you need to submit accurate, complete documentation, sponsors can dramatically reduce clinical trial costs and gain powerful data for commercial reimbursement.

References

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