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The 21st Century Cures Act, Section 3051: Ensuring Patient Access to Breakthrough Medical Devices

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On December 13, 2016, Section 3051 of the 21st Century Cures Act added "Breakthrough Device" provisions to the Food, Drug and Cosmetic Act. This program is intended to help patients obtain more timely access to medical device technologies that provide more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases, for which no approved or cleared treatment exists, or that offer significant advantages over existing approved or cleared alternatives.

Draft Guidance

The FDA has moved quickly, releasing "Breakthrough Devices Program: Draft Guidance for Industry and Food and Drug Administration Staff" on October 25, 2017.[1] (The comment period closed December 24, 2017.) This guidance, when finalized, will supersede the Expedited Access Pathway (EAP) and Priority Review Programs.

The guidance relies heavily on Risk-Benefit Considerations and Post Market Data, with reference to the existing FDA Benefit-Risk Guidance,[2] and postmarket vigilance requirements as conditions of approval as a breakthrough device.

The Breakthrough Devices Program will replace FDA's Expedited Access Pathways (EAP) program by making future 510(k)s eligible, as well as Premarket Approval applications (PMA) and De Novo device submissions. Any device previously granted EAP designation will automatically receive designation as a Breakthrough Device.[3]

For devices not previously granted EAP designation, sponsors should request priority review from the FDA at any time before submitting a device application (PMA, 510[k] or De Novo), and the Agency must respond within 60 days.[4]

Under the Breakthrough Devices Program, the FDA will work with device sponsors to try to reduce the time and cost from development to marketing decision, without changing the FDA's PMA approval standard of reasonable assurance of safety and effectiveness, the standards for granting De Novo requests, or any other standards of valid scientific evidence.

The guidance stresses interactive and timely communication, balancing pre- and post-market data collection, and embracing flexible and efficient clinical study design. Features include priority review, more interactive review with senior FDA management involvement, and assignment of a case manager. As usual, the extent to which the FDA can provide these features will depend on the availability of resources.

Participation in the Breakthrough Devices Program is only at the request of the sponsor and with the FDA's agreement. If the FDA determines that a device might be eligible for the Breakthrough Device Program and the sponsor has not yet requested a Pre-Submission (Pre-Sub) seeking Breakthrough Device designation, the FDA intends to inform the sponsor of the new program.[3]

Sponsors seeking designation for a Breakthrough Device should also be aware that a section of the legislation, not covered in this article, is relevant to Medicare reimbursement for such products.[5]

Devices Eligible for Breakthrough Device Designation

Devices subject to premarket approval applications (PMAs), premarket notification (510[k]), or requests for De Novo designation are eligible for Breakthrough Device designation if the following criteria are met:

1. The device provides a more effective treatment or diagnosis of a life-threatening or irreversibly debilitating human disease or condition.

AND

2. The device meets at least one of the following criteria:
    a. Represents breakthrough technologies;
    b. No approved or cleared alternatives exist;
    c. Offers clinically meaningful advantages over existing approved or cleared alternatives, including the potential, when compared to existing approved alternatives, to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients' ability to manage their own care (such as through self-directed personal assistance), or establish long-term clinical efficiencies; or
    d. The availability of which is in the best interest of patients.[1]

The FDA strongly recommends that sponsors interested in the Breakthrough Devices Program contact the Agency early in the development of their device. In most cases, a sponsor should request Breakthrough Device designation prior to beginning an Investigational Device Exemption (IDE) pivotal study, so the FDA and the sponsor can make sure the data being collected in the pivotal study will meet the needs of the device's marketing submission.[3]

A request for Breakthrough Device designation should be a standalone submission (i.e., no other requests should be included with the request for Breakthrough Device designation), submitted via the eCopy program as a Pre-Sub to the appropriate center's Document Control Center. There are no user fees for participation in the program.[3]

Acknowledgement

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References

1. FDA Guidance Breakthrough Devices https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm581664.pdf
2. FDA Benefit-Risk Guidance https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM404773.pdf
3. FDA Expedited Access pathway Program: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/ucm441467.htm
4. Cures Act Encourages Breakthrough Devices, Exempts Medical Software: http://www.fdanews.com/articles/180015-cures-act-encourages-breakthrough-devices-exempts-medical-software
5. 21st Century Cures Section 2998, To amend title XVIII of the Social Security Act to ensure prompt coverage of breakthrough devices under the Medicare program, and for other purposes. https://www.congress.gov/bill/114th-congress/senate-bill/2998/text?q=%7B%22search%22%3A%5B%22breakthrough%22%5D%7D&r=1

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