

Aurora Health Care

Clinical Trials

Medicare Part A & B Contractor Prior Notification of Humanitarian Use Devices & HUD Claims

Date: 08/23/2003

Rev: 04/2004

PROCEDURE STATEMENT:

All Aurora Health Care employees have a responsibility to maintain a high level of integrity in the billing process, including prior claim submission notification to either Medicare contractor; the Part A Fiscal Intermediary or Part B Carrier for a Humanitarian Use Device (HUD).

PURPOSE OF PROCEDURE:

The purpose of this procedure is to outline the steps necessary prior to proceeding with a HUD and the associated Medicare billing. As part of its reimbursement consideration, Medicare requires that the provider initiate prior notification to both the Part A and Part B Fiscal Intermediary and Carrier respectively for HUDs. (An exception to this requirement exists for the emergency deployment of a HUD.) Without prior notification, the FI and/or Carrier may not process the claim. (Note: Neither the Fiscal Intermediary nor Carrier pre-authorizes payment for a HUD. This process simply provides Medicare with prior notification of a provider's use of a HUD and intention to submit a claim.)

ACCOUNTABILITY:

The clinical research coordinator (or other clinician as assigned) working with the physician who is requesting HUD approval has the primary communication initiation and notification responsibility as it relates to billing. (In the absence of a CRC, the physician retains primary responsibility for HUD usage notification to the billing staff.) The Special Projects Representative has responsibility for assuring that the HUD billing criteria are met prior to claim submission.

PROCESS:

The research coordinator (or other clinician as assigned) working with the physician who is requesting HUD approval will complete this process in concert with the physician, IRB, special projects representative in the central business office (CBO) and materials management coordinator in the clinical department where the HUD will be used.

DEFINITIONS:

- **Clinical Research Coordinator "Coordinator"** – Registered nurse (or health care professional) assigned to or assisting the Physician responsible for carrying out the deployment of the HUD and its related procedures.
- **CMS** - Centers for Medicare & Medicaid (formerly known as HCFA; Health Care Financing Administration)
- **Contractor** - The term CMS uses to identify its claim processors. The Part A contractor is also known as the Fiscal Intermediary, the Part B contractor is also known as the Carrier.
- **HUD** - Humanitarian Use Device. As defined in 21 CFR Part 814, a HUD is a device intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect or is manifested in fewer than 4,000 individuals in the United States per year.

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- **IRB Submission** - While a HUD is not clinical research; the FDA asks that the provider's Institutional Review Board (IRB) perform a full board review of the clinician's initial HUD submission. Subsequent uses may be approved through an expedited review or under the Aurora IRB policies and procedures for "emergency use.
- **Medical Director** - Each contractor appoints a medical director to work with providers. In this instance the Medical Director is the recipient of the provider's HUD prior notification letter.
- **Off-label "Emergency" HUD Use** - HUDs may be used off-label **ONLY** in an **EMERGENCY** situation for cases in which a physician determines that prior IRB review cannot be obtained in time to prevent serious harm or death to the patient. If use of a HUD in an off-label manner occurs in an emergency situation during the delivery of an otherwise medically necessary Medicare covered service, all associated services may be considered for coverage with the exception of the HUD itself. The HUD (when deployed off-label in an emergency circumstance) cannot be billed, but all other associated care and services are billable and may be considered for coverage.
- **Off-label "Planned" HUD Use** - Wisconsin's Fiscal Intermediary, UGS has determined that Medicare will NOT reimburse any provider who pre-plans to deploy a HUD in an off-label fashion. If use of a HUD in an off-label manner is a planned event, (i.e., the reason for admission is use of the HUD in an off-label fashion), the entire hospitalization and all associated services (except any complications arising from the HUD deployment whether that complication occurs during that stay or a subsequent admission) are **NOT** covered Medicare benefits. A bill to Medicare cannot be submitted (except for complications arising from the event, which are billable to Medicare.)
- **Part A Fiscal Intermediary** – The Centers for Medicare & Medicaid (CMS) contractor who receives and processes Part A (hospital) Medicare benefit claims for reimbursement.
- **Part B Carrier** - The Centers for Medicare & Medicaid (CMS) contractor who receives and processes Part B (physician) Medicare benefit claims for reimbursement.
- **Prior Claim Submission Notification** – If a provider intends to submit a Medicare claim to a CMS Contractor for a HUD, that provider is required to submit a letter of prior notification to that contractor. The Part A Fiscal Intermediary has instructed that this process is required for devices approved by FDA as HUDs. Where prior notification cannot occur because of time constraints associated with emergency patient treatment, the provider is nevertheless required to submit notification to the contractor after use of the HUD, but before claim submission.

PROCEDURES: These procedures are requirements necessary for Medicare reimbursement for a HUD.

1. Once the Physician determines that a labeled use of an approved HUD will be requested the Coordinator (or physician in the absence of a CRC) must initiate the following actions:
 - Submit a letter to the HUD manufacturer to obtain approval for HUD usage.
 - Receive HUD manufacturer response. If approved, continue ...

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- Develop and submit a HUD submission and Informed Consent template to the Aurora IRB for review. (Follow IRB policy HU1001; Humanitarian Use Device, IRB Review)
 - Receive IRB response. If approved, continue ...
2. Following the developed letter template, complete Contractor letter to the Medical Director providing prior notification of a labeled HUD use. (See Attachment A.) Each of the four documents identified here must be attached to the Medical Director's letter.
- Copy of the Physician's IRB HUD submission
 - Copy of the IRB approval letter
 - Copy of the Physician's HUD manufacturer "request for use" letter
 - Copy of the HUD manufacturer approval letter

Aurora employed CRCs submit this letter to the Part A Fiscal Intermediary Medical Director on behalf of Aurora's hospital claim.

Non-Aurora employed CRCs will submit their letter to the Part B Contractor Medical Director for the physician's professional services claim. The non-Aurora employed CRCs immediately forwards a copy of the Part-B letter and all attachments to Aurora's Special Projects Representative (SPR) at Aurora's Central Business Office (CBO) at the Forest Home Center. (Please forward this information simultaneous to Carrier mailing. In turn Aurora's SPR will craft a letter with the same attachments to the Part A Fiscal Intermediary Medical Director. See step #4 below.)

Note: if the labeled use of the HUD was in an emergency situation and prior contractor notification was not possible, instead send the letter to the Medical Director (using the same procedures outlined herein) no later than 14 days after the emergency HUD deployment.

3. Coordinator (Aurora employed or non-Aurora employed CRCs) shall also provide a copy of all documentation (Contractor letter with all attachments) to the Special Projects Representative in the Milwaukee Central Business Office and the Research Medical Auditor. (The CBO SPR maintains a copy of these documents in the specific billing/claim HUD file.)
4. SPR will write the prior-notification letter to the Part A Fiscal Intermediary Medical Director for all HUDs where the associated CRC is not Aurora employed. The SPR will follow the attached letter template and include as attachments all documents forwarded by the CRC to the SPR. (The CBO SPR maintains a copy of these documents in the specific billing/claim HUD file.)
5. Coordinator shall provide the materials management coordinator in the area where the HUD will be used prior notification of a HUD use. (As example, the EP lab or Cath lab materials management coordinator if the HUD will be deployed in the EP or Cath lab.) The Coordinator will advise the Materials Management coordinator of the following:
- Procedure date
 - Patient name
 - Insurance information
 - Physician name
 - HUD name and manufacturer

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The Coordinator will advise the Materials Management Coordinator that this is a HUD and as such must be billed at cost. No mark-up to a HUD is allowed.

6. Materials Management Coordinator will take appropriate action within the materials management system to assure that the HUD is not marked up, but rather billed on a claim at Aurora's purchased cost. No mark-up to a HUD is allowed.
7. Materials Management Coordinator will be available to the SPR in the CBO to discuss the HUD to assure that when the billing occurs the SPR correctly bills the HUD at Aurora's cost to purchase, without any added mark-up.
8. Special Projects Representative (SPR) in the Central Business Office is responsible to assure several essential elements are completed in preparation for individual patient claim submission. These include:
 - Contractor has been appropriately pre-notified of an intended HUD use (SPR is in possession of the physician's IRB submission, contractor letter and all attachments.)
 - The HUD is billed at Aurora's cost to purchase. The SPR will work with the materials management coordinator in the clinical area responsible for the device deployment if there is any question as to whether the price listed on the claim is "at cost."
 - Adding the Humanitarian Device Exemption (HDE) number in the remarks section of the claim form
9. In order to assess whether the HUD was deployed according to its label, and thereby is a billable service/supply to Medicare, the SPR will route all HUD claims to the Research Medical Auditor prior to claim submission.
10. Research Medical Auditor reviews all HUD deployment patient medical records to determine whether:
 - The device was deployed as labeled – and provide the SPR with an “ok to bill” response
 - The device was deployed off-label, but in an emergency during an otherwise covered procedure – and provide the SPR with an “ok to bill procedure; device not billable” response
 - The device was deployed off-label, but in an emergency during an otherwise non-covered procedure – and provide the SPR with a “do not bill” response
 - The device was deployed off-label as a planned non-emergency procedure, – and provide the SPR with a “do not bill” response
11. SPR submits claim (or does not submit claim) according to the direction received from the Research Medical Auditor’s review, analysis and final disposition assessment.

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Attachment A

Date

Dr. James W. Cope
Medical Director
United Government Services, LLC
401 W. Michigan Avenue
Milwaukee, Wisconsin 53201

Re: Prior Notification of the use of a Humanitarian Use Device (HUD)
Manufacturer's Name & HUD Name

Dear Dr. Cope:

Please accept this correspondence as prior notification of an impending use of a Humanitarian Use Device (HUD.)

The following information is included at your request:

1. Copy of the physician's letter to the HUD manufacturer
2. Copy of the physician's letter to the Aurora IRB
3. Copy of the Aurora IRB's letter to the physician authorizing the HUD use
4. Copy of the HUD manufacturer letter to physician authorizing the HUD use

Additionally we take note of two other items of guidance from you. The HUD will be billed on the claim at Aurora's cost to purchase from the manufacturer. Secondly, the claim will contain the HUD HDE number in the "remarks" section.

Sincerely,