LOYOLA UNIVERSITY HEALTH SYSTEM

COVERAGE ANALYSIS: FREQUENTLY ASKED QUESTIONS AND OTHER HELPFUL TIPS

What is a Coverage Analysis?
A Coverage Analysis or CA is a systematic review of all the clinical items and services associated with a clinical trial to determine appropriate billing. It delineates the items and services to show where they will be billed – sponsor, Medicare or third party payer.

Who is responsible for developing a Coverage Analysis?
At Loyola University Medical Center (LUMC) PharmaSeek Financial Services ("PharmaSeek") is responsible. In July 2015, LUMC engaged PharmaSeek to provide Coverage Analysis development support. The research office is coordinating the development efforts for existing studies that do not have a CA and new studies requiring a CA. The CA Development SOP can be found on Loyola.Wired / Clinical Research Policies and Procedures.

What documents are needed to develop a CA?
Study documents may include the following:

- Protocol
- Clinical Trial Agreement
- Budget
- Funding Sheet (for Cooperative Group Studies)
- National Coverage Analysis (for Cooperative Group Studies)
- Informed Consent Form
- FDA Approval Letter
- CMS (Medicare) Letter

Who is responsible for providing the documents required to develop a Coverage Analysis?
The Principal Investigator, coordinator, or designated study team member is responsible for providing the study documentation to the research office.

Who is responsible for reviewing a Coverage Analysis?
The CA goes through multiple layers of review and approval. The Principal Investigator, coordinator, or designated study team member is ultimately responsible for reviewing and approving the Coverage Analysis. The research office reviews the CA to ensure consistency with the CTA, budget and other applicable study documents. Patient Financial Services is responsible for reviewing and approving the CA from a billing perspective.

What is a Billing Grid?
In short, the outcome of the CA process is the billing grid which is the protocol's schedule of events with delineation as to who is responsible for paying for the item or service. Along with the delineation, the billing grid provides the justification of all routine costs, why they are/are not eligible for billing to Medicare and/or third party payer based on National Coverage Determinations (NCDs) or Local Coverage determinations (LCDs).

Is the PI/Study Team expected to make recommendations on billing designations in the billing grid?
Yes, if the PI/Study Team disagrees with a billing designation based on their clinical expertise they will need to provide the justification and rationale supported by publications or historical documentation in order to change the designation.

What is NCT #?
Also known as a "clinicaltrials.gov identifier", the NCT # is a unique identification code given to each clinical study registered on ClinicalTrials.gov. The format is the letters "NCT" followed by an 8-digit number (for example, NCT00012345).

Who is responsible for obtaining NCT #?
The sponsor of the study must register the trial on www.clinicaltrials.gov to generate the NCT#. For commercially sponsored studies, this registration is usually completed by the industry sponsor, and the NCT code can be found by searching the site. For investigator initiated studies it is the responsibility of the investigator or study team to register the study on clinicaltrials.gov and obtain the NCT code. Navigate to http://www.clinicaltrials.gov/ct2/help/for-researcher for further information.

Where do I find NCT #?
The sponsor can provide the NCT # or it can also be found on the www.clinicaltrials.gov website under each study.

What do I do with NCT #?
As of 01/01/2014, the NCT # is required on all claims that are sent to Medicare or third party billing. As such, Loyola University Medical Center requires the PI, study team staff, or designee to ensure that the NCT # is entered in the Research Portal, uploaded to the Epic Research Module and documented on all pertinent forms where it is requested.

If my study has a National Coverage Analysis do I still need a LUMC/LUC coverage analysis?
Yes, while a National Coverage Analysis is typically provided for Cooperative Group Studies they are developed only using National Coverage Determinations or NCDs. The analysis developed by PharmaSeek considers NCDs and Local Coverage Determinations or LCDs. LCDs typically supersede the coverage of an NCD and therefore, can change a billing designation.

How do I know if my study is a qualifying clinical trial?
Drug & Biologic Trials
For drug and biologic trials the study must be a "qualifying clinical trial" according to CMS. A study is qualifying if it meets the mandatory requirements set forth by CMS. The four questions below will assist you in determining if your study meets the mandatory requirements noted. If all four questions are answered “yes,” then the study is qualifying. This indicates that the study qualifies for Medicare reimbursement of routine costs that are reasonable and necessary.

Conditions for Qualifying Clinical Trial

- The subject or purpose of the trial is the evaluation of an item or service that falls within a Medicare benefit category (e.g., physicians' service, durable medical equipment, or diagnostic test) and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids)
- The trial has therapeutic intent (i.e., the trial is not designed exclusively to test toxicity or disease path physiology)
- For a trial of a therapeutic intervention, the trial must enroll patients with diagnosed disease rather than healthy volunteers
- The trial is considered to be a DEEMED study:
    - Trials funded by NIH, CDC, AHRQ, CMS, DOD, or VA;
- Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD, or VA;
- Trials conducted under an investigational new drug application (IND) reviewed by the FDA; and Drug trials that are exempt from having an IND under 21 CFR 312.2(b)(1) will be deemed automatically qualified.

What if a study is not qualifying?
If any one of the four questions is answered “no,” then the study is not qualifying. Only charges for routine care may be billed to Medicare and/or a third party payer and medical clinical trials identifiers are not needed.

Requirements for Medicare Coverage of Routine Costs (Clinical Trail Policy 310.1)
Any clinical trial receiving Medicare coverage of routine costs must meet the following three requirements:

- The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category (e.g., physicians' service, durable medical equipment, diagnostic test) and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).
- The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent.
- Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.

The three requirements above are insufficient by themselves to qualify a clinical trial for Medicare coverage of routine costs. Clinical trials also should have the following desirable characteristics; however, some trials, as described below, are presumed to meet these characteristics and are automatically qualified to receive Medicare coverage:

1. The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes;
2. The trial is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use;
3. The trial does not unjustifiably duplicate existing studies;
4. The trial design is appropriate to answer the research question being asked in the trial;
5. The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully;
6. The trial is in compliance with Federal regulations relating to the protection of human subjects; and
7. All aspects of the trial are conducted according to the appropriate standards of scientific integrity.

Devices
For device studies, answer the following questions (these questions are also embedded into the "Clinical Trials Budget Tool" in the Research Portal).

- Is the device being studied an implantable device?
- Is the device being studied an IDE?
- Is the device being studied a Category A or B?
- Is the device being studied being provided for free from the sponsor?

IDE Devices
All IDE device trials must be pre-approved before participants can be enrolled. Pre-approval is garnered by submitting a "device packet" to CMS for review and approval.

- *Category A* are innovative devices in which "absolute risk" has not been established (i.e., initial questions of safety and effectiveness have not been resolved) and thus FDA is unsure whether the device type can be safe and effective.
- *Category B* are device types believed to be in classes I or II or device types believed to be in class III where the incremental risk is the primary risk in question (i.e., underlying questions of safety and effectiveness of that device type have been resolved). This category includes device types that can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type. Non-significant risk studies may also be included in this category.

In general for billing and budgeting purposes, Category A devices are not covered but the procedure to implant the device may be. However, Category B devices may be covered as well as the procedure to implant the device.

What about other devices such as HUDs and PMAs?
If the study will bill routine cost items or services to Medicare, Medicare may cover non- significant risk (FDA IDE not required) devices. They must be considered reasonable and necessary and meet all other applicable Medicare coverage requirements. Medicare has assigned the determination of coverage for non-significant risk devices to the Medicare contractor(s).

A Humanitarian Device Exemption (HDE) or Humanitarian Use Device (HUD) is a device that is intended to benefit fewer than 4,000 patients in the United States per year. Humanitarian devices are not research, but an exception from approved PMA devices. HUD billing requires approval by the Medicare Fiscal Intermediary.

Do I need to worry about billing if my sponsor provided the device for free?
Whenever there are items or services being billed, regardless of payer, there is always a need to be aware of the billing.

Do I need to worry about billing if my sponsor is not providing the device for free?
Whenever there are items or services being billed, regardless of payer, there is always a need to be aware of the billing. In this instance, since the sponsor is not providing the device for free; you must ensure all necessary pre- approvals have been obtained from CMS before the items and services can be billed to the patient or patient insurance. You must also ensure the NCT # and other coding requirements are on the claims.