

Coverage of IDE Clinical Trial Costs: Navigating the Medicare Maze

by Jeffrey D. Zigler, JD

Regulatory professionals recognize the value of clinical research in the medical device development process. The reward of obtaining third-party insurance coverage during a clinical trial is significant, but seeking such coverage by third-party payers has proven complex and confusing even for the most seasoned of professional teams.

That is exactly why multinational corporations looking to study medical technologies, and even those small- and mid-cap companies undergoing recent financing challenges have in the past hired reimbursement consultants to help them navigate this third-party payer maze.

This article provides a helpful roadmap for regulatory professionals attempting to navigate the constantly changing process created by the body of laws and regulations governing Medicare Contracting Reform (as defined in section 911 of the *Medicare Prescription Drug, Improvement, and Modernization Act* of 2003) and provide guidance on navigating the largest single payer of clinical research in the US—the Centers for Medicare and Medicaid Services (CMS).

Regulatory professionals who seek opportunities to manage the Medicare coverage process and who successfully navigate the nuances of Medicare Contracting Reform may reap substantial benefits. In setting out to navigate Medicare’s maze to clinical trial coverage, a brief history and legislative intent behind Medicare’s policy of coverage for clinical trial costs is essential to solving the puzzle.

Medicare’s Policy of Coverage for Clinical Trial Costs

Since President Bill Clinton issued his 2000 Executive Memorandum to the Department of Health and Human Services, the Medicare program has operated under a spirit of encouraging beneficiaries’ involvement in clinical trials of technologies which may benefit their health, as long as there is some assurance of safety.^{1,2} Items now covered by Medicare include “routine clinical costs” defined by CMS in the Medicare Claims Processing Manual as “all items and services that are otherwise generally available to Medicare beneficiaries...that are provided in either the experimental or the control arms of a clinical trial.”³

Emerging technologies undergoing the US Food and Drug Administration (FDA) Investigational Device Exemption (IDE) clinical study may also be deemed reasonable and necessary for Medicare-eligible populations by care providers. In certain cases, an investigational device or medical service itself may also be covered by Medicare.⁴

To this end, CMS and FDA have agreed that Medicare will also pay for a certain category of investigational device or service (“Category B”) implanted or performed during FDA-approved

IDE clinical trials.^{5,6} Such devices represent “Non-experimental/Investigational” technology.

Payment for a Category B IDE device and the related services may not exceed what Medicare would have paid for a comparable approved device and related services.⁷

Conditions of Coverage by Medicare: MAC Pre-determination Requests

Following FDA’s approval of the IDE, but prior to a site’s treatment of Medicare beneficiaries, pre-determinations of coverage by Medicare Administrative Contractors (MACs) are required for Medicare to process and pay claims for services provided under the IDE’s protocol or performed in the normal course of care during the study.

Currently, there are 11 private companies that have traditionally contracted with the government to process the nation’s Medicare claims as “carriers” or “fiscal intermediaries,” which follow the Medicare Claims Processing Manual to process providers’ submitted claims for payment under applicable fee schedules and coverage policies, and respond to provider and beneficiary inquiries about Medicare.⁸

These contractors, or MACs, are responsible for the receipt, processing and payment of Medicare fee-for-service claims, for both Part A (inpatient hospital) and Part B (outpatient hospital, physician and DME) claims processing, appeals and coverage pre-determination requests.⁹

Pre-determination is the process by which CMS, through its MACs, determines coverage of routine and investigational services or products during an IDE. The pre-determination process for each IDE clinical study site begins with a submission by the sites’ Part A and Part B Medicare providers, making a request for approval from the MAC.

In some cases, a clinical trial sponsor’s submission of confidential or other study-wide materials is appropriate prior to an individual site’s submission. Such documents may include the study’s protocol and FDA correspondence, as well as relevant clinical articles in satisfaction of MAC requirements.

Unique Medicare Contractor Views on Conditional IDE Approvals

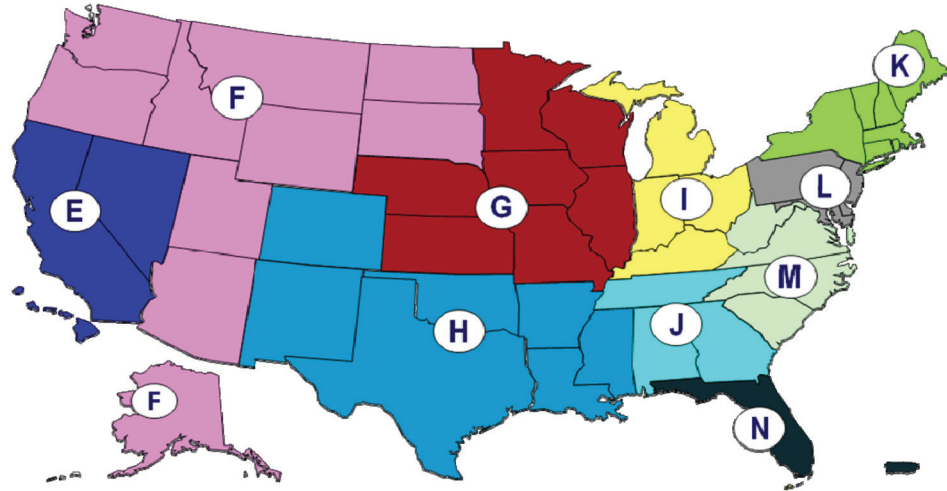
One specific barrier to entry for MAC pre-determination requests is FDA’s conditions to its approval of an IDE study. No matter how insignificant the conditions may seem in terms of ultimate study success, an early, negative decision by FDA deeply impacts how the Medicare coverage process for submitting clinical study sites will go.

This is because CMS has granted authority to the various MACs to consider granting pre-determination of coverage even when the sponsor has only been granted conditional

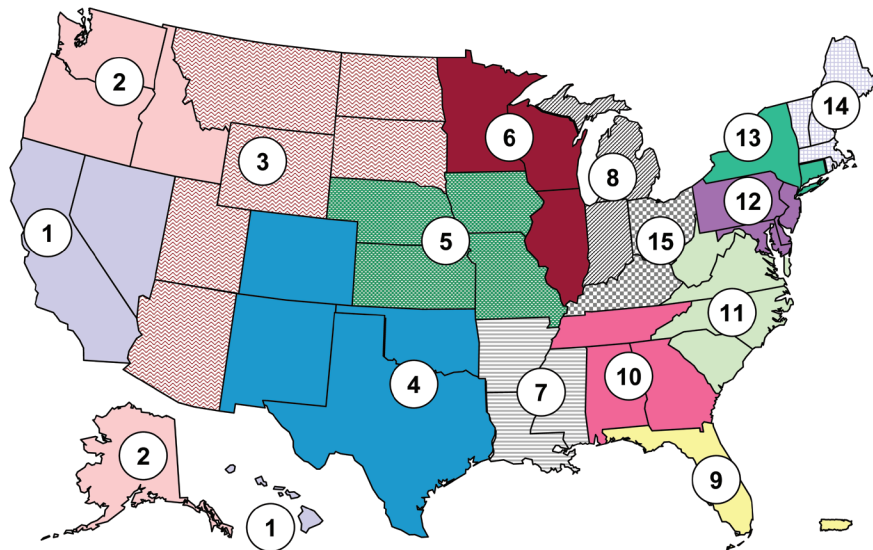
CMS Contracting Reform: A Moving Target

Tracing Medicare's Goals for Contracting Reform Explains the Confusion among Clinical Trial Sites Submitting IDE Requests

CMS' Current Ideal for Consolidated 15 A/B MAC Jurisdictions



CMS' Future Ideal for Consolidated 10 A/B MAC Jurisdictions



The maps tell only a small part of the bigger story here. Approximately half of all states in the U.S. and Puerto Rico are in a 'split jurisdiction' situation, meaning they may submit to more than one MAC, for one reason or another. This may occur because:

1. The Medicare contracting process is in contest for that jurisdiction (and so all claims route to the old, 'legacy' carrier or fiscal intermediary, for now);
2. Individual hospitals or other facilities belonging to larger health systems may need to ignore their geographic jurisdictional MAC, and instead deal with the health system's MAC, in another jurisdiction.

approval by FDA to proceed with the study. FDA's conditions may speak to the device's safety, or may deal with manufacturing, study design, statistical analysis or other more administrative features of the study.

Depending upon the nature of the conditions, MAC medical directors have the autonomy to grant full or conditional pre-determination of coverage to submitting study sites, independent of FDA's unconditional study approval.

INNOVATIVE FLEXIBLE RELEVANT VALUABLE



EVERYTHING BUT EASY

When we developed RAPS Online University, we wanted to make sure you'd get something out of it. Something to help you do your job better and get ahead as a regulatory professional in the healthcare products industry. Or simply sharpen up to prepare for the Regulatory Affairs Certification exam.

Which is to say, we made sure the courses are valuable and relevant.

And we wanted you to be able to take advantage of what RAPS Online University has to offer according to your own needs and schedule, and at your own pace.

So we made it flexible. Innovative. And accessible.

About the only thing we left out was "easy."

Because our goal from the beginning was to build the gold standard in ongoing education for regulatory professionals. Which we did. And continue to do.

We never said we wanted it to be easy.

Try a free demo of RAPS Online
University at RAPS.org/Udemo



RAPS ONLINE UNIVERSITY
Essential knowledge. Well earned.

RAPS.org/OnlineU

Assuming such issues with FDA approval of an IDE may be overcome for purposes of MAC pre-determination request submission, the requirements for submissions vary. Universally, submissions are required to include all applicable Medicare National Provider Identifier (NPI) numbers.

While all MACs require such common information about the study, as well as a copy of applicable site-specific regulatory documents, variations in additional requirements range from providing a laborious description of obtaining informed patient consent at the site to specific direction on financial disclosure language within those consent forms, and sometimes even a copy of the fully-executed clinical study agreement between sponsor and provider. These additional requirements may have a significant impact on study start-up goals for the sponsor and any given study site.

Medicare Contracting Reform is a Moving Target for Study Sites

A major challenge for sponsors of multi-center clinical trials is the differing interpretations Medicare contractors ascribe to their obligation to respond to clinical study providers' requests. When communicating with Medicare providers, including these pre-determination of coverage requests for IDEs, at a minimum MACs are

required to follow all applicable CMS manuals and transmittals on provider communications, all of which are unfortunately vague on the issue of responsiveness to providers' requests.

Yet some MACs interpret CMS Transmittal 100-09 as requiring contractors to respond to pre-determination inquiries or otherwise communicate with study sites' Part A and B providers within 45 business days.¹¹ However, since only certain of the MACs invoke Transmittal 100-09 in this context, and others do not, there is an apparent disparate impact for any IDE study spanning more than one jurisdiction.

In one IDE clinical trial, sites reported response rates ranging from five days with one MAC to more than 70 days with others before final pre-determinations were granted, causing confusion and frustration at the site level (and with the sponsor).

Additionally, Medicare Contracting Reform may appear to be somewhat of a moving target because any number of clinical investigators participating in the study may belong to health systems whose claims are administered by a MAC outside the regional territory.

For instance, an Oregon hospital that is part of a health system based out of Ohio would map to the MAC for the state of Ohio. This confusion is compounded by the fact that various MACs have differing requirements for submission of coverage requests, as well as different stated timelines for review.

Conclusion

There is widespread confusion and disparate impact created by Medicare's Contracting Reform efforts with private contractors across the US. Regulatory professionals who seek opportunities to manage the constantly changing Medicare coverage processes and who successfully navigate the nuances of Medicare Contracting Reform may reap substantial benefits.

As reimbursement of clinical services performed by investigators and other care providers represents a financial obstacle for many sponsors, it is important for savvy regulatory professionals to assist in the coverage process.

Although coverage is readily available by Medicare for the cost of care provided during a clinical study, regulatory professionals must work in concert with their clinical and reimbursement counterparts to successfully navigate the Medicare maze so study sponsors can offset the costs of clinical research.

References

1. The White House. President Clinton takes new action to encourage participation in clinical trials. <http://clinton3.nara.gov/WH/New/html/20000607.html>. Accessed 19 October 2011.
2. US Department of Health & Human Services. Medicare Coverage—Clinical Trials. www.cms.gov/ClinicalTrialPolicies/Downloads/finalnationalcoverage.pdf. Accessed 19 October 2011.

Stressed about an upcoming FDA AdComm?



We can help.



The Communication Strategy Company.

WWW.ECGLINK.COM

+1-201-894-8200

TEAM @ ECGLINK.COM

FDA/CMS 'Category B' Designations

Any One of the Following Six 'Category B' Designations by FDA Will Allow Medicare's Coverage, Once Pre-Determinations are Obtained

B(1) Devices, regardless of the classification, under investigation to establish substantial equivalence to a predicate device, i.e., to establish substantial equivalence to a previously/currently legally marketed device

- Category B(1) devices are typically those Class II devices seeking marketing clearance with FDA via the 510(k) pathway, and are undergoing a clinical trial in support of that application.

B(2) Class III devices whose technological characteristics and indications for use are comparable to a PMA-approved device

- A Category B(2) designation is typically granted to devices which seek PMA approval to enter the market after another, similar product has already been granted a PMA approval from the FDA. Examples would include joint replacement devices that perform similar to devices already PMA-approved.

B(3) Class III devices with technological advances compared to a PMA approved device, i.e., a device with technological changes that represent advances to a device that has already received pre-market approval (generational changes)

- Category B(3)-designated devices are those which represent the evolution of an already PMA-approved device. An example would be a material design change to the device, which would require additional clinical study to support its use in similar patient populations, for the same indications.

B(4) Class III devices that are comparable to a PMA-approved device but are under investigation for a new indication for use. For purposes of studying the new indication, no significant modifications to the device were required

- Sponsors of clinical trials whose target technology has received a Category B(4) designation are seeking a new or updated indication for use for the device.

B(5) Pre-amendments Class III devices that become the subject of an IDE after FDA requires premarket approval, i.e., no PMA was submitted or the PMA was denied

- The 1976 Medical Device Amendments to the Food, Drug and Cosmetic Act provide regulations for medical devices, including their classification and reclassification (Class II to Class III).

B(6) Non-significant risk device investigations for which FDA required the submission of an IDE

3. US Department of Health & Human Services. Medicare National Coverage Determinations Manual Chapter 1, Part 4 § 310.1. www.cms.gov/manuals/downloads/ncd103c1_Part4.pdf. Accessed 19 October 2011.
4. In some cases, Category A devices may also be covered by Medicare, but this would be determined following individual review by MACs' pre-determination processes. US Department of Health & Human Services. Medicare Claims Processing Manual, Chapter 32, § 68 *et seq*, "Investigational Device Exemption (IDE). www.cms.hhs.gov/manuals/downloads/clm104c32.pdf. Accessed 19 October 2011.
5. Per this agreement, the process of CMS' pre-determination and coverage will assure Medicare beneficiaries greater access to advances in proven medical technology; encourage clinical researchers to conduct high quality studies; and clarify Medicare coverage of reasonable and necessary medical services during clinical trials for investigational devices. FDA. Implementation of the FDA/HCFA Interagency Agreement Regarding Reimbursement Categorization of Investigational Devices, September 15, 1995 (D95-2). www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080302.htm. Accessed 19 October 2011.
6. Op cit 4.
7. US Department of Health & Human Services. Medicare Benefit Policy Manual. Chapter 14.
8. There are 15 regional MAC jurisdictions across the United States and its territories, and 11 private contractors which serve them: Cahaba Government Benefit Administrators (GBA); Cigna Government Services; First Coast Service Options; Highmark Medicare Services; National Government Services; National Heritage Insurance Corporation; Noridian Administrative Services; Palmetto Government Benefits Administrators (GBA); Pinnacle Business Solutions; TrailBlazer Health Enterprises; and Wisconsin Physicians Service.
9. California Health Advocates. 23 New Medicare Administrative Contractors Replace Medicare's Current Contracts. www.cahealthadvocates.org/news/basics/2008/23new.html. Accessed 19 October 2011.
10. US Department of Health & Human Services. CMS Manual System—CMS Transmittals 25 and 26. www.cms.hhs.gov/Transmittals/downloads/R25COM.pdf. www.cms.hhs.gov/manuals/downloads/com109c06.pdf. Accessed 19 October 2011.

You may also be interested in the following resources:



Good Clinical Practice (GCP) (RAPS Online University Course)



Understanding and Managing the Clinical Trial Process (RAPS Online University Course)



Good Clinical Practice: A Q&A Reference Guide May 2011

Visit RAPS.org/store