Clinical Research Billing Compliance Frequently Asked Questions

Guidance for device studies / Equipment Used in Clinical Studies / Special billing rules for Managed Care plan

1. What are the steps for setting up a Humanitarian Use Device (“HUD”) protocol?

Critical steps to follow when setting up a HUD/HDE protocol:

1. Obtain HDE (Humanitarian Device Exemption) approval from the FDA to use the HUD in the desired population.
2. Obtain IRB approval for use of the HUD under the FDA-approved HDE protocol
3. Provide HDE documentation to RRI
4. Document required HDE and FDA approval criteria in the study subject’s medical record to support claim submissions.

Resources:

For FDA, HDE guidance:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/HumanitarianDeviceExemption/default.htm

2. Does Medicare apply coverage determinations for non-significant risk (“NSR”) device studies?

Yes. The Medicare Administrative Contractors (“MAC”) (Noridian for University California, Irvine Health) are responsible for making coverage determinations on non-significant risk devices and are expected to apply the same coverage criteria, where appropriate, to the NSR devices as are applied to FDA-approved Category A and B IDE Devices.

3. **How does the Investigator ensure there is appropriate approval from CMS to bill 3rd party payors for the items/services on the device study protocol?**

   For Investigator-initiated IDE and non-significant risk device studies, the Investigator will need to work with Research Revenue Integrity (RRI) to submit the device study information to the local MAC (Noridian) for approval to bill Medicare/3rd party payors. For industry-sponsored device studies initiated after January 1, 2015, the sponsor has the obligation to submit directly to CMS for approval to bill Medicare. The Investigator should initiate this communication early, as the approval or denial letter may be needed to complete contract negotiations and coverage analysis certification.

   For more information: Please contact Research Revenue Integrity (RRI) at 714-456-3922.

4. **What are the pitfalls to avoid when using equipment/device provided to UC Irvine Health at no cost for use in a clinical study?**

   1. Billing the patient/insurance for diagnostic or treatment services using the no-cost equipment/device – When study equipment or device is provided free of charge, there is no device charge or equipment fee to the Health System; therefore no reimbursement may be requested from a payor for the cost of using the involved device/equipment.
   2. Using the equipment/device for purposes outside the award/contract - If the equipment/device is provided at no cost for use in a clinical study, any use of the equipment/device outside the parameters of the study award or agreement is a violation of the award terms, or a breach of the contract, without obtaining an amendment or other form of agreement from the sponsor/manufacturer of the equipment or device.
   3. Keeping equipment/device for clinical use after completion of the study without proper terms of purchase, lease, etc. - The use of the no-cost equipment/device provided for a study under a study agreement is limited in scope and period to the conduct of the study, unless the contract expressly provides otherwise. If the equipment is to be kept and used for other purposes after completion of the study, appropriate arrangements and agreements need be in place.

5. **What are the requirements when billing approved Investigational Device Exemption (IDE) studies?**

   Noridian, the local MAC with jurisdiction over the Medicare Advantage (MA) plan's service area, determines coverage of IDE studies.

   Providers participating in and seeking Medicare reimbursement for items and services in Category A or B IDE studies, prior to submitting claims, are responsible for checking the CMS Coverage Website to identify whether CMS (or Noridian) has approved the study for purposes of Medicare coverage.

Routine Care Items and Services for Inpatient and Outpatient Billing in Category A IDE Studies

Medicare covers routine care items and services furnished in an FDA-approved Category A IDE study if CMS determines that the Medicare coverage IDE study criteria are met. Category A devices are statutorily not covered by Medicare. The Category A IDE device shall not be reported on institutional/practitioner claims.

Effective for claims with dates of service on or after January 1, 2014, it is mandatory to report a clinical trial number on claims for items/services provided in clinical trials and claims should include Z00.6, and the Q0 or Q1 Modifiers.

Routine Care Items and Services for Inpatient and Outpatient Billing in Category B IDE Studies

Medicare may make payment for a Category B IDE device and routine care items and services furnished in an FDA-approved Category B IDE study if CMS determines prior to the submission of the first related claim that the Medicare coverage IDE study criteria are met. The MAO (Medicare Advantage Organizations) is responsible for payment of routine care items and services in CMS-approved Category B IDE studies, as well as the Category B device under study in Category B IDE studies.

Institutional providers must bill the Category B IDE number on a 0624 revenue code line with charges in the covered charges field. If the Category B IDE device is provided free-of-charge, outpatient prospective payment system providers must report a token charge and should not be billed by hospital inpatient providers.

On a 0624 revenue code line, institutional provider must include all of the following:

- Category B IDE device HCPCS code
- Q0 or Q1 as appropriate for claims with dates of service on or after 1/1/14
- Category B IDE number
- Charges for the device billed as covered charges

For additional guidance, see Pub. 100-02 Medicare Benefit Policy Manual, Chapter 14 for complete Medicare coverage requirements for items and services in Category A and B IDE studies.

6. How are services of approved device studies billed for Managed Care enrollees?

As of January 1, 2015, Medicare Advantage (MA) organizations are responsible for payment of claims (routine care items and services in CMS-approved Category A & B IDE studies) related to enrollees' participation in both Category A and B IDE studies that are covered by the MAC (Medicare Administrative Contractors) with jurisdiction over the MA plan's service area. The MAO (Medicare Advantage Organizations) is also responsible for CMS-approved Category B devices. CMS will not approve Category A devices because they are statutorily excluded from coverage.

For additional guidance, see Medicare Claims Processing Manual Chapter 4 - Section 10.7.2 (Rev. 121, Issued: 04-22-16).

7. Can an investigator enroll a subject prior to MAC (Noridian) approval for the device study?

No. Approval is needed prior to enrolling a subject in the device study.

For more information: Please contact Research Revenue Integrity (RRI) at 714-456-3922.