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Research Billing Buzz

A Newsletter from the Office of Clinical Research Billing Compliance

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Investigational Devices

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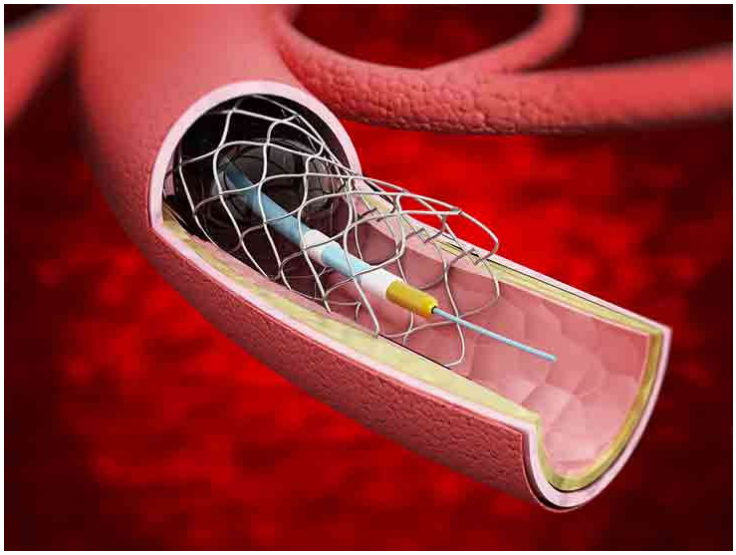

Investigational Devices

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Healthcare providers use many different devices in the course of a day, from a tongue depressor to a stethoscope and from an x-ray machine to a ventilator. However, in this edition of the *Research Billing Buzz* we will review Investigational Device Exemptions (IDE), how to obtain Medicare's approval to bill for these procedures and what can you do to help.

The Basics

A device is defined by the Food and Drug Administration (FDA) as:
"an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, 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 any of its primary intended purposes."

If a product is labeled, promoted or used in a manner that meets the definition in section 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act it will be regulated by the FDA as a medical device and is subject to premarketing and postmarketing regulatory controls.

Based on the FDA definition, the Center for Medicare and Medicaid Services (CMS) has strict rules on how seek approval to bill for participants receiving a research device.

First Things First – Approval

Sponsors with Food and Drug Administration (FDA) approval letters dated January 1, 2015 or later that are seeking Medicare coverage for Category A or B IDE studies must submit a request packet to CMS. This includes a letter that describes the scope and nature of the IDE study. CMS created a checklist and 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.

However, **if the study is initiated by the Principal Investigator** (there is no material sponsor and/or the PI holds the FDA IDE) it becomes his/her

responsibility to submit the information to CMS and obtain approval. Hopkins cannot bill Medicare for participants that receive an IDE device without this approval. Please note that we need this approval regardless of who pays for the device, even if the device is provided free of charge.

To check if the IDE has approval you can search the CMS Approved Database. To read about more types of devices check out our Acronyms and Abbreviations Document

Billing for Investigational Devices

To bill for IDE studies CRBC also needs to obtain approval from *Novitas*, our local Medicare representative. One of your Analysts will email you to obtain contact information with the sponsor of the study, a copy of the FDA letter (if it is not uploaded in eIRB), and a copy of the CMS approval letter.

CRBC will bill Medicare with all required information, including the research participant diagnosis code (Z00.6), the device number and the National Clinical Trial (NCT) number.

What Can You Do?

If you are considering a study that meets the FDAs definition described above, confirm that the sponsor has CMS approval and ask for a copy of both the FDA and CMS letter, as CRBC needs them to receive approval from our local carrier (Novitas). It is also helpful if you upload both letters to eIRB, the CRBC Analyst always check there before contacting you

If you invented the device (or hold the FDA IDE), then it is your responsibility to request approval from the FDA and CMS. We need this documentation to be able to bill to Medicare.

Need Help?

If you need help, have questions or want to suggest topics for future newsletters you can email us at:

CLINIRESBILLING@exchange.johnshopkins.edu

For more information, visit the **Research Revenue Cycle Website**

Research Rev Cycle Website

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