Welcome to today's FDA/CDRH Webinar

Thank you for your patience while we register all of today's participants.

If you have not connected to the audio portion of the webinar, please do so now:

U.S Callers: 877-917-9491

International Callers: 1-212-287-1619

Passcode: PW1052941

New FDA Draft Guidance

"FDA Categorization of Investigational Device Exemption (IDE) Devices to Assist the Centers for Medicare and Medicaid Services (CMS) with Coverage Decisions"

Carla M. Wiese
Policy Analyst for the Early Feasibility Program
Office of Device Evaluation
Center for Devices and Radiological Health

Agenda

- Why IDEs are conducted and why they are categorized
- Why there is new guidance related to CMS categorization
- What the changes are between the old policy and the new policy
- Considerations when changing from Category A to B
- How a category designation may affect coverage in a study
- Other factors that may impact coverage

Why Are IDE Studies Conducted?

An investigational device exemption (IDE) allows an investigational device to be used in a clinical study in order to collect safety and effectiveness data.

- FDA approval of an IDE submission indicates FDA has determined:
  - The sponsor has provided adequate data to support initiation of the study.
  - There are no subject protection concerns to preclude initiation of the study after IRB approval.
  - Benefit-risk profile for the study is favorable.

Reference: 21 CFR 812

Why Are IDE studies Conducted? Continued…

Generally, an IDE study is conducted to answer outstanding questions about safety and effectiveness.

However, the extent to which initial questions of safety and effectiveness are already addressed depends on many factors.

Why IDEs Are Categorized

- **An Interagency Agreement (IA) between CMS and the FDA was made in 1995 to support CMS' decision making for coverage. As part of this agreement, FDA assigns a device with an FDA approved IDE to one of two categories:**
  - Experimental/Investigational (Category A)
  - Non-experimental/Investigational (Category B)

- **This agreement allowed for expanded coverage to include some investigational devices.**

Why IDEs Are Categorized

- The category designation was to be based on the extent to which "initial questions of safety and effectiveness" have been answered.
- Specific criteria were defined in the 1995 IA for how FDA would determine the appropriate category.
- The categorization has been used by CMS as part of its determination of whether or not items and services meet the requirements for Medicare coverage.

Why There is New Guidance Related to CMS Categorization

1) The previous FDA policy regarding categorization did not adequately articulate criteria that are relevant to certain studies such as feasibility studies.
2) The previous policy did not contain sufficient guidance regarding how a category designation may change from A to B.
3) The previous criteria did not consider all regulatory pathways. (e.g. de novo submission)

Additional Factors

CMS changed from local Medicare Administrative Contractor review and approval of IDE studies to a centralized review and approval of IDE studies effective January 1, 2015.

Interactions between FDA and CMS since that time have highlighted a need for changes to categorization in order to improve consistency.

	1995 Interagency Agreement	Draft Guidance
Changes	Detailed criteria were used to designate an IDE device category.	Criteria have been simplified to ensure that devices fall into the correct category.
Changes	Limited or no visibility to how a category change may occur as knowledge is gained.	Draft guidance provides an explanation of how a category change may occur.
Changes	No examples provided.	Examples provided.
The same	FDA review team makes the category designation.	Unchanged
The same	Category designation is to be based on the degree to which initial questions of safety and effectiveness are resolved.	Unchanged
The same	The categorization will then be used by CMS as part of its determination of whether or not items and services will be covered.	Unchanged

Draft Guidance

Draft guidance is proposed documentation not yet ready for implementation.

Issuance Date: June 1, 2016

Comment period closes: August 1, 2016

www.regulations.gov
docket # FDA-2016-D-1159

Regulatory Context: Category A

Category A: Experimental

42 CFR 405.201(b):

"…a device for which 'absolute risk' of the device types has not been established (that is, initial questions of safety and effectiveness have not been resolved) and the FDA is unsure whether the device type can be safe and effective."

Proposed Criteria: Category A

FDA intends to consider a device to be in Category A if one or more of the following criteria are met:

1. **No PMA approval, 510(k) clearance or de novo request has been granted for the proposed device or similar devices, and non-clinical and/or clinical data on the proposed device do not resolve initial questions of safety and effectiveness.**

Proposed Criteria: Category A

2. The proposed device has different 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 non-clinical and/or clinical data on the proposed device also do not resolve these questions.

Proposed Criteria: Category A

3. The proposed device is being studied for a new indication or new intended use for which information from the proposed or similar device related to the previous indication does not resolve initial questions of safety and effectiveness. Available non-clinical and/or clinical data on the proposed device relative to the new indication or intended use also do not resolve these questions.

Category A Example

A device is completely novel and has no, or limited, previous human use and there are initial questions of safety and effectiveness. There is adequate non-clinical information to support initiation of an early feasibility study that will provide data to inform potential device design or procedural improvements.

Category A Example

An already approved or cleared device is being evaluated for a new intended use or indication wherein the device will be placed in a different anatomical location.

The device's technology is unchanged from what was initially approved; however, it is uncertain as to whether the device can be safely placed in the new anatomical location and whether the device can also be effective in the new anatomical location. Therefore, there are inadequate data to resolve the initial questions of safety and effectiveness relative to the new intended use or indication.

Regulatory Context: Category B

Category B: Nonexperimental/Investigational

42 CFR 405.201(b)

"…a device for which the incremental risk is the primary risk in question (that is, initial questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA premarket approval or clearance for that device type."

Proposed Criteria: Category B

FDA intends to consider a device to be in Category B if one or more of the following criteria are met:

1. **No PMA approval, 510(k) clearance or de novo request has been granted for the proposed device or similar devices; however, available clinical data (e.g., feasibility study data) and/or non-clinical data for the proposed device or a similar device resolve the initial questions of safety and effectiveness.**

Proposed Criteria: Category B

2. The proposed device has similar 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. Additional non-clinical and/or clinical data on the proposed device may have been used in conjunction with the leveraged information to resolve these questions.

Proposed Criteria: Category B

3. The proposed device is being studied for a new indication or new intended use; however, information from the proposed or similar device related to the previous indication resolves the initial questions of safety and effectiveness. Additional non-clinical and/or clinical data on the proposed device may have been used in conjunction with the leveraged information to resolve these questions.

Category B Example

Adequate data have been gathered from non-clinical testing and the clinical results of a feasibility study such that initial questions of safety and effectiveness have been resolved. A pivotal study will be initiated to provide the primary clinical evidence for the safety and effectiveness of the device in support of a future marketing application.

Category B Example

An approved device will be evaluated for a new indication.

Data exist on the approved device for another similar indication, and non-clinical data have also been supplied such that the initial questions of safety and effectiveness related to the new indication have been resolved. The new study to be conducted will provide further data regarding device performance for this new indication.

When Are IDEs Categorized?

The FDA review team will make a categorization decision at the time of the first approval (full or conditional) of an IDE study.

A categorization change will be considered for study expansion or upon a request for re-designation.

The category is included in FDA's approval letter for the IDE.

Information That May Support a Category Change

- Nonclinical test data
- External data on the technology (e.g. data from other similar devices)
- Preliminary clinical data on the device

Example of a Change From Category A to B

Adequate data have been gathered on a device from non-clinical testing, the completion of an early feasibility study within the United States (US), as well as a small non-US clinical study such that initial questions of safety and effectiveness have been resolved. Additional data are needed to help inform a pivotal study design; therefore, a traditional feasibility study will be initiated.

Although the early feasibility study was originally designated as Category A, adequate data as described above have since been gathered to support a change to Category B for the traditional feasibility study.

How a Categorization Designation May Affect Coverage in a Study

- If the study is designated Category A: the device may not be covered but routine care and services may be covered.
- If the study is designated Category B: then the device and routine care and services may be covered.

Other Factors That May Affect Coverage in a Study

- Has a previous national coverage decision been made for the device type and/or procedure?
  - A coverage decision may supersede the category designation.
- Will the device be adjunctive to a procedure in which a coverage decision has been made?
  - A coverage decision may supersede the category designation.
- Is the device relevant to the Medicare population?
- Have other CMS criteria been met (reference the CMS website link at the end of this presentation)?
- Others…

Links

Link to the FDA Draft Guidance

"FDA Categorization of Investigational Device Exemption (IDE) Devices to Assist the Centers for Medicare and Medicaid Services (CMS) with Coverage Decisions"

- http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm504091.pdf

Link to a CMS website

"Medicare Coverage Related to Investigational Device Exemption (IDE) Studies"

- https://www.cms.gov/medicare/coverage/IDE/index.html

Questions?

Contact CDRH's Division of Industry and Consumer Education (DICE) at dice@fda.hhs.gov, 1-800-638-2041, or 301-796-7100

Slide Presentation, Transcript and Webinar Recording will be available at:

http://www.fda.gov/training/cdrhlearn

Under "How to Study and Market Your Device" Heading