2016 NCURA Region I Spring Meeting

Basics of Clinical Trial Billing and Coverage Analysis

May 2, 2016

AGENDA

May 2nd, 2016
Welcome & Introductions
Clinical Research Billing
-Overview and Background
-Regulations and Guidelines
Conducting a Coverage Analysis
-Qualifying Clinical Trials
-Developing the Billing Grid
Resources

BIOGRAPHY

Director, Huron Consulting Group

Beth Belt

Beth has over 15 years of experience in healthcare regulatory compliance. She has served on engagements for healthcare systems, academic medical centers, community hospitals, and renal dialysis facilities. Beth advises clients within compliance, operations, and research departments for the healthcare provider community, including development and implementation of processes associated with the clinical trial revenue cycle and related Medicare regulations.

Prior to providing compliance and research advisory services, Beth held several key positions at Dana Farber Cancer Institute, including the Administrator for the Center for Clinical and Translational Research, Project Manager for the Clinical Trial Billing Project, as well as the Billing Compliance Manager.

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Clinical Research Billing

Overview and Background

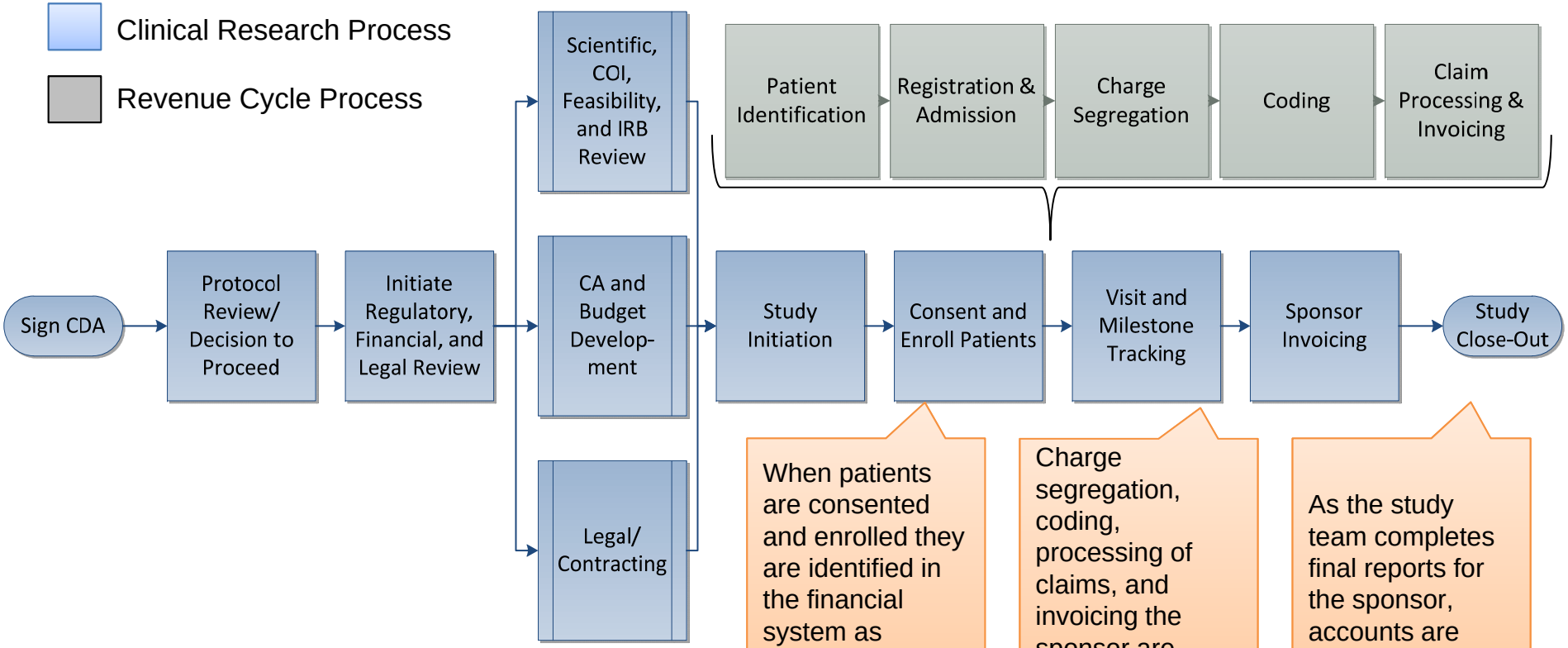
Overview of Clinical Research Billing

The research billing process (depicted on the left) is complex and requires coordination and harmonization between partnering institutions (the hospital and physician practices). The steps in the process are as follows:

- Coverage Analysis
- Budgeting and Contracting
- Identifying Research Patients
- Registration and Admission
- Charge Segregation
- Coding
- Claims Processing and Invoicing
- Study Close-out and Residual Balances

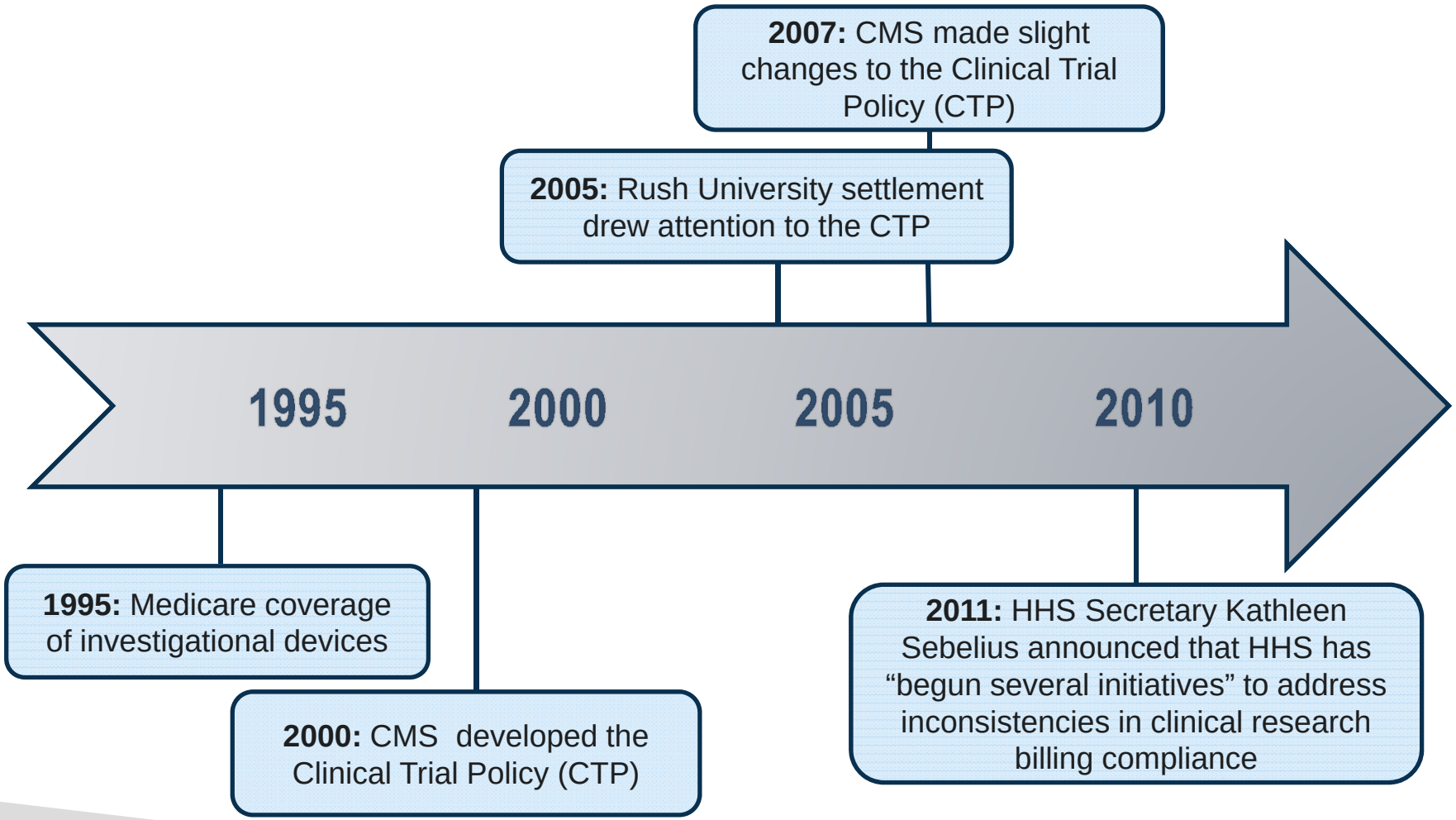
Understanding the Processes

The Clinical Research and Revenue Cycle Process



Importance of a Research Billing Compliance Program

Historical Context of Medicare and Clinical Trials



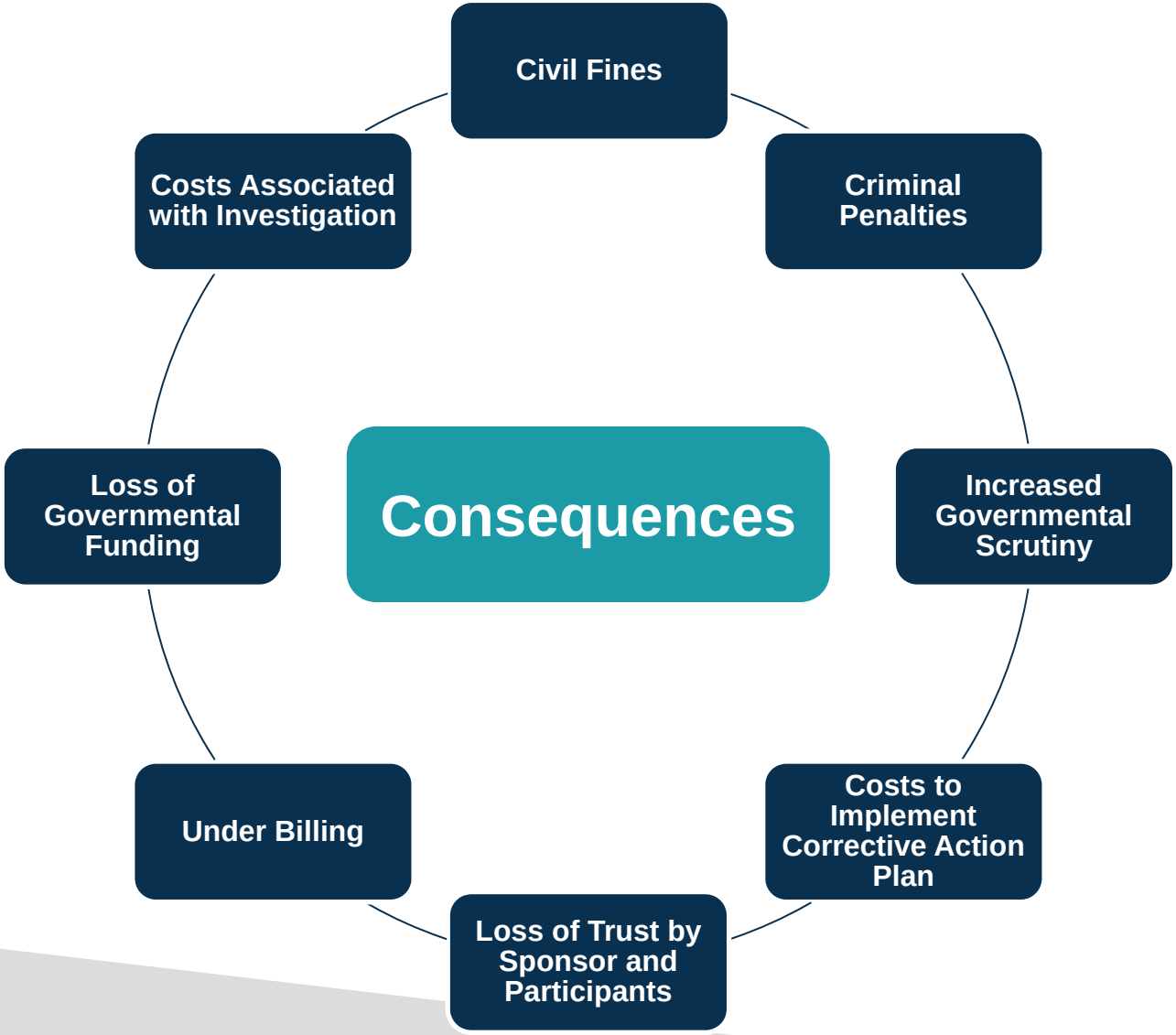
Importance of a Research Billing Compliance Program

Why Is This Important?

Public Settlements

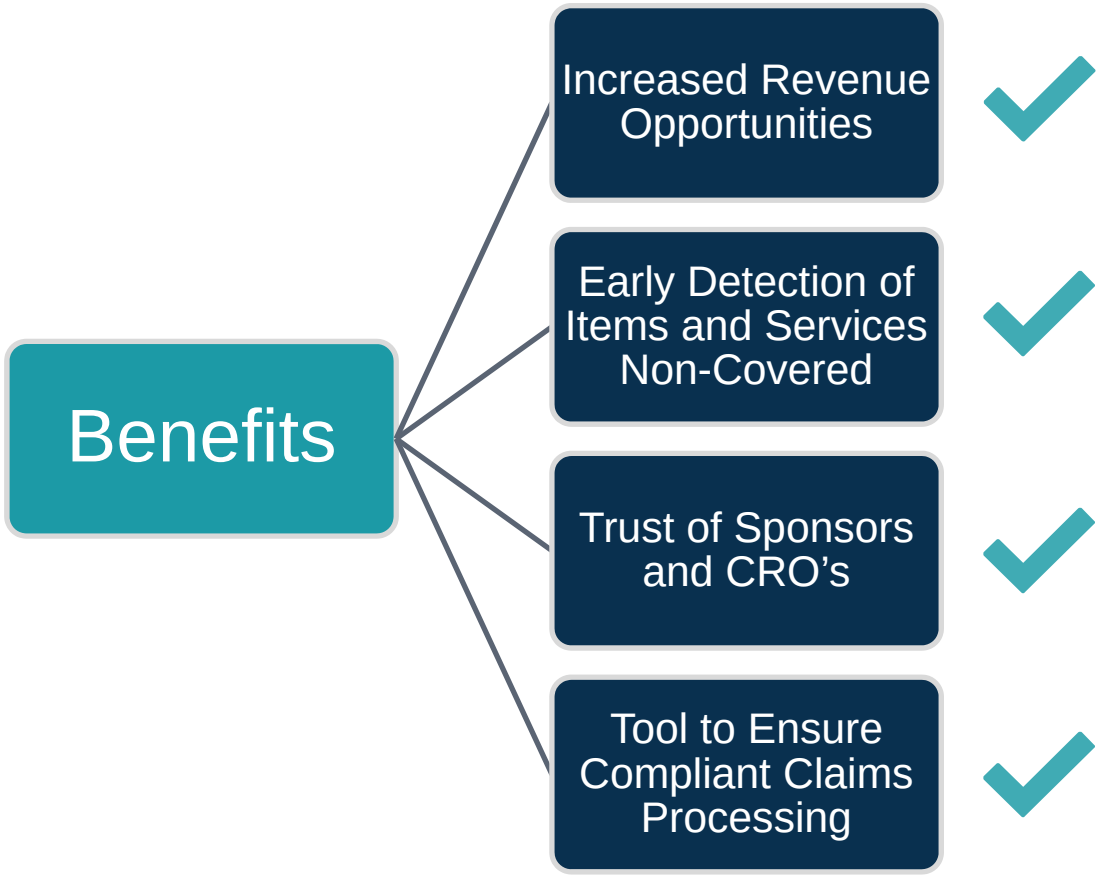
Importance of a Research Billing Compliance Program

Consequences of Not Having a Billing Compliance Program



Importance of a Research Billing Compliance Program

Benefits of Having a Billing Compliance Program



Clinical Research Billing

Rules and Regulations

Overview of the Regulations and Guidelines

Clinical Trials Policy (2007)

- Medicare's current Clinical Trial Policy (CTP) as of July 9, 2007
  www.cms.gov/Medicare/Coverage/ClinicalTrialPolicies/index.html
  - "Effective for items and services furnished on or after September 19, 2000 Medicare covers the **routine costs** of qualifying clinical trials, as such costs are defined below, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicare rules apply."

- What is covered by Medicare:
  - Items and services typically provided absent a clinical trial;
  - Items and services required for provision of an investigational item or service (e.g. administration of a non-covered chemotherapy), clinically appropriate monitoring if effects of item/service, or prevention of complication; and
  - Items and services needed for the reasonable and necessary care arising from provision of an investigational item/service, in particular, for the diagnosis and treatment of complications from participation in the research protocol.

Overview of the Regulations and Guidelines

Clinical Trials Policy (2007)

- What is covered (continued)
  - If the investigational item itself would be covered outside of the trial, it is still covered within the trial; or
  - The investigational item could also be covered as part of a Coverage with Evidence Development Trial.
    - www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html

      Examples-
      - Allogenic Hematopoietic Stem Cell Transplant for MDS
      - Artificial Hearts
      - FDG PET and Other Neuroimaging devices for Dementia
      - Off-Label Use of Colorectal Cancer Drugs
      - Transcatheter Aortic Valve Replacement
- What is *not* covered?
  - Items and services typically provided solely to satisfy data collection and analysis needs and are not used in the clinical management of the patient (e.g. monthly CT Scans for conditions usually requiring a scan every three months); and
  - Items and services customarily provided by research sponsors free of charge for any enrollee in the trial.

Overview of the Regulations and Guidelines

Clinical Trials Policy (2007)

- What is a Qualifying Clinical Trial?
  - Purpose of the trial must be for the evaluation of an item or service with a benefit category
  - Must have therapeutic intent
  - Must enroll patients with a diagnosed disease
  - Must be “deemed” (i.e. must meet the seven desirable characteristics defined by the CTP)

Overview of the Regulations and Guidelines

Clinical Trials Policy (2007)

Seven Desirable Characteristics

1	2	3	4	5	6
The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes;	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;	The trial does not unjustifiably duplicate existing studies;	The trial design is appropriate to answer the research question being asked in the trial;	The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully;	The trial is in compliance with Federal regulations relating to the protection of human subjects; and

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All aspects of the trial are conducted according to the appropriate standards of scientific integrity.

Overview of the Regulations and Guidelines

Clinical Trials Policy – Automatically Qualifying Clinical Trials

Effective September 19, 2000, clinical trials that are “deemed” to be automatically qualified (i.e. automatically meet the seven desirable characteristics) are:

- Trials funded by NIH, CDC, AHRQ, CMS, DOD, and VA;
- Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD, and 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).

Overview of the Regulations and Guidelines

Clinical Trial Policy – Investigational Device Trials

- The CTP does not withdraw coverage from Investigational Device Exemptions (IDE) Category B trials, but there have been reports of Medicare contractors denying these trials because the support for “therapeutic intent” was insufficient.
- Part of the Second Consideration of the Clinical Trial Policy in 2007 (that was not implemented) included the following statements:
  - “This policy is not applicable to, and does not change Medicare coverage according to the regulations on Category A and Category B IDE found in 42 CFR 405.201-405.215, 411.15, and 411.406.”; and
  - “Since humanitarian use devices (HUDs) with an FDA approved humanitarian device exemption (HDE) are not addressed in this policy, local contractors may continue to make determinations about the coverage of HUDs.”

Overview of the Regulations and Guidelines

Investigational Device Exemptions (IDE) – Category A & B

An approval for a Category A (Experimental) IDE study will allow coverage of routine care items and services furnished in the study, but not of the Category A device, which is statutorily excluded from coverage. An approval for a Category B (Non-experimental / investigational) IDE study will allow coverage of the Category B device and the routine care items and services in the trial." (BPM Ch. 14 and CMS.gov.)

Category A

- Experimental device
- An "absolute risk" of the device type has not been established
- **Never covered by Medicare**
- FDA is unsure the device type can be safe and effective
- Medicare covers routine care items and services furnished in an FDA-approved Category A IDE study if CMS (or its designated entity) determines that the Medicare coverage IDE study criteria are met

Category B

- Non-experimental device
- Incremental risk is the primary risk in question
- **May be covered by Medicare**
- The device type can be safe and effective because other manufacturers have obtained FDA premarket approval or clearance for that device type
- Medicare may make payment for a Category B IDE device and routine care items and services furnished in an FDA-approved Category B IDE study if CMS (or its designated entity) determines prior to the submission of the first related claim that the Medicare coverage IDE study criteria are met

Source: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c14.pdf

Overview of the Regulations and Guidelines

CMS Investigational Device Trials Prior to 2015

- For IDE studies approved by the FDA prior to January 1, 2015, providers that have been or will participate in these IDE trials and anticipate filing Medicare claims should continue to submit their requests to their Medicare Administrative Contractor (MAC).
- Documents currently may include, but are not limited, to the following:
  - Submission Checklist
  - Name and Narrative Description of Device
  - Study Protocol
  - Informed Consent Form
  - Un-redacted/Unconditional FDA Approval Letter
  - IRB Approval Letter

Overview of the Regulations and Guidelines

CMS Investigational Device Trials (2015)

- **Effective as of January 1, 2015**, interested parties (i.e. study sponsors) that wish to seek Medicare Coverage must submit a request electronically or by hard copy for review and approval to the central CMS office as published in the CMS Medicare Benefit Policy 100-02, Chapter 14- Medical Devices, § 20.1 and per the Physician Fee Schedule CY2014 Final Rule.
- Documents to be submitted include the following:
  - Request letter that includes the scope and nature of the study and how the study meets the Medicare Coverage IDE Study Criteria that is consistent with the previously mentioned seven desirable characteristics and deemed trials and is provided in the next slide
  - FDA approval letter
  - IDE study protocol
  - One IRB approval letter
  - NCT number
  - Supporting documentation, as appropriate
- CMS will post IDE study approvals on the CMS Coverage website. Healthcare providers and Medicare Contractors must check the site prior to submitting claims or making payment.
- https://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies.html

Overview of the Regulations and Guidelines

Medicare Claims Processing Manual, Chapter 32

Type of Study	Hospital Charges (UB-04) Inpatient Claims	Hospital Charges (UB-04) Outpatient Claims	Professional Charges (CMS-1500)
Qualifying Clinical Trial **Medicare Clinical Trial Policy** • Instructions apply to conventional care, including treatment of complications • Billing provider must include in the medical record the following information: trial name, trial sponsor, and sponsor-assigned protocol number	• *ICD-10 diagnosis code Z00.6* as the secondary diagnosis code for trial participation • *ICD-10 diagnosis code Z00.6* as the primary diagnosis code for healthy controls only • *Condition Code 30* (qualifying clinical trial) reported at the claim level for both trial participants and healthy controls • *NCT#* • Include Z00.6, Condition Code 30 and NCT# regardless of whether all services on the claim are related to the clinical trial or not	• *ICD-10 diagnosis code Z00.6* as the secondary diagnosis code for trial participation • *ICD-10 diagnosis code Z00.6* as the primary diagnosis code for healthy controls only • *Q1 Modifier*- for both participants and healthy controls- apply to each service identified as conventional care only on line items related to the clinical trial • *Q0 Modifier*- for each service identified as investigational • *Condition Code 30* (qualifying clinical trial) reported at the claim level for both trial participants and healthy controls • *NCT#* • Include Z00.6, Condition Code 30, NCT# regardless of whether all services on the claim are related to the clinical trial or not Note: CMS will return claims as unable to process if Z00.6 and NCT# are not on claim with the Condition Code 30	• *ICD-10 diagnosis code Z00.6* as the secondary diagnosis code for trial participation • *ICD-10 diagnosis code Z00.6* as the primary diagnosis code for healthy controls only • *Q1 Modifier*- for both participants and healthy controls- apply to each service identified as conventional care only on line items related to the clinical trial • *Q0 Modifier*- for each service identified as investigational • *NCT#* preceded by “CT”

Overview of the Regulations and Guidelines

Affordable Care Act

The Affordable Care Act (ACA) refers to two separate pieces of legislation – the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 – that, together expand Medicaid coverage to millions of low-income Americans.

Impact of the Affordable Care Act on Clinical Trials

Section 2709 applies to all approved clinical trials. An approved clinical trial, as **defined in the statute**, is a **phase I, II, III, or IV** clinical trial that relates to the **prevention, detection or treatment of cancer or other life-threatening diseases** that also satisfies one of three requirements:

1. The trial is **federally funded**;
2. The trial is conducted under an **investigational new drug application**; *or*
3. The trial is **exempt from such an investigational new drug application**.

Overview of the Regulations and Guidelines

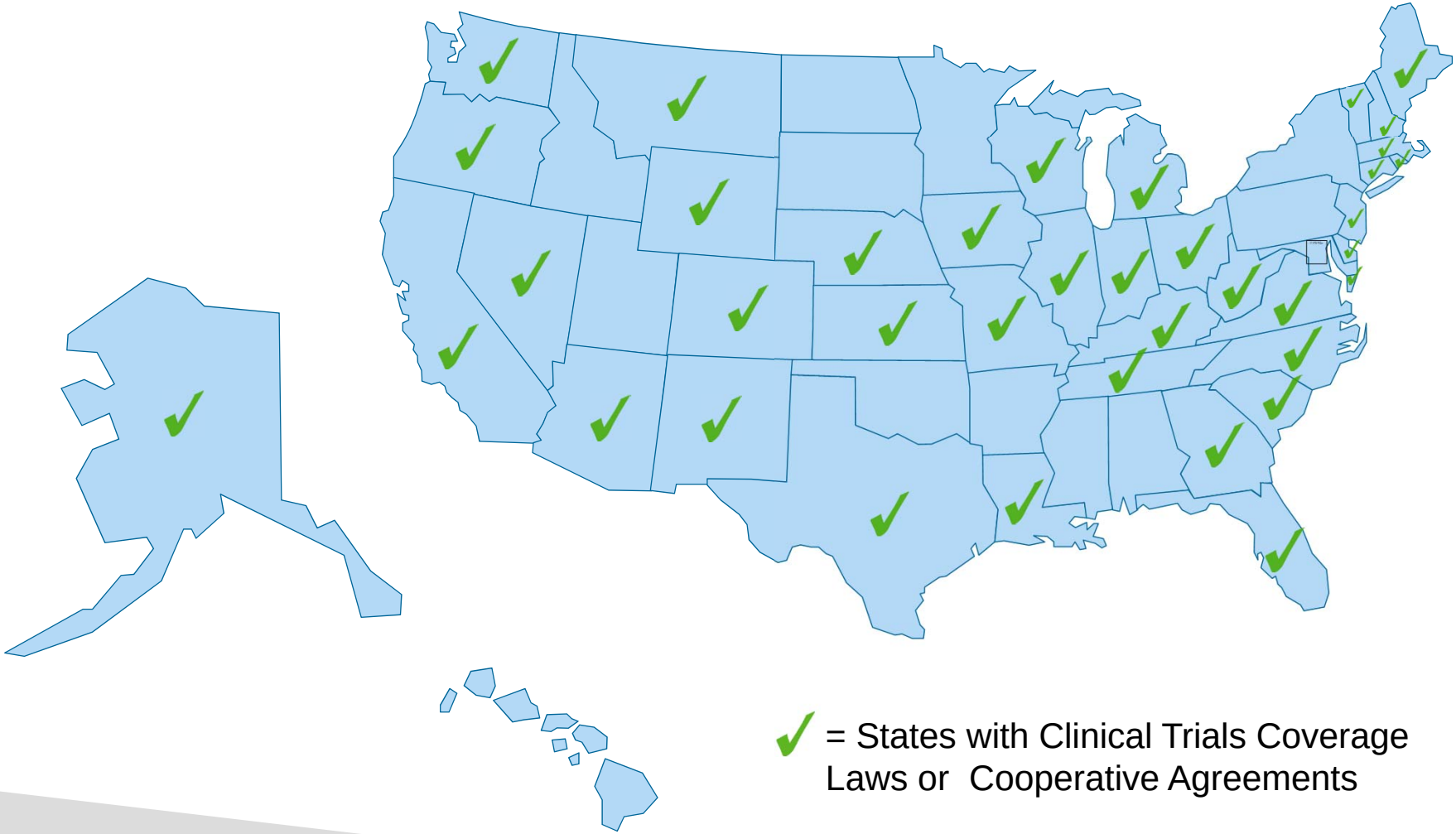
Affordable Care Act

In a provision of the "Act," insurers are prohibited from denying or limiting coverage for routine clinical care for individuals enrolled on a clinical trial **that would otherwise be provided if the individual was not a study participant.** If a group health plan or a health insurance issuer offering group or individual health insurance coverage provides coverage to a qualified individual, then such plan or issuer may not:

1. Deny the individual participation in the clinical trial;
2. Deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and
3. Discriminate against the individual on the basis of the individual's participation in such trial.

Overview of the Regulations and Guidelines

States with Laws Related to Clinical Trials



✓ = States with Clinical Trials Coverage Laws or Cooperative Agreements

Source: http://www.asco.org/insurance-coverage-clinical-trial-participants

Overview of the Regulations and Guidelines

Other Billing Considerations for Clinical Trial Participation

- Many states have laws related to clinical trials coverage or cooperative agreements.
  - Understand applicable state regulations
- Certain commercial payers have started to release their own versions of Clinical Trial Policies, some of which follow Medicare's CTP in detail.
- Conduct a periodic review of the top payers at your institution to see if new policies or guidelines have been released. Certain payers have policies consistent with the CMS Clinical Trial Policy
  - Aetna Policy # 0466: Clinical Trials, Coverage of Routine Patient Care Costs
    - http://www.aetna.com/cpb/medical/data/400_499/0466.html
  - UnitedHealthcare: Routine Costs in a Clinical Trial (NCD 310.1)
  - https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Main%20Menu/Tools%20&%20Resources/Policies%20and%20Protocols/Medicare%20Advantage%20Reimbursement%20Policies/R/RoutineCostsClinicalTrials_NCD310-1_02042013.pdf

Conducting a Coverage Analysis

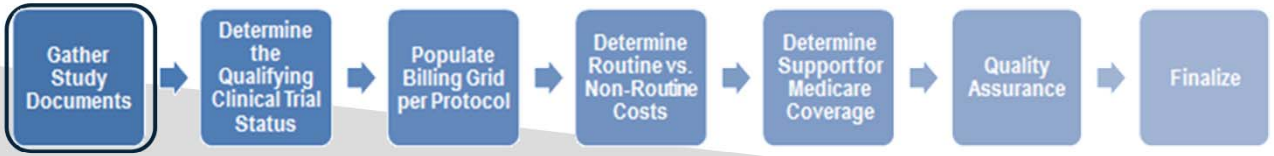
Qualifying Clinical Trials

Conducting a Coverage Analysis

Gather Study Documents

Before starting the Coverage Analysis, gather the latest versions of the following study documents from the study team, Clinical Research Administration department or electronically through your institution's intranet:

- Protocol
- Informed Consent Form (ICF)
- Clinical Trial Agreement (CTA)
- Investigator's Brochure (IB)
- FDA Investigational New Drug (IND)
- Device approval letter from the FDA
- MAC / CMS IDE approval letter / online documentation providing approval for billing
- Draft Internal Budget
- Supporting Documentation from the study team, such as the IRB Approval Letter



Conducting a Coverage Analysis

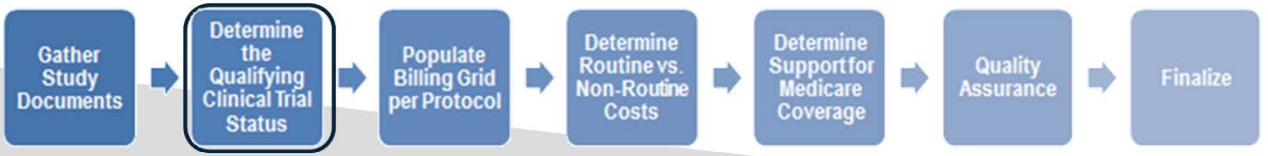
Determine Qualifying Status

1. The evaluation of the trial's item or service must fall within a Medicare Benefit Category

2. The trial must have therapeutic intent, and not be designed exclusively to test toxicity or disease pathophysiology

3. Therapeutic trials must enroll patients with a diagnosed disease. Diagnostic trials may enroll healthy patients to have a proper control group

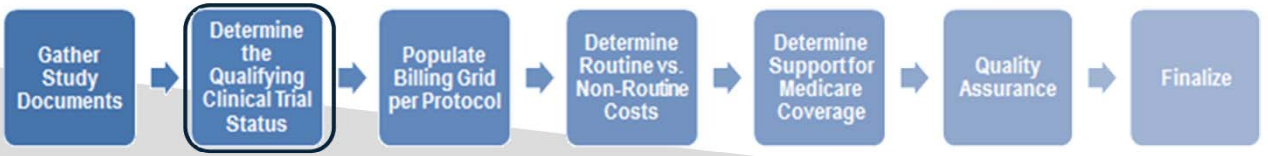
4. Must meet the seven desirable characteristics



Qualifying Clinical Trials

Non-Qualifying Clinical Trials

- If the trial does not meet the four mandatory criteria or is not deemed through Sponsor type, IND application, or 21 CFR 312.2 exemption, claims should not be submitted to Medicare for coverage of the routine costs.
  - However, in some cases, institutions may determine that if protocol driven (and medically necessary) services would have occurred regardless of participation in a clinical trial, Medicare should still be billed regardless of the non-qualifying status.
- Steps to take when a non-qualifying trial is identified:
  - Inform the PI and study team the trial is a non-QCT; and
  - Encourage re-negotiation of the CTA/budget with the sponsor to provide additional funding for items previously believed to be covered (when applicable).
    - ➢ If not done, the institution may need to cover the remaining costs.
- As a reminder, the CTP states Medicare beneficiaries enrolled in a non-qualifying clinical trial are not held liable if the trial was misrepresented as qualifying.



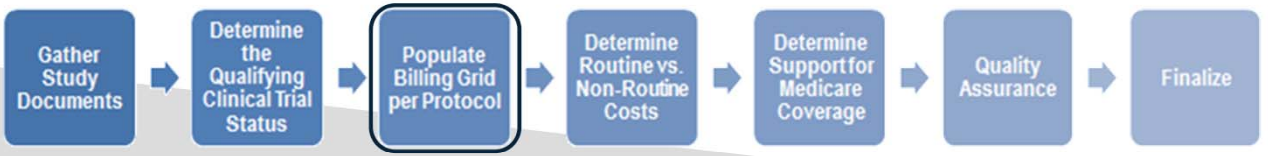
Conducting a Coverage Analysis

Developing the Billing Grid

Developing the Billing Grid

Populate Billing Grid with Protocol Driven Items and Procedures

- Read through all study documents, with a focus on the Protocol and ICF, to familiarize yourself with the study.
  - Within the Protocol, review the ‘Schedule of Events’, ‘Study Treatment’ and ‘Study Procedures’ sections in detail. Review the footnotes related to the ‘Schedule of Events’
  - Take note of items and procedures that are listed as “required” for all patients in any section of the Protocol or ICF but may not be specifically listed in the ‘Schedule of Events’
    - Examples include:
      - Pre-medications
      - Administration of a study drug
      - Collection procedures (venipuncture, biopsy)



Developing the Billing Grid

Populate Billing Grid with Protocol Driven Items and Procedures

Billing Grid

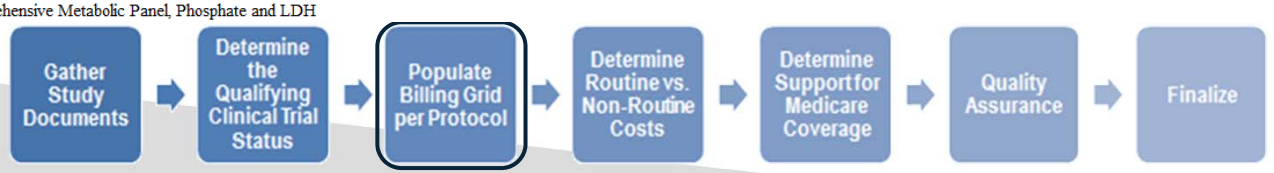
	Protocol Related Items and Services	Location in Protocol or ICF	CPT / HCPCS Codes	Q0 or Q1 Modifier ?	Visit Schedule									
						Treatment Visits								
					Screening	Cycle 1 Day 1	Cycle 1 Day 7	Cycle 1 Day 14	Cycle 2 Day 1	Cycle 2 Day 7	Cycle 2 Day 14	End of Treatment	Disease Assessment Visit	Survival Assessment Visit
1	Informed Consent and, if applicable, HIPAA				X									
2	Tissue (Submission)				X			X	X	X	X	X	X	X
3	Medical History				X	X		X	X	X	X	X		
4	Physical examination				X	X		X	X	X	X	X		
5	Vital signs				X	X		X	X	X	X	X		
6	ECOG performance status				X	X		X	X	X	X	X		
7	Electrocardiogram (ECG)				X	X								

Protocol - Schedule of Events

Visit	Screening	Trea								
		Cycle 1 Day 1	Cycle 1 Day 7	Cycle 1 Day 14						
Informed Consent and if, applicable, HIPPA	X									
Tissue (Submission)	X			X	X	X	X	X	X	X
Medical history	X	X		X	X	X	X	X		
Physical examination	X	X		X	X	X	X	X		
Vital signs	X	X		X	X	X	X	X	X	
ECOG performance status	X	X		X	X	X	X	X		
Electrocardiogram	X	X								
Pregnancy test	X	X								
Hematology[1]	X	X	X	X	X	X	X	X		
Blood Chemistry[2]	X	X		X	X	X	X	X		
Urinalysis	X	X				X		X		
Randomization	X									
Administration of study treatment		X	X	X	X	X	X			

[1] Hematology includes CBC with Differentials

[2] Blood Chemistry includes Comprehensive Metabolic Panel, Phosphate and LDH

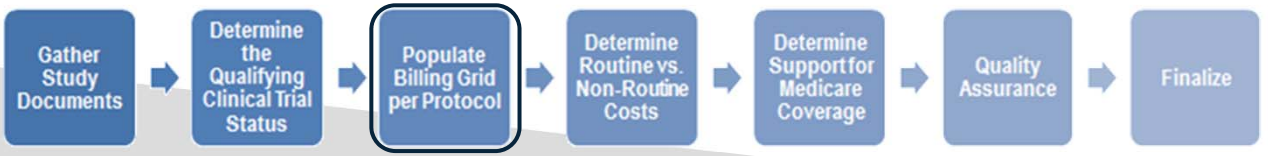


Developing the Billing Grid

Populate Billing Grid with Protocol Driven Items and Procedures

- Populate the CPT / HCPCS Codes column, if applicable.
  - Reach out to the study team and / or the Coding Department if you need assistance
  - Utilize 'N/A' or leave the field blank for Time & Effort items, such as Informed Consent or Adverse Events, as there is no CPT / HCPCS codes associated with Time & Effort
  - Similarly, if an item is sent to a Central Laboratory, there is also no CPT / HCPCS code because the test will be performed at a external research laboratory which will not generate a billable charge

	Protocol Related Items and Services	Location in Protocol or ICF	CPT / HCPCS Codes
1	Informed Consent and, if applicable, HIPAA	p. 15	N/A
2	Tissue (Submission)	p. 15	N/A
3	Medical History	p. 15	N/A
4	Physical examination	p. 15	99201-99215, 99241-99245, G0463
5	Vital signs	p. 15	N/A
6	ECOG performance status	p. 15	N/A
7	Electrocardiogram (ECG)	p. 15	93000-93010



Developing the Billing Grid

Designations and Definitions

- Develop designations and definitions that meet your institution's needs and add to the Billing Grid.
- During the analysis, these designations will replace the 'X' on the Billing Grid and provide guidance to those who conduct charge segregation.
- Below is an example of commonly seen designations and their descriptions:

Designations	Descriptions	Examples
S	Routine Cost (Standard of Care): Item is a routine cost based on Medicare guidelines. This item can be billed to the insurance or patient.	IV Administration, Physical Exam
R	Non-Routine Cost (Research): Item is billable but being performed for research purposes only. This item should or is paid for by the sponsor.	Investigational Drug, PK Sample
NB	Non-Billable: Item is non-billable and is included as part of sponsor-paid research staff time.	Adverse Events, Randomization

Developing the Billing Grid

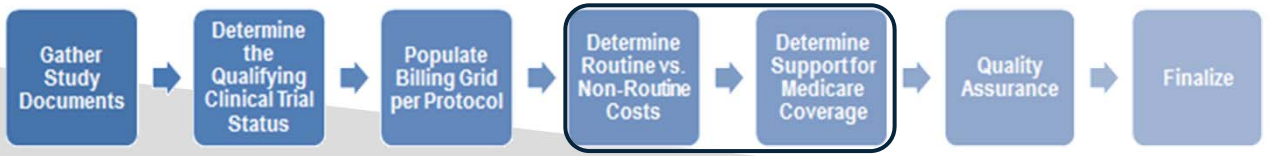
Clinical Trial Policy – Routine Costs Versus Non-Routine Costs

- Medicare considers a **routine cost** (also known as standard of care or conventional care) to be any item and service that would have otherwise been available to the beneficiary regardless of clinical trial participation.
- To determine if a cost is considered routine, review established conventional care references, such as the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology, which is an evidence-based and consensus-driven document that strives to ensure that all patients will receive optimal outcomes.
- The routine cost must be a Medicare covered benefit and considered medically necessary.
- The routine cost may be affected by the Local Coverage Determinations (LCDs), the National Coverage Determinations (NCDs), the CEDs, or the regulations on Category B IDEs.
  - Ensure you have the most up-to-date information by periodically reviewing the CMS website for updates.

Developing the Billing Grid

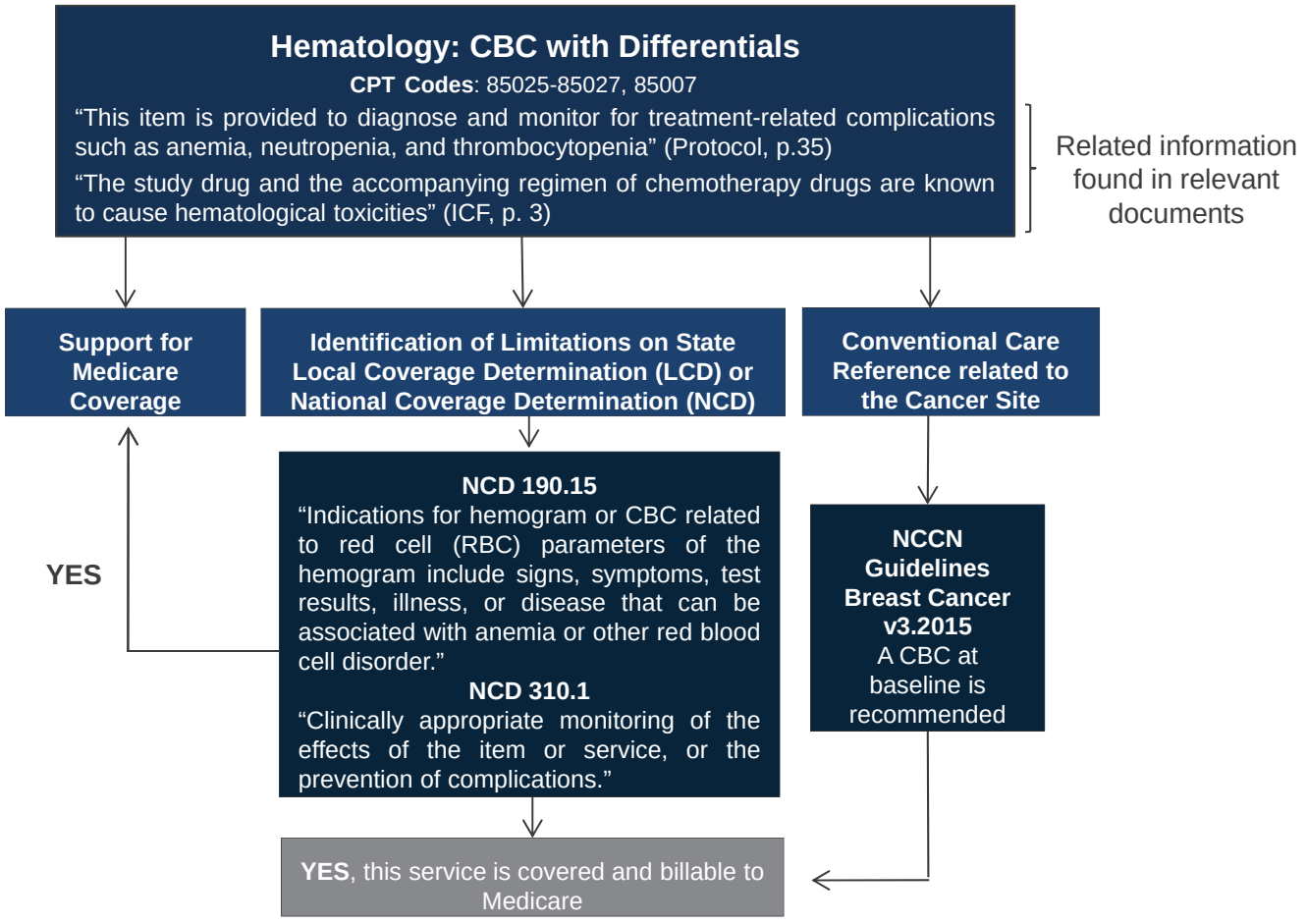
Determine Routine Costs and Support for Medicare Coverage

- Review the Protocol and ICF to understand why the test / procedure is being done.
  - Information may be provided in the Adverse Events and Inclusion / Exclusion Criteria sections.
- Determine if there is a conventional care reference that would support the item or procedure to be done as frequently as required by the Protocol.
  - References: NCCN Guidelines for Oncology, AHA Guidelines, NCBI (PubMed) Articles, etc.
- Identify NCDs, LCDs and / or text description by searching on the Medicare Coverage Database using the identified CPT / HCPCS Codes in the search engine (https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx). This will determine whether coverage is excluded or limited.
- Verify the item / service is a covered benefit by reviewing the Medicare Benefit Policy Manual.
- If the item / service appears to be done for research-related purposes (no support through conventional care references, the CTP or Protocol), but the CTA and Budget does not list the item / service, designate the item as 'R' and leave a Follow-Up item.



Developing the Billing Grid

Determine Routine Costs and Support for Medicare Coverage

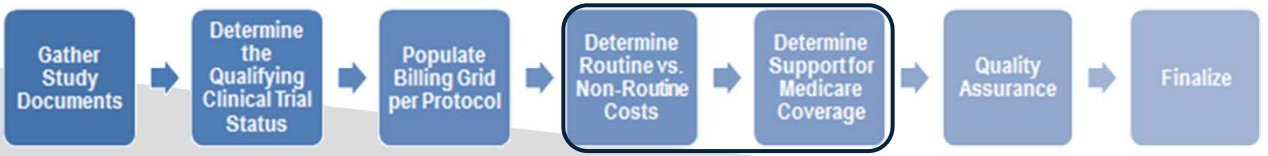


Developing the Billing Grid

Modifier Q1 or Q0

- Add Modifier Q1 or Q0 under the ‘Q0 or Q1 Modifier?’ column.
- If the item is designated as ‘R’, state ‘No’.
- If the item is designated as ‘NB’, state ‘N/A’.

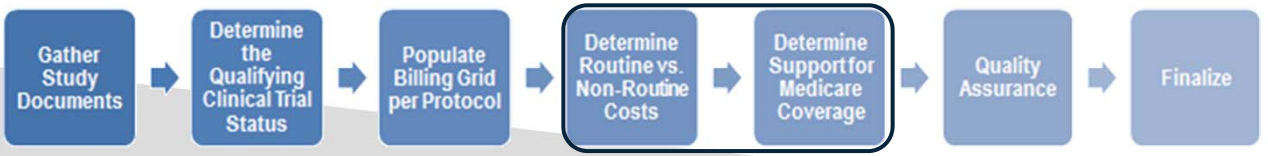
Modifier	Descriptions	Example(s)
Q1	**Routine clinical service** provided in a clinical research study that is in an approved clinical research study • Covered if otherwise coverable by Medicare in a QCT or an approved IDE trial	IV Administration, Pregnancy Test
Q0	**Investigational clinical service** provided in a clinical research study that is in an approved clinical research study • Covered if otherwise coverable by Medicare in a QCT or an approved **Category B** IDE trial	Study Drug



Developing the Billing Grid

Modifier Q1 or Q0

	Protocol Related Items and Services	Location in Protocol or ICF	CPT / HCPCS Codes	Q0 or Q1 Modifier ?	Visit Schedule										Comments
						Treatment Visits									
					Screening	Cycle 1 Day 1	Cycle 1 Day 7	Cycle 1 Day 14	Cycle 2 Day 1	Cycle 2 Day 7	Cycle 2 Day 14	End of Treatment	Disease Assessment Visit	Survival Assessment Visit	
26	Investigational Drug: HCG-0123 (IV)	p. 15	J9999	Q0		R			R	R	R				Per the draft study budget, this item is paid for by the sponsor.
27	Premedication: Aloxi (IV)	p. 15	J2469	No		R			R	R	R				Per the draft study budget, this item is paid for by the sponsor.
28	Premedication: Dexamethasone (IV)	p. 15	J1100	No		R			R	R	R				Per the draft study budget, this item is paid for by the sponsor.
29	IV administration	p. 15	96413, 96415, 96417, 96365, 96366, 96367	Q1		S			S	S	S				This item is required for the provision of IV medications used in the study. Coverage supported by NCD 310.10.
30	Capecitabine (PO)	p. 38	J8520, J8521	Q1		S			S	S	S				According to NCCN guidelines for Breast Cancer (v3.2015), this treatment regimen is considered conventional care.

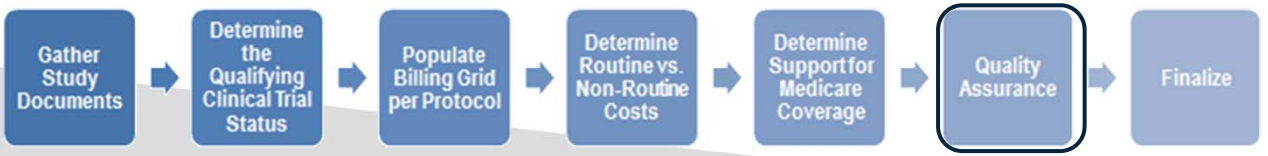


Developing the Billing Grid

Quality Assurance

- Conduct a self-review of the Billing Grid.
  - Compare the 'Protocol List of Items and Services' against the 'Schedule of Events' in the Protocol, ICF, and draft Study Budget to ensure all items and services are captured accurately
  - Review the 'CPT / HCPCS Code Ranges' to ensure consistency and accuracy
  - Review all the Designations to ensure all items and services listed for a specific visit are accurate and consistent with the study documents
  - Review the draft Study Budget, CTA, and ICF to ensure the items paid for by the sponsor are designated appropriately
  - Review the items and services designated as billable to the insurance to ensure there is accurate documentation to support billing to Medicare, any limitations on coverage from the Benefit Policy Manual, NCDs and / or LCDs are document, that complications are referenced appropriately, and / or conventional care is documented

- Appoint a Manager or another employee to conduct a full review of the Coverage Analysis.



Developing the Billing Grid

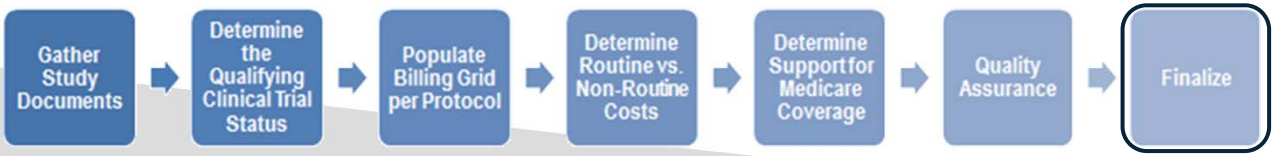
Finalize

1. Request the PI (with additional study team members, if appropriate) review the Coverage Analysis and provide guidance / feedback.

2. Implement any feedback or requested changes into the Coverage Analysis (as long as changes do not conflict with known coverage limitations).

3. Obtain the necessary internal signatures to consider the document as finalized.

4. Provide the Coverage Analysis to other departments or groups.
   - Budget development
   - Charge segregation
   - CTMS calendar building



Resources

Resources

CMS

Clinical Trial Policy (NCD 310.1):

- https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=1&ncdver=2&bc=BAABAAAAAAAA

Claims Processing Manual:

- https://www.cms.gov/regulations-and-guidance/guidance/manuals/internet-only-manuals-ioms-items/cms018912.html

Benefit Policy Manual:

- https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-Ioms-Items/Cms012673.html

Coverage with Evidence (CED):

- https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/

Approved IDE Studies:

- https://www.cms.gov/Medicare/Coverage/IDE/Approved-IDE-Studies.html

CMS Guidance is found in the Benefit Policy Manual (BPM) Chapter 14: Medical Devices

- www.cms.gov/manuals/Downloads/bp102c14.pdf

Resources

Clinical Care Guidelines

National Comprehensive Cancer Network (NCCN):

- http://www.nccn.org

NIH National Cancer Institute (NCI):

- http://www.cancer.gov

American College of Cardiologists / American Heart Association (ACC/AHA) Joint Guidelines:

- http://my.americanheart.org/professional/StatementsGuidelines/Statements-Guidelines_UCM_316885_SubHomePage.jsp

Agency for Healthcare and Research Quality – National Guideline Clearinghouse:

- http://www.guideline.gov

National Center for Biotechnology Information – PubMed:

- http://www.ncbi.nlm.nih.gov/pubmed/

UpToDate, Inc. (Wolters Kluwer)

- http://www.uptodate.com

Resources

Coding and Coverage Determination Software

MedAssets – KnowledgeSource (previously known as CodeCorrect)

- http://www.medassets.com/payors/compliance-and-reference-solutions

MediRegs (Wolters Kluwer) – Compliance & Regulation Suite

- http://www.wolterskluwerlb.com/health/product/mediregs

Optum - EncoderPro:

- https://www.optumcoding.com/Product/20510/