

MEDICARE/COVERAGE ANALYSIS NEED POLICY

PURPOSE

The purpose of this policy is to outline the parameters of when a Medicare/Coverage Analysis (MCA/CA) is to be performed for a research study at The Queen's Medical Center (QMC).

SCOPE

The requirement for MCA/CA applies to all clinical research studies at QMC, regardless of expected inclusion or exclusion of Medicare beneficiaries and the source of funding. Every clinical research study is reviewed to determine whether an MCA/CA (full or modified) is required or exempt.

DEFINITIONS

Medicare/Coverage Analysis: A Coverage Analysis is a comprehensive evaluation of the financial aspects and billing procedures with a clinical trial. A Medicare Coverage Analysis determines if the research study is a deemed and Qualified Clinical Trial through a systematic review of clinical trial documents, published practice guidelines, industry guidelines, local and government regulations including Local Coverage Determinations (LCD), and National Coverage Determinations (NCD) that determines the billing status of all items and services.

Clinical Trial Management System (CTMS): A system used to manage and maintain planning, performing, reporting, and financial functions, along with participant contact information, visit completion, tracking deadlines and milestones of a clinical trial.

Study Shell: An entry into the CTMS to document the study details including but not limited to study documents, sponsor information, Principal Investigator (PI) and coordinator, visits and elements.

PURPOSES OF A COVERAGE ANALYSIS:

1. Identify billable items
2. Distinguish conventional care vs research costs
3. Develop a billing plan
4. Budgeting and Sponsor agreements
5. Financial loss assessment
6. Informed consent confirmation
7. Consistency across all documents (protocol, informed consent, contract/grant, budget, funding sheet) of the study

POLICY and PROCEDURES

1. The Coordinator, Coverage Analysis will determine if a MCA/CA is needed based on this policy and the required study documents.
2. All studies that generate a charge to the patient/payor, research account and/or invoice require a MCA/CA be performed regardless of the funding source.

3. The following types of study may qualify for a modified MCA/CA:
 - a. When the entire study consists of non-billable procedures, or time and effort paid for by the study (i.e., interviews, questionnaires, surveys, registry studies, data collection only).
 - b. Observational Studies:
 - There is no investigational/experimental item or service.
 - All services are conventional care where the services are to be billed as normal.
 - c. Blood Draw Studies:
 - Studies that solely consist of blood draw(s) that are being performed at QMC.

4. The following types of studies do **not** require a coverage analysis, but will require a study shell to be built in CTMS:
 - a. No enrolled patients at QMC sites:
 - The entire clinical research population for the study is not seen at QMC sites (i.e., patients are in a Community Clinic).
 - The entire clinical research population may or may not be seen at QMC and does not have to be a registered QMC patient (i.e., volunteers, community centers, etc.).
 - b. When the entire prospective research study has no funding and is data collection only from patient medical records.
 - c. IRB Exempt Studies without any funding:
 - DHHS regulations in 45 CFR 46.101 outlines categories of minimal risk research as being exempt from the federal policy for the protection of human subjects.
 - The study must be submitted to the IRB for review and if approved, they will send an exempt certification letter.
 - c. Compassionate Use/Expanded Access Studies:
 - Studies that refer to the use of an investigational new drug (IND) outside of a clinical trial by people with serious or life-threatening conditions who do not meet the enrollment criteria for the clinical trial in progress.
 - These studies are not considered research, although they still require IRB approval. There is usually no transmittal of data to the Sponsor.
 - d. Humanitarian Use Device (HUD/HDE)

- HUDs are medical devices intended to benefit patients in treatment/diagnosis of disease/condition that affect not more than 8,000 individuals in the United States per year. FDA may grant an HDE, which is an exemption from the effectiveness requirements of federal medical devices.
- These studies are not considered research, although they still require IRB approval.