UW MEDICINE IDE/HDE DEVICE COVERAGE AND BILLING

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DEFINITIONS

Investigational Device Exemption (IDE)- An approved IDE means that an IRB (and FDA for significant risk devices) has approved the sponsor's study application and all the requirements under 21 CFR 812 are met. The FDA assigns a special identifier number that corresponds to each device granted an IDE. For purposes of assisting CMS in determining Medicare coverage, the FDA places all approved IDEs in one of two categories – Category A or Category B.

Humanitarian Use Device (HUD) -As defined in 21 CFR 814.3(n), a HUD is an **FDA approved** "medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year." The FDA approves an HDE (Humanitarian Device Exemption) to allow the manufacturer to market the device. The HDE indicates that the device is legally approved for specific indications.

NORIDIAN ADMINISTRATIVE SERVICES LLC

Medicare fiscal intermediaries (FIs) are private insurance companies that serve as the federal government's agents in the administration of the Medicare program, including the payment of claims. Our local FI is Noridian Administrative Services.

NoridianPart A
Part A claims processing covers services provided through hospitals and post-hospital care. **Facility Fees**.

NoridianPart B
Part B claims processing covers doctor visits, lab tests, and certain prescribed outpatient services. **Profees.**

MEDICARE COVERAGE
IDE vs. HUD

IDE:
Requires application to Noridian for approval to bill the IDE device (Category B only) and/or related study services regardless of if they are standard of care. If the FDA has assigned a device an IDE number Medicare requires it to have been reviewed and approved by Noridian (both profee and facility) . Approval applies only to use of the IDE device and related services in Medicare patients *enrolled in the study*, and is required prior to the service date.

HDE:
Requires application to Noridian for general approval of the device and related services at each institution. Approval only applies when the device is used according to the indications stated by the FDA.

COMPLIANCE RISKS OF IMPROPER BILLING

IDE/HDE:

If required processes are not followed and/or approvals are not obtained in advance of submitting a claim to Medicare, the risks to both hospital and physician claims include:

- No payment for services rendered
  - Payment denial
  - Denial may include up to the full hospital stay & profees
  - Improper payment with subsequent repayment
- Possible false claims risk

MEDICARE **IDE** DEVICE COVERAGE PROCESS

•Submit the applications (Part A and Part B) for IDE billing approval to Noridian. We cannot bill until we receive written approval.

•When the review is complete, Noridian sends a notification letter with the determination. If IDE billing is approved, the following services are eligible for Medicare payment for patients enrolled in the IDE device study:

-Routine services related to Category A device furnished in conjunction with an FDA approved clinical trial, **but not** the Category A device itself

-Routine services related to Category B device furnished in conjunction with an FDA approved clinical trial, **including** the Category B device itself

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MEDICARE **HDE** DEVICE COVERAGE PROCESS

- Submit the applications (Part A and Part B) for HDE billing approval to Noridian. We cannot bill until we receive written approval.
- When the review is complete, Noridian sends a notification letter with the determination. If HDE billing is approved, the device and all related services are eligible for Medicare payment if:
  - The device is used only according to the FDA indications
  - Claims must be stopped at PFS for special billing

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PART B APPLICATION

For both HDEs & IDEs a separate Part B application must be signed by every physician that will be billing for this procedure.

EMERGENT USE OF AN IDE

For subjects not meeting inclusion criteria into the study but who are in a life threatening situation where the device might help.

As soon as possible but no later than 5 days notify the IRB , Noridian, the study sponsor and the FDA.

Payment is not guaranteed but the sooner the request for coverage is received the better chance we will have of being paid for services

Please contact Compliance to hold the claim.

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CUSTOMIZATION OR OFF LABEL USE?

Raise your hand! Let Compliance know so we can assist with the coverage and billing risk assessment

UW MEDICINE EXAMPLES

IDE –Cardiac Surgery ***Partner study***

HDE -Neurosurgery ***Neuroform Stent***

Customized or Off Label use of an FDA approved device - Vascular ***PMEG study***

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COMPLIANCE

RESOURCE MATERIALS

More details on using devices at Compliance web site.

More details on IDE and study start up at CRBB web site.