

42 C.F.R. § 405.212

Medicare Coverage IDE study criteria.

(a) For Medicare coverage of items and services described in § 405.211, a Category A (Experimental) or Category B (Nonexperimental/investigational) IDE study must meet all of the following criteria:

- (1) The principal purpose of the study is to test whether the device improves health outcomes of appropriately selected patients.
- (2) The rationale for the study is well supported by available scientific and medical information, or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.

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