

Aurora Health Care
Clinical Trials
Coverage Analysis

Revision Date: 04/30/2003/ Rev 08/26/2005

PROCEDURE STATEMENT:

All Aurora Health Care employees have a responsibility to maintain a high level of integrity in the clinical trial process, from study budgeting to coverage analysis.

PURPOSE OF PROCEDURE:

The purpose of this policy is to outline the steps necessary for an efficient and effective process to complete a Medicare coverage analysis for a clinical trial. This enables the institution to make informed, fact-based decisions relative to the financial costs and benefits associated with each individual clinical trial. It also ensures that charges submitted to Medicare are appropriate.

ACCOUNTABILITY:

The Medical Auditor Analyst has the responsibility to complete the coverage analysis following the process outlined herein.

PROCESS:

Using various tools, including either the device or drug/biological checklist along with applicable NCDs and LCDs, the medical auditor assigned to the research study is responsible to complete the coverage analysis.

DEFINITIONS:

- **Billable as Standard of Care** – Those specific elements of medical services rendered under the umbrella of the Clinical Trial which have been determined to be reimbursable by a third-party payor, specifically Medicare. (Note: There is a difference between the “standard of care” term in a clinical setting and when used in a billing setting. The two contexts are different and may yield different results from care vs. billing perspectives. This analysis focuses specifically on what’s covered as a billable Medicare covered benefit.)
- **Clinical Research Coordinator** – Most often the nurse (or health care professional) assigned to or assisting the Principal Investigator responsible for carrying out the defined protocol of the clinical trial.
- **Clinical Trial** – The systematic investigation of the effects of materials (i.e., investigational drugs, devices) or methods (i.e., surgery, radiation) on a disease state conducted according to a formal study plan (protocol). Generally a clinical trial refers to the evaluation of potential treatment methods (drugs, surgery, etc.) although methods of prevention, detection or diagnosis may also be the subject of a clinical trial.
- **Coverage Analysis** – The process completed by a Medical Auditor Analyst whereby the study protocol/clinical study agreement is reviewed against Medicare billing rules and regulatory criteria to determine which study services are billable to Medicare and which are not.
- **“Debriefing”** – The process whereby the medical auditor analyst and clinical research coordinator discuss and “debrief” on the study protocol/clinical study agreement relative to what is or is not billable to a third-party payor, specifically Medicare.

- **External Research Coordinator** – A Clinical Research Coordinator or assistant employed by the Investigator.
- **Medical Auditor Analyst**- An RN member of the Medical Audit team, with the requisite expertise to review a clinical research study protocol and perform a coverage analysis in order to determine what is and what is not billable to Medicare as a covered benefit.

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- **Sponsor** – The organization (or individual) who has designed the clinical trial protocol and with whom Aurora Health Care and the Principal Investigator contract for the delivery of medical services in conformance with the trial protocol.

PROCEDURES:

1. The Clinical Research Assistant (CRA) will forward the study protocol/clinical study agreement provided by the Clinical Research Coordinator (CRC)/External Research Coordinator (ERC).
2. The Specialist for Research Business Operations (RBOS) will notify the Medical Auditor Analyst when the study budget is available on the e-workbook.
3. The co-operative group study protocols (ECOG, RTOG, CTSU, SWOG, CALGB) will be sent by the Clinical Trial Manager.
4. You will receive a copy of a study protocol/clinical study agreement along with all appropriate attachments –sponsor budget template, FDA approval letter/s, IND number/exemption, IDE number, IRB submission form, Informed consent document and all sponsor information related to reimbursement.
5. Review the study protocol/clinical study agreement in its entirety. Identify, then highlight or make note of the following:
 - a. Each and every medical service (procedure, test, lab, interpretation, etc.) that must be completed for each enrolled participant.
 - b. Each and every activity that must be completed by either the principal investigator or clinical research coordinator aside from each medical service identified above.
6. Next, determine from the study protocol or clinical study agreement which of the medical services **and** which of the investigator/coordinator activities will be either reimbursed by the study sponsor, or provided by the study sponsor for free. Specifically:
 - a. Identify which items/services are reimbursable by Medicare.
 - b. Identify non-covered or non-reimbursable items and services.
 - c. Identify the item/service to be provided free-of-charge by the sponsor.
7. Based upon whether the study is for a drug/biologic or a device, use the appropriate “Clinical Trials Coverage Analysis Checklist.” For either checklist, complete the following elements of the document:

- **Trial Title**
- **Sponsor**
- **Sponsor Protocol Number**
- **IND or IDE number**
- **Date Received in Medical Audit:**
- **Medical Auditor Name**
- **To whom forwarded upon completion**
- **Identify if a Medicare Deemed Qualifying Trial**
- **Recommendation for proceeding with Trial based upon coverage analysis**

8. Next, using the appropriate checklist, begin the coverage analysis.

For drugs, biologics (See attachment; Clinical Trials Coverage Analysis Checklist):

- **Step 1: Medicare Benefit Category?**
- **Step 2: Deemed Qualifying Trial?**
- **Step 3: National Coverage Decision(s)**
- **Step 4: National Coverage Decision – Non-Coverage**

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- **Step 5: Local Coverage Determinations (LCDs) {formerly LMRPs}**
- **Step 6: Sponsor Covered Items and Services**
- **Step 7: Routine Cost Analysis**
- **Step 8: Non-covered items or services**

For devices (See attachment; Clinical Trials Coverage Analysis – Investigational Devices Checklist):

- **Step 1: Investigational Device Exemption (IDE) Number**
 - Is the device a Category A device?
 - Is the device a Category B device?
 - **Copy of the FDA Approval Letter**
- **Step 2: National Coverage Decision(s)**
- **Step 3: National Coverage Decision – Non-Coverage**
- **Step 4: Local Coverage Determinations (LCDs) {formerly LMRPs }**
- **Step 5: Care Related to a Non-Covered Investigational Device**
- **Step 6: Sponsor Covered Items and Services**
- **Step 7: Non-covered items or services**

9. Based upon the coverage analysis, determine which services are therefore billable to Medicare [or a third-party payor], and which services are not billable because: (a) the sponsor is reimbursing Aurora/Investigator for the service, (b) the sponsor is providing the item free of charge, or (c) the service/device is not a billable service/device as determined by Standard of Care and/or Medicare rules.
10. Compare the results of the coverage analysis to the budget provided by the RBOS or ERC. Specifically review for the following:
- Are there any services/devices not paid for or provided by the sponsor that are also **not** billable to Medicare [or a third party payor]? If so, make note of these for discussion with the CRC/ERC during the protocol debriefing.
 - Are there any services/devices that **are** billable to Medicare [or a third-party payor] for which the sponsor will pay or provide free of charge? If so make note of these for discussion with the CRC/ERC during the protocol debriefing. These items must be clearly identified in both the coverage analysis and study budget to direct the billing office to refrain from billing for these services/devices.
 - Are there any services/devices not paid by the sponsor **and** not billable to Medicare [or a third-party payor]? If so make note of these for discussion with the CRC/ERC during the protocol debriefing. Additionally these must be noted in the coverage analysis. These services/devices must be: (a) either negotiated for reimbursement from the sponsor, (b) charged to the patient/subject, or (c) approved as a cost which will be written-off by Aurora Health Care.

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11. In the coverage analysis, clearly specify and delineate the following:
- Which services/items are billable to Medicare [or a third-party payor]
 - Which services/items are NOT billable to Medicare [or a third-party payor]
 - Which services/items are not billable to Medicare [or a third-party payor] AND are not being reimbursed by the sponsor.
12. Make a final recommendation in favor or in opposition of this protocol based upon your coverage analysis of what is billable and being reimbursed by the sponsor. Note that final recommendation on the cover of the coverage analysis checklist. Sign and date your recommendation.
13. Provide a copy of your final documentation to the CRC/ERC assigned to this protocol.
14. Notify the Contract Manager in the Department of Clinical Research (DCR) when the coverage analysis is completed in the e-workbook or provide a copy electronically.
15. Notify the Research Specialist in the Central Business Office [and in the AMG Billing Office as appropriate] when the coverage analysis is completed in the e-workbook or provide a copy electronically

16. If the study protocol sponsor is paying for/ providing all the required services and items, an abbreviated coverage analysis is acceptable.
17. If any study/protocols are not reviewed from a coverage analysis perspective because of resource constraints, simply attach the appropriate checklist and note across the face of the checklist "NOT REVIEWED DUE TO RESOURCE CONSTRAINTS." Sign the checklist and date it.