

**AURORA HEALTH CARE METRO REGION
CLINICAL INFORMATION SERVICES (CIS)
POLICY AND PROCEDURE**

- TITLE:** **Investigational/Research Related Case Handling and Notification**
- PURPOSE:** To: (1) accurately identify and document in the medical record, a patient's participation in a clinical trial, and (2) define a mechanism from this medical record documentation to notify the Central Business Office (CBO) of any patient visits that include evidence of a research related treatment or cares or use of investigational devices, medications, etc.
- POLICY:** All patient activity that involves the use of an investigational device or medication, or for whom the care, evaluation or treatment involves a research protocol will be documented in the medical record as such. CIS will collect this information for the clinical abstracting system, as well as notify the CBO of all cases found.
- BACKGROUND:** As required by Aurora policy and government billing regulations, a patient's participation in a clinical trial must be documented in the medical record. Documentation within the medical record substantiates: (1) whether the item or service was reasonable and necessary, and (2) whether the service or item can be billed to a third party.
- Coding, which began as a way to track disease has evolved into a method to substantiate payment to providers. Coders are trained in the various aspects of a disease and in applying the correct diagnosis and CPT codes to a bill for submission to a third party payer. A coder will review medical record documentation and apply the correct codes for the service performed.
- The medical record for a research patient will contain each of the following elements: (1) Trial Name, (2) Sponsor Name, (3) Protocol Number, (4) the Informed Consent document

PROCEDURE:CIS Clerical Staff

1. Sort all incoming documentation to assemble the documents in an orderly fashion by patient, by account number, and by date of service. Specific documents are to be prioritized for filing to ensure incorporation prior to the chart being given to the coding staff. These priority documents include research consents, research coordinator progress notes and research billing forms.
2. Charts are available to the coders to begin the coding process at the appropriate day post-visit, according to normal documentation processing requirements.

CIS Coding Staff

The basis for the coding requirements of the National Coverage Determination for Clinical Trials are stated in the Medicare Coverage Policy ~ Clinical Trials Provider Bulletin and other subsequent guidance from CMS. (A more recent update from CMS, Program Transmittal AB-01-142, updated the requirements of the NCD and should be used for services after January 1, 2002.) The following appears in the Program Transmittal AB-01-142:

For inpatient charges and all other intermediary and RHHI processed services occurring on or after January 1, 2002, routine care for Medicare qualifying clinical trials must be identified with diagnosis code V70.7 (examination of a participant in a clinical trial). V70.7 is reported as the second or subsequent diagnosis code (generally the third or subsequent diagnosis for HHAs) on the HCFA-1450 or electronic claim equivalent.

1. All research codes are placed on a case based on the documentation provided by the clinical research staff. This documentation is in the form of an informed consent signed by the patient and the research coordinator, a progress note completed by the coordinator, or a clinical trials billing form, also completed by the coordinator.

Use the “Research IRB#” field in Clintrac to fill in the Institutional Review Board approval number of any visit that has a research informed consent (assuming the consent is NOT marked as a “Screen Failure”), research coordinator progress note or research billing form in it.

2. Following the National Coverage Determination guidelines, ICD 9 CM Code “V70.7” will be added to all cases meeting research criteria, after January 1, 2002. It is mandatory to sequence this code into the set that will pass to the billing system, even if it bumps out another important diagnosis code.

3. In the instance where there is no specific code for an investigational device, or it is evident that the device has not been used before, the coder will contact the Coding Specialist at their site who will contact the Medical Audit Coverage analyst.

CIS Coding Specialist

1. Run the daily “Newly Identified Research Cases” list each weekday and fax to the Special Projects Billing Representative in the CBO. This report identifies all newly coded cases that have a value in the Research IRB# field.