

42 C.F.R. § 405.211

Coverage of items and services in FDA-approved IDE studies.

(a) *Coverage of routine care items and services for Category A (Experimental) devices.* Medicare covers routine care items and services furnished in an FDA-approved Category A (Experimental) IDE study if CMS (or its designated entity) determines that the Medicare coverage IDE study criteria in § 405.212 are met.

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