FDA Guidance on Categorization of IDE Devices & FDA Industry Webinar January 16, 2018

01-07-18 • alert • katherine leibowitz

The U.S. Food and Drug Administration (FDA) issued final guidance entitled, FDA Categorization of Investigational Device Exemption (IDE) Devices to Assist the Centers for Medicare and Medicaid Services (CMS) with Coverage Decisions on December 4, 2017 The guidance modifies FDA's policy on categorizing investigational device exemption (IDE) devices, which assists CMS in determining whether or not an IDE device should be covered (reimbursed) by CMS.

This post outlines how Medicare covers IDE studies of Category A vs. Category B devices, and highlights how a sponsor may be able to change the device from Category A (no Medicare reimbursement for the device) to Category B (Medicare coverage of the device) during the lifecycle of a clinical trial.

Obtaining reimbursement coverage for a marketed medical device is challenging, and the earlier a manufacturer starts obtaining coverage, the sooner its device begins building up a reimbursement track record. If your company has ongoing IDE studies of Category A devices, the guidance and FDA webinar mentioned below will provide valuable information about categorization and potential pathways for changing those devices to Category B devices, which makes the devices themselves eligible for Medicare coverage (if other CMS requirements are met).

Background:

The guidance implements the December 2, 2015 memorandum of understanding between CMS and FDA by further explaining the framework that FDA intends to follow for categorizing IDE study devices as Category A or Category B. CMS uses FDA's categorization as a factor in evaluating whether or not an IDE device receives Medicare coverage.

Category A vs. Category B Devices:

FDA designates each IDE study device as Category A or Category B in the IDE (original or supplemental) approval letter to the sponsor.

Category A devices are experimental. Initial questions of safety and effectiveness have not been resolved. If certain criteria are met, Medicare may cover only routine care items and services furnished in an FDA-approved Category A IDE study. Medicare will not cover the investigational device.

Category B devices are nonexperimental/investigational. Initial questions of safety and effectiveness have been resolved. If certain criteria are met, Medicare may cover both the investigational device and routine care items and services furnished in an FDA-approved Category B IDE study.

Changing a Device from Category A to Category B:

In the guidance, FDA differentiates between three types of studies: early feasibility studies, traditional feasibility studies and pivotal studies. FDA clarifies that a device can change categories during the series of studies and explains how this process occurs. The guidance explains that there are situations when sufficient data are provided to resolve initial

questions of safety and effectiveness (e.g. data from a feasibility study becomes available), and, accordingly, a change of device category from Category A to Category B for subsequent studies of the same device may be merited.

The guidance lists the following as examples of data that may support a category change:

- Peer-reviewed studies on the same or a similar device.
- Premarket or postmarket data from studies conducted outside the U.S. on the same or a similar device.
- Reference to commercialization of a device of a similar type.
- Preliminary clinical data on the device (e.g., initial data from a staged study or feasibility study).
- Additional non-clinical data on the same or a similar device may be included as supporting information.

FDA Webinar for Industry:

On January 16, 2018, the FDA will host a webinar for industry to discuss and answer questions about this final guidance. Access the webinar. Registration is not required.

Access the FDA Guidance.

If you have any questions or would like more information about these developing issues, please contact the following:

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