

Investigational Device Exemption

The Investigational Device Exemption (IDE) guidelines established by CMS on November 1, 1995, provide coverage for the use of some Category A and approved Category B devices with a Food and Drug Administration (FDA)-approved IDE. IDE coverage is contingent on approval by TrailBlazerSM of the IDE application for reimbursement.

Medicare may provide reimbursement for some investigational devices and related services. Related services may be furnished in preparation for device use, contemporaneously with and necessary to the use of the device, and as follow-up care after device use. Coverage is contingent on TrailBlazer's approval of the application for reimbursement.

Medicare covers the use of devices that are "reasonable and necessary for the diagnosis and treatment of an injury or illness or to improve the functioning of a malformed body member" (Social Security Act, Section 1862.9(A)(1)(A)). By law, CMS may only pay for medical services considered reasonable and necessary. Consequently, Medicare denies coverage of experimental devices due to the absence of medical necessity, which cannot be established when the safety and effectiveness of a device are unknown. A device the FDA has categorized as investigational, including devices being studied under IDEs, is presumed to be experimental. Historically, this interpretation meant that a medical device required either clearance or FDA pre-marketing approval, based on evidence establishing the device's safety and effectiveness, to qualify for payment.

Prior to submitting claims for Category B IDE devices and/or for services associated with Category A or B IDE investigations, providers must submit all required information for Medicare contractor review and approval.

Applying for Coverage

To apply for coverage of a Category B device and/or associated routine services or for routine services associated with Category A IDE investigations:

- Submit the information outlined on the Pre-Approval Submission Checklist. Applications will not be considered for review until all required information has been received.
- Mail submissions to the Medical Directors.
- Provider notification will occur, in writing, upon approval/disapproval. If an application is approved, the claim payment systems will be set to accept the provider's claims.

Coverage Criteria

Coverage criteria for IDEs include:

- **The device must pose no significant risk to patients and must be potentially effective** (i.e., produce or contribute to a therapeutic advantage).

Implementation of this criterion required the FDA to refine its classification system to reflect differences in presumed safety. As a result, devices studied in clinical trials under IDEs fall into two categories: A and B. The new classification system distinguishes between “investigational” devices that may be considered for Medicare payment and devices that are truly “experimental” or breakthrough technologies that may not be considered for Medicare payment under the IDE coverage policy.

Category A devices are novel, first-of-a-kind technologies. These are innovative devices for which initial questions of safety and effectiveness have not been resolved, and the absolute risk of the device type has not been established. The FDA has insufficient evidence to determine whether these device types can be safe and effective. Category A devices remain non-covered, though coverage for routine services associated with approved Category A IDE investigations became effective January 1, 2005, when the approved device is used for the diagnosis, monitoring or treatment of an immediately life-threatening disease or condition.

Note: *The Medicare Prescription Drug, Improvement and Modernization Act (MMA) of 2003, Section 731(b) allows some coverage, in accordance with the Clinical Trials Policy (Internet-Only Manual (IOM) Pub. 100-03, Section 310.1) – not IDE coverage – of the routine patient care costs associated with specific studies that involve specific Category A devices (IOM Pub. 100-03, Chapter 1, Section 20.7; IOM Pub. 100-04, Chapter 32, Sections 69.0–69.11).*

Category B devices are newer generation devices of already proven technologies. Initial questions of safety and effectiveness of these devices have been resolved. Devices in this category represent evolutionary changes in proven technologies and will be viewed as potentially reasonable and necessary by Medicare. These devices may be eligible for coverage and payment under the IDE coverage legislation.

Note: *This legislation does not guarantee that all Category B devices undergoing clinical trials will be covered under Medicare. The contractor makes the final coverage decision based on the submission of the required documentation.*

- **The device must be used in the context of an FDA- and Institutional Review Board-approved study.** The approved study protocol limits the use of the device to a predetermined limited number of sites and predetermined limited number of patients.
- **The device must have an assigned IDE number.** This identification number allows the Medicare contractor to establish special claims processing procedures associated with the study.
- **The device must meet all Medicare coverage requirements.** This policy change does not mean that all Category B devices undergoing clinical trials will be covered under Medicare.