

Reimbursement Policy

Will insurance cover my treatment with an investigational device?

In the past Medicare coverage was denied for devices which were under an IDE and had not yet received premarket notification clearance and/or premarket approval because the treatments were considered experimental. However, there are devices which are refinements of existing technologies or replications of existing technologies made by other manufacturers. Many of these devices are under an FDA-approved IDE as a means of gathering the scientific information needed for FDA to establish the safety and effectiveness of that particular device, even though there is evidence that the device type can be safe and effective.

On September 8, 1995, FDA entered into an agreement with the administrator of the Medicare program, the Health Care Finance Administration (HCFA), to provide information about devices under an IDE to aid in its reimbursement decisions. [Please note that HCFA is now known as the Centers for Medicare & Medicaid Services (CMS).] Under this agreement certain devices could be viewed as "reasonable and necessary" by Medicare and treatments could be covered if all other applicable Medicare coverage requirements are met. Specifically, FDA will place all IDEs it approves in one of two categories:

Category A - Experimental

The IDE involves innovative devices in which "absolute risk" has not been established (i.e., initial questions of safety and effectiveness have not been resolved and thus FDA is unsure whether the device type can be safe and effective)

Category B - Investigational; Non-experimental

The clinical investigations involves device types believed to be in classes I or II or device types believed to be in class III where the incremental risk is the primary risk in question (i.e., underlying questions of safety and effectiveness of that device type have been resolved). This category includes device types that can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type. Nonsignificant risk studies may also be included in this category.

FDA provides the category determination on the IDE approval letter to the sponsor and also forwards this information to HCFA.

It is hoped that this agreement will provide Medicare beneficiaries with greater access to advances in medical technology and encourage clinical researchers to conduct high quality studies of newer technologies.

Please note that this agreement covers Medicare coverage only. FDA has no authority over commercial health insurance carriers. Many commercial health insurance carriers do not cover any investigational devices. It is advised that you check with your insurance company before you receive treatment with an investigational device.

For additional guidance, see "Implementation of the FDA/HCFA Interagency Agreement Regarding Reimbursement Categorization of Investigational Devices 9/15/95 (D95-2)" <http://www.fda.gov/cdrh/d952.html>

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