Drug/Device Coverage Requirements

Device study Coverage Requirements

Investigators participating in an Investigational Device Exemption (IDE) Study that plans to request reimbursement for study procedures and materials from Medicare or third-party payers must ensure the following:

1. CMS IDE study coverage has been approved by CMS or local Medicare contractor
    - CMS approval of coverage for Category A devices applies to the routine care items and services required by the study, but not the experimental device
    - CMS approval of coverage for Category B devices allows for coverage of the routine care items and services required by the study as well as the investigational device.
2. Other devices that may be covered by Medicare include
    1. Premarket Approval (PMA)
    2. Humanitarian Device Exemption (HDE)
    3. 510(k) approved devices
    4. IRB-approved Non-Significant Risk (NSR) devices
3. UCLA Value Analysis Committee (VAC) approval has been granted – If the study requires UCLA to purchase or use a new or replacement technology/device, then a VAC Request Form must be submitted for review

Drugs Study Coverage Requirements

Medicare will cover the cost of QCTs that are conducted under an Investigation New Drug (IND) reviewed by the FDA. IND exempt studies are deemed automatically qualified for coverage until further qualifying criteria are available. Once the qualifying criteria are available, the Principal Investigators of the study must certify that the study meets all qualifying criteria for Medicare coverage of routine costs. The new qualification will apply to the prospective study charges generated.

Please see Related Guidance for more information.

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