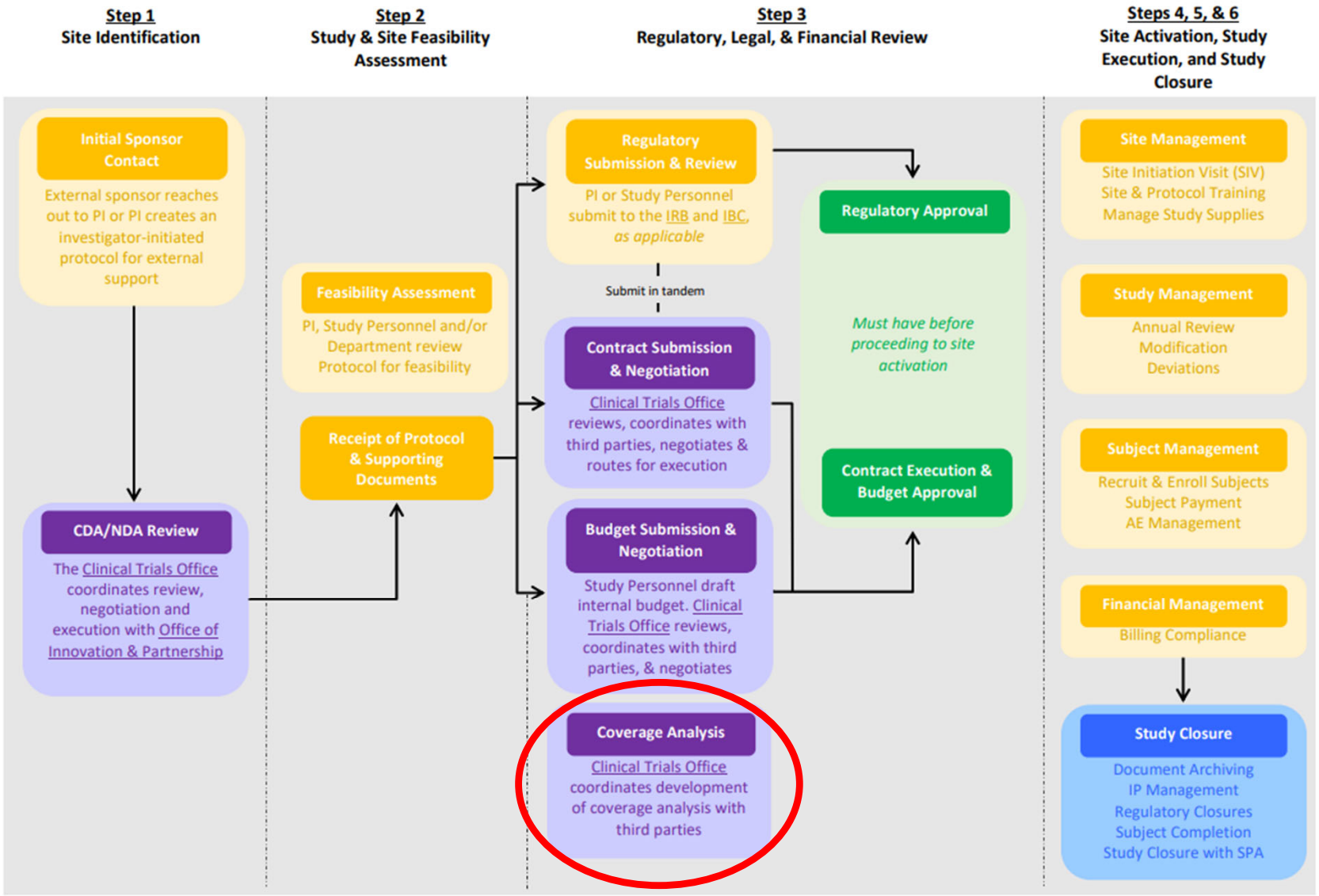
Medicare Coverage Analysis for Clinical Trials

Office of Research Services
Professional Development Knowledge Base

Clinical Trial Start-Up



What is Medicare Coverage Analysis?

Analysis required for all clinical trials involving tests, procedures, and interventions associated with a clinical trial that are invoiced to third party payers (i.e., Sponsors) to determine what costs, if any, can be covered by Medicare. **MCA is one of the most useful documents for building a clinical trial budget and clinical trial billing compliance.**

What Medicare Will Cover

- Routine costs of qualifying clinical trials, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials
- All items and services that are otherwise generally available to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national non-coverage decision) that are provided in either the experimental or the control arms of a clinical trial

What Medicare Will Not Cover

- The investigational item or service, itself unless otherwise covered outside of the clinical trial
- Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g. monthly CT scans for a condition usually requiring quarterly scans)
- Items and services customarily provided by the sponsors free of charge for any enrollee in the trial

Rules to Have at Your Fingertips

The Rules cannot be found all in one place.

Drug Trials

- Clinical Trial Policy (CTP) – National Coverage Determination (NCD) 310.1

Device Trials

- Medicare Benefit Policy Manual - Chapters 14 & 15

Other Relevant Rules

- Coverage with Evidence Development (CED)
- Medical Claims Processing Manual – Chapter 32

Qualifying Clinical Trials Determination

Step 1: Is it a Deemed Trial

Step 2: Does the study investigate an item or service that Medicare pays for (falls in a benefit category)?

Step 3: Does the trial have therapeutic intent?

Step 4: Are the items/services reasonable and necessary for the diagnosis or the treatment of a diagnosed disease?

Step 1: Deemed Trial

Deemed trials have the following desirable characteristics:

1. The principal purpose 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 compliant 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.

Step 1: Deemed Trial

<u>One of the following</u> must be true in addition to the trial having the 7 desirable characteristics:

1. The study is funded by National Institutes of Health (NIH), Centers for Disease Control & Prevention (CDC), Agency for Healthcare Research & Quality (AHRQ), Centers for Medicare & Medicaid Services (CMS), Department of Defense (DoD), or Veterans Affairs (VA); *or,*

2. The study is supported by a center or cooperative group funded by the NIH, CDC, AHRQ, CMS, DoD, or VA; *or,*

3. The study is conducted under an Investigational New Drug (IND) application reviewed by the FDA; *or,*

4. The study is IND exempt under 21 CFR 312.2(b)(1)

Step 2: Benefit Category

Does the study investigate an item or service that Medicare pays for (falls in a benefit category)?

The Clinical Trial Policy (CTP) – National Coverage Determination (NCD) 310.1 lists 72 benefit categories. Relevant Benefits Categories include:

- Drugs & Biologicals
- Diagnostic Imaging
- Laboratory & Diagnostic Services
- Medical & Surgical Procedures

Step 3: Therapeutic Intent

Does the trial have therapeutic intent?

Demonstrating Therapeutic Intent

Any study with a measurable efficacy endpoint as part of the (a) primary or secondary objective or aim, or (b) statistical analysis plan if the study does not have well defined objectives	Any study where all arms of the study include conventional treatment and the investigational drug is added to the conventional regimen	Any oncology study where the treatment is directed by genetic testing and only subjects with specific genetic characteristics are enrolled into the study whereby only those subjects most likely to respond are enrolled

The trial cannot be designed exclusively to test toxicity or disease pathophysiology. CMS has no specific recommendation regarding what is a sufficient design to determine therapeutic intent. Review the protocol for objectives indicating therapeutic intend.

Tip: Prepare for defense of intent to bill by documenting your determination of therapeutic intent in the coverage analysis.

Step 4: Diagnosed Disease

Are the items/services reasonable and necessary for the diagnosis or the treatment of a diagnosed disease?

Medicare only covers items and services that are reasonable and necessary to "diagnose or treat" illness or injury, with limited exceptions. Review the protocol eligibility requirements for a diagnosis of illness or injury.

Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.

Tip: Prepare for defense of intent to bill by documenting your determination that items and services are reasonable and necessary.

Tip: Prevention trials are not considered qualifying clinical trials.

Determining Routine Costs: Questions to Ask to Support Billing

Question 1: Would physician perform this service at the required frequency for a patient not in the study?

Question 2: Is physician able to document the medical necessity of the item or service in the medical record for every subject?

Question 3: Will physician use the test for the direct clinical trial management if every patient enrolled in the research study?

If any answer is NO, it is probably not a routine cost

If all answers are YES: (a) ask the PI for support, (b) ask the PI to articulate one or two lines of solid clinical reasoning, or (c) consider the use of a PI statement regarding E/M visit frequency.

Investigational Device Exemption (IDE) Request

Category B IDE with identifying number beginning with G

- Device for which the "absolute risk" of the device type has not been established and the FDA is unsure whether the device type can be safe and effective
- Medicare covers routine care items and services furnished in a Category A IDE study if CMS determines that the Medicare Coverage IDE study criteria are met
- Medicare will cover most costs, but not the cost of the device.

Category A IDE clinical study

- Device for which the "absolute risk" of the device type has not been established and the FDA is unsure whether the device type can be safe and effective
- Medicare covers routine care items and services furnished in a Category A IDE study if CMS determines that the Medicare Coverage IDE study criteria are met
- Medicare will cover most costs, but not the cost of the device.

Post-Market approval studies or registries of carotid stents

Studies of proximal embolic protection devices (EPDs) in carotid artery stenting (CAS) procedures.

Tip: If you plan to participate in and IDE clinical study *AND* anticipate filing Medicare claims, you must notify your Medicare contractor

Tip: IDE requests are not required for Humanitarian Use Devices (HUDs), Post-market approval studies or registries of devices other than carotid stents, or Clinical Studies other than those described.

MCA at LSU Health New Orleans

For almost all eligible studies, LSUHSC requires use of a third-party service provider to conduct the Medicare Coverage Analysis.

Why do we use a third party to complete the MCA?

By using a third-party with expertise in MCA, LSUHSC ensures consistency, and institution's risk is minimized. Major financial compliance risks exist with MCA, sometimes even when there is no malicious intent.

What do we need to provide for the third-party service provider to complete the MCA?

- Study Protocol
- Sponsor Budget
- Draft Informed Consent
- Draft Clinical Trial Agreement

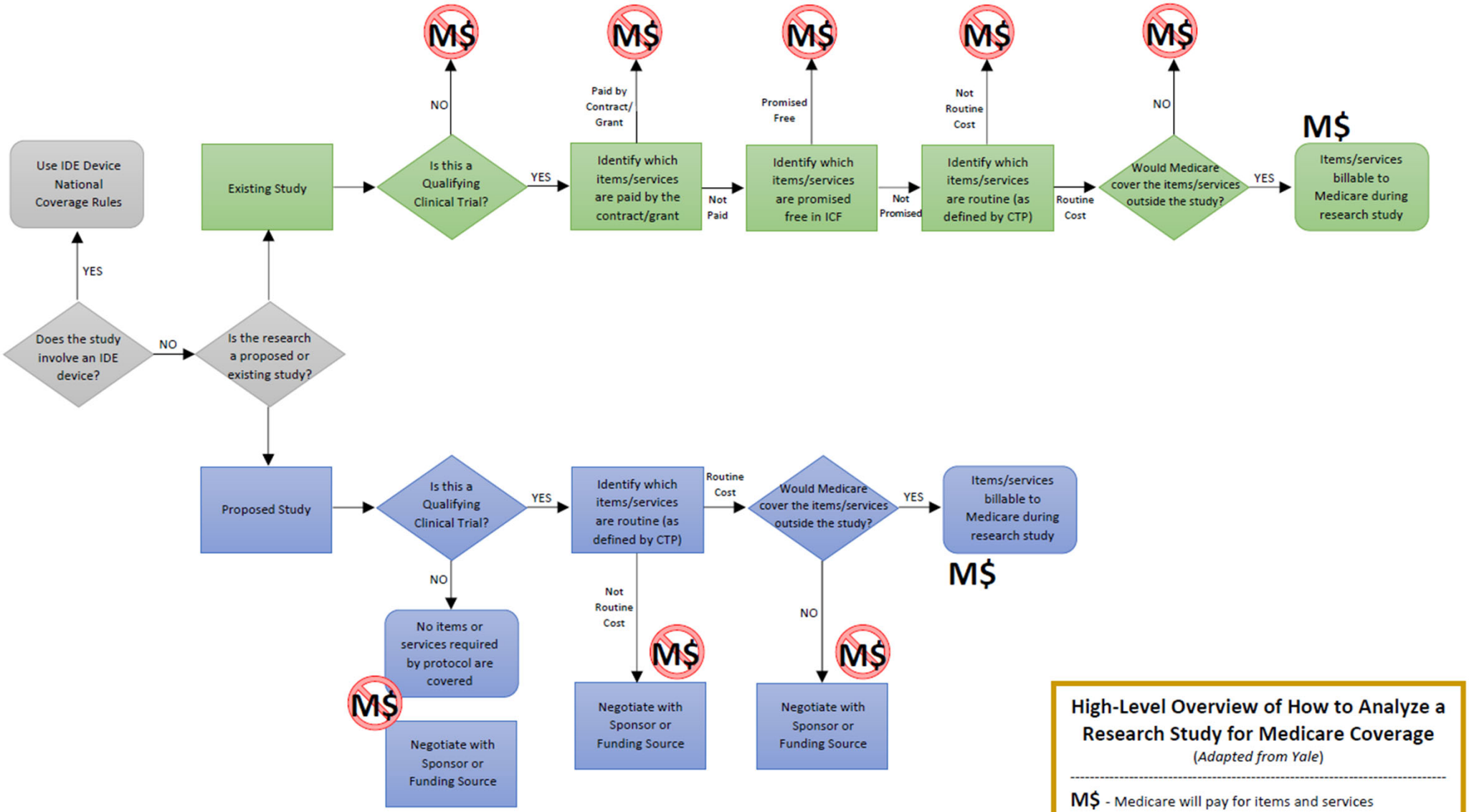
Once complete, the Clinical Trials Office will provide the study team with the billing summary listing all items and services that can be billed to Medicare.

Who pays for the MCA to be completed by the third-party?

The initial MCA fee is built into the LSU Health standard start-up costs. Revisions to the MCA will be invoiced to the Sponsor at the rate determined by the third-party.

Appendix

High-Level Overview: Analyzing a Clinical Trial for Medicare Coverage



High-Level Overview of How to Analyze a Research Study for Medicare Coverage

(*Adapted from Yale*)

M$ - Medicare will pay for items and services

M$ - Medicare will NOT pay for items and services

Qualifying Trials

Must be ***one*** of 4 types of trials deemed to meet 7 desirable characteristics

1. Funded by NIH, CDC, AHRQ, CMS, DOD, or VA

OR

2. Supported by center or cooperative group funded by NIH, CDC, AHRQ, CMS, DOD, or VA

OR

3. Conducted under an investigational new drug application (IND) reviewed by the FDA

OR

4. IND Exempt under 21 CFR 312.2(b)(1)

ONE of these MUST BE TRUE

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Must meet ***all three*** necessary requirements

1. Evaluate an item or service that falls within a Medicare benefit category
2. Have therapeutic intent
3. Enroll patients with diagnosed disease

ALL of these MUST BE TRUE

Investigational Device Exemption

CATEGORY A	CATEGORY B
Trials involve immediately life-threatening condition (if trial was initiated before 1/1/2010)	All trials
Device not covered	Device covered if not provided free by sponsor or promised free. Reimbursement may not exceed amount for comparable marketed device
Routine care services covered	Routine care services covered
Medicare contractor approval required	Medicare contractor approval required
Device is never covered Services ▪ IDE Number ▪ ICD-10 Code Z00.6 (Secondary Diagnosis) ▪ Q0 or Q1 Modifier - Physician Services - Outpatient Services ▪ Condition Code 30 (outpatient only) ▪ NCT# ▪ Revenue code 056 if device is provided for free	Device ▪ IDE Number ▪ HCPCS device code (if applicable) (Physician and outpatient) ▪ Q0 (Physician and Outpatient) ▪ Charges or token charge (outpatient) Services ▪ IDE Number ▪ ICD-10 Code Z00.6 (Secondary Diagnosis) ▪ Q0 or Q1 Modifier - Physician Services - Outpatient Services ▪ Condition Code 30 (outpatient only) ▪ NCT#