

# Qualifying Clinical Trials

## **Investigational Devices and the National Coverage Decision (NCD)**

A manufacturer or sponsor-investigator must generally [obtain an Investigational Device Exemption \(IDE\)](#) from the FDA before the device can be properly used in a clinical trial.

### **Category A Devices**

These devices are experimental investigational devices for which the initial questions of safety and effectiveness have not been established. The device itself is not covered by Medicare, as they are not deemed “reasonable and necessary.” However, routine costs are covered if the device is furnished in conjunction with an FDA-approved clinical trial in the diagnosis, monitoring, or treatment of an immediately life-threatening disease or condition.

### **Category B Devices**

These devices are non-experimental investigational devices for which the initial questions of safety and effectiveness have been resolved, or it is known that the device type can be safe and effective. The devices themselves may be covered if they are considered “reasonable and necessary” and if all other applicable Medicare coverage requirements are met.