



# Mercy Research

## Billing Compliance & Medicare Coverage Analysis

May 14, 2026

# Today's Agenda



- 1 Research Compliance: Protect your Site and Study Participants
- 2 Medicare: The Driving Force of Billing Compliance
- 3 Coverage Analysis: An Introduction to the Basics
- 4 Practical Use Application: Interpreting the Coverage Analysis
- 5 Questions

\*Please mute yourself and put all questions in the chat

# Insert Poll

**How would you describe your experience with creating, interpreting, or working with a coverage analysis (CA)?**

- A. New to the world of CAs (Beginner)
- B. Comfortably navigating the basics (Intermediate)
- C. CA whisperer (Advanced)

# Insert Poll

**Which U.S. President first executed legislation enabling investigational drug trial coverage for Medicare beneficiaries?**

1. Franklin D. Roosevelt (1944)
2. John F. Kennedy (1962)
3. Bill Clinton (2000)
4. Barack Obama (2012)

# Research Billing Compliance: Protect Your Sites and Study Participants



# History of Research Billing Compliance

Medicare begins to cover routine care items with clinical trials

- 1995 – Medicare covers investigational devices
- 2000 – Medicare’s Clinical Trial Policy Introduced (NCD 310.1)
- 2007 – Updates to Clinical Trial Policy

Institutions/Health Systems begin to receive fines for billing compliance violations

- \$1M-\$4.3M
- Rush, University of Alabama – Birmingham, Cornell, Emory University

Institutions/Health Systems begin to develop coverage analysis process

- Need a system to show what will and will not be billed to the patient/their insurance
- Billing compliance is more than a coverage analysis on file

# Medicare: The Driving Force of Billing Compliance



# Why are Medicare rules used for coverage analysis?

1. Medicare as the driving force for a framework for clinical trial coverage. Most clinical trial billing rules in the United States are generally shaped by the Medicare Program's Clinical Trial Policy and Medicare's device trial coverage regulations.
2. These coverage determinations are considered the "gold standard" on which private insurance carriers base their coverage decisions, although tend to be more limiting than private payors.
3. Many states have adopted clinical trial coverage laws similar to Medicare, Medicare rules may still be cited for research billing consistency.
4. It is not practical to budget on non-Medicare rules since Medicare drives the reimbursement rules in the United States. Medicare incorporates the "most favored nation" clause.

# Medicare Coverage Policies: NCDs vs. LCDs

## NCDs

National Coverage  
Determination

- NCDs set national rules
- Issued by CMS
- Apply to all study sites
- Set the **national standard** for what Medicare covers
- Take precedence over LCDs

## LCDs

Local Coverage  
Determination

- LCDs apply those rules locally
- Issued by local Medicare contractors (MACs)
- Apply only to your site's region
- Clarify coverage details
- Cannot conflict with NCDs, provides local guidance no NCD exists

# NCD 310.1

## Routine Costs in Clinical Trials

### Routine Costs in a clinical trial include:

- Items or services required solely for the provision of the investigational item or service (e.g., administration)
- The clinically appropriate monitoring of the effects of the item or service, or the prevention of complications
- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service
- Items and services typically provided absent a clinical trial (**conventional care**)
- **“Conventional Care” does not equate to “Standard of Care”**

## Conventional (Routine) Care vs. PI Preferred Treatment (SOC)

### CMS Conventional Care

- Services/items provided whether or not a clinical trial exists
- Based on published guidelines and established medical practice
- Determines what Medicare will pay for in a trial
- Legally binding for Medicare billing

### PI Preferred Treatment (SOC)

- Based on physician/institutional treatment preferences
- May vary by region, facility, or provider
- Does not determine Medicare coverage

**Medicare coverage is based on conventional (routine) care – not PI preference**

**According to NCD 310.1, which of the following best defines a “routine cost” in a clinical trial?**

- A. Any service labeled as “standard of care” in the study protocol
- B. Services provided only because the patient is enrolled in a trial
- C. Items or services that would typically be provided absent a clinical trial
- D. Any service the PI considers medically appropriate

**Which of the following services is MOST likely considered a routine cost under NCD 310.1?**

- A. Extra blood draws collected only for pharmacokinetic research
- B. Imaging performed solely to meet a protocol endpoint
- C. Lab tests needed to monitor for medication toxicity
- D. Data collection questionnaires

# Coverage Analysis: An Introduction to the Basics



# What is Medicare Coverage

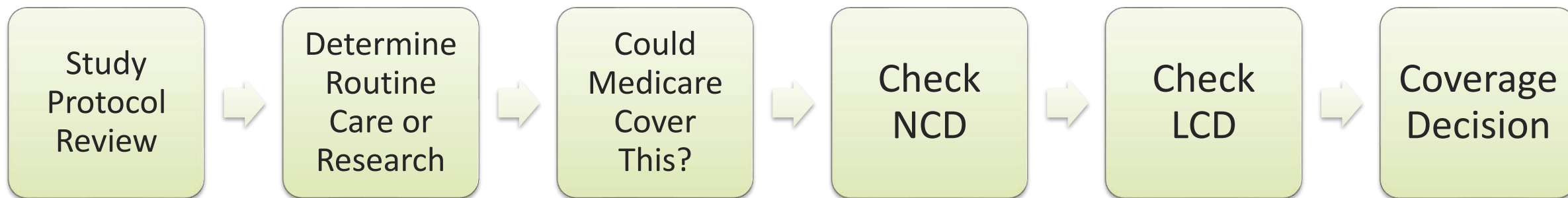
## Analysis?

A detailed listing of all potential billable patient care items and service required for a clinical trial.

The CA is one of the most useful documents for building a clinical trial budget and ensuring billing compliance.

Items and Services	Protocol Location	CPT/ HCPCS Codes	Screening	Treatment				EOT Visit	Safety Follow-up	Unscheduled Visit	Analysis		
				Cycle 1	Cycle 2	Cycle 3	Cycle 4+						
				D1								+7D <sup>2</sup>	+7D
				-28 to -1D									
<b>Time &amp; Effort</b>													
Informed Consent	Prot. P. 31-34	N/A	R								<b>All Visits:</b> This item is paid for by the sponsor (Sponsor Budget).		
Inclusion/Exclusion Criteria	Prot. P. 31-34	N/A	R							R-Inv	<b>All Visits:</b> This item is paid for by the sponsor (Sponsor Budget).		
Concomitant Medications and Procedures	Prot. P. 31-34	N/A	R	R	R	R	R	R	R	R-Inv	<b>All Visits:</b> This item is paid for by the sponsor (Sponsor Budget).		
ECOG Performance Status	Prot. P. 31-34	N/A	R	R	R	R	R	R	R	R-Inv	<b>All Visits:</b> This item is paid for by the sponsor (Sponsor Budget).		
<b>Local Labs</b>													
CBC with Differential and Platelets <sup>6</sup>	Prot. P. 31-34	85025, 85007, 85027	R	S(Q1)	S(Q1)	S(Q1)	S(Q1)	R	R	R-Inv	<b>Screening, EOT Visit, Safety Follow-up:</b> This item is paid for by the sponsor (Sponsor Budget). <b>Treatment:</b> According to NCD 190.15, a CBC is indicated to monitor blood counts in patients diagnosed with malignant neoplasms and receiving therapeutic agents. A CBC once per cycle is reasonable and necessary to monitor the patient's cancer.		
Comprehensive Metabolic Panel <sup>6</sup>	Prot. P. 31-34	80053	R	S(Q1)	S(Q1)	S(Q1)	S(Q1)	R	R	R-Inv	<b>Screening, EOT Visit, Safety Follow-up:</b> This item is paid for by the sponsor (Sponsor Budget). <b>Treatment:</b> A CMP once per cycle, prior to an infusion, is reasonable and necessary to monitor the patient's cancer during treatment.		

# Coverage Analysis Workflow



NCCN and other guidelines inform routine care determination but do not override NCDs or LCDs

For example, NCCN may recommend CT imaging every 8-12 weeks for a cancer type. That helps us call the CT scan routine care...but whether Medicare pays for it depends on NCD and LCD criteria

# Approach to Protocol Review

Review the Schedule of Events including footnotes  
Do not assume these are the only protocol required items!

Examples:

- Are the labs being done locally or centrally?
- Which labs specifically are required (“chemistry” is not a lab 😊)
- Is hospitalization required?
- What types of imaging can be done?
- Are other medications and/or supportive medications required?
- Are central reads required and/or response assessments?
- How many PK are required at a visit? Will a room need to be used for extended PK time periods?

\*Items promised free

Check the ICF and protocol (example: study drugs or other medications)

**It is worth your time (and budget) to check for other protocol requirements!**

# Practical Use Application: Interpreting the Coverage Analysis



# Billing Designation Key

- **Standard of Care (SOC) / Routine Care / Routine Cost**  
Items or services billable to Medicare, third-party insurance, or the patient.
- **Research**  
Items or services that are protocol-required and paid directly by the study sponsor.
- **Research Invoiceable**  
Sponsor-paid items or services that require separate invoicing outside of routine per-patient payments.
- **Non-Billable**  
Items or services not billed on a claim, including:
  - Bundled services (not separately billable)
  - Items provided at no charge (e.g., study drug)
- **Split Designation (SOC / Research)**  
Items or services that may be billable to insurance under certain circumstances and sponsor-paid in others.  
*Common example:*  
Imaging performed at Screening, where billing determination depends on the screening window and timing of the most recent SOC scan

# Practical Use: Example 1

## Split Billing Designations

Items and Services	Protocol Location	CPT/ HCPCS Codes	Screening	Treatment			EOT Visit	Tumor Evaluation Visit After Cycle 3	Survival Follow-Up with ePRO (can be completed via phone call)	Unscheduled Visit	Analysis
				Cycle 1	Cycle 2	Cycle 3+					
CT Scan (chest) <sup>9</sup>	Prot. P. 31-34	71250, 71260, 71270	S(Q1)/R-Inv			R-Inv		S(Q1)R-Inv (Q6W for 30W, then Q12W)		R-Inv	<p><b>Screening:</b> Either a CT scan or an MRI may be performed (Protocol, p. 84). According to the NCCN Imaging Appropriate Use Criteria, "Small Cell Lung Cancer," v.2.2026, ("NCCN AUC"), this scan is conventional care at diagnosis (NCCN AUC). Therefore, this scan is reasonable and necessary for the clinical management of the patient at screening. Coverage supported by NCD 220.1.</p> <p>If this scan falls outside of the patient's SOC window at screening, then this item is used for research purposes and is not billable at screening.</p> <p><b>C3 Treatment Visit and Beyond:</b> Screening: Either a CT scan or an MRI may be performed (Protocol, p. 84). According to the NCCN Imaging Appropriate Use Criteria, "Small Cell Lung Cancer," v.2.2026, ("NCCN AUC"), this scan is conventional care every 8-12 weeks to monitor tumor response (NCCN AUC). Therefore, this scan is reasonable and necessary for the clinical management of the patient at select Tumor Evaluation Visits. Coverage supported by NCD 220.1.</p> <p>If this scan falls outside of the patient's SOC window at screening, then this item is used for research purposes and is not billable at screening.</p> <p><b>Unscheduled Visit:</b> This item is reimbursed by the sponsor upon invoice (sponsor budget).</p>

# Practical Use: Example 2

## Conditional Footnotes

Protocol Required Items	CPT/HCPCS Codes	Research Modifier	Screening <sup>1</sup>	Chemotherapy (Cycle = 3 Weeks) <sup>2</sup>				Maintenance Therapy (Cycle = 4 Weeks) <sup>2</sup>			Follow-up Period EOT	Billing Analysis
				C1D1	C2D1	C3D1	C4D1 <sup>22</sup>	C5	C6	C7+		
				Week 0	Week 3	Week 6	Week 9	Week 12	Week 15/16 <sup>24</sup>	To Disc. (q4w) 20 to PD <sup>23</sup>		
<b>Time &amp; Effort</b>												
Informed Consent <sup>3</sup>	N/A	No	R									This item is paid for by the Sponsor (Sponsor Budget).
Inclusion/Exclusion Criteria	N/A	No	R	R <sup>4</sup>								This item is paid for by the Sponsor (Sponsor Budget).
Randomization	N/A	No		R <sup>5</sup>								This item is paid for by the Sponsor (Sponsor Budget).
AE/SAE Review	N/A		R	R	R	R	R	R	R	R	R	This is not a billable item or service.
<b>Local Labs</b>												
CBC with Differential and Platelets <sup>9</sup>	85025, 85007, 85027	No	R	R-Inv <sup>10</sup>	R	R	R	R	R	R	R	This item is paid for by the Sponsor (Sponsor Budget).
Comprehensive Metabolic Panel <sup>9</sup>	80053	No	R	R-Inv <sup>10</sup>	R	R	R	R	R	R	R	This item is paid for by the Sponsor (Sponsor Budget).

Footnote 10: If screening laboratory assessments are performed within 3 days prior to Day 1 (first infusion day), they do not need to be repeated at Day 1 (Protocol, p. 53).

# Practical Use: Example 3

## Provided Study Drug and IV Administration

Protocol Required Items	CPT/HCPCS Codes	Research Modifier	Screening <sup>1</sup>	Chemotherapy (Cycle = 3 Weeks) <sup>2</sup>				Maintenance Therapy (Cycle = 4 Weeks) <sup>2</sup>			Follow-up Period EOT	Billing Analysis
				C1D1	C2D1	C3D1	C4D1 <sup>22</sup>	C5	C6	C7+		
				Week 0	Week 3	Week 6	Week 9	Week 12	Week 15/16 <sup>24</sup>	To Disc. (q4w) 20 to PD <sup>23</sup>		
<b>Study Medications or Study Device</b>												
Durvalumab (IV)	J9173	Q0		NB	NB	NB	NB	NB	NB	NB		The study drug will be provided by the sponsor (Protocol, p. 88).
IV Administration (Durvalumab)	96413, 96415, 96416, 96417	Q1		S	S	S	S	S	S	S		Coverage for the administration of the investigational agent is supported by NCD 310.1.

### Key Billing Determinations

- The investigational study drug (Durvalumab) is provided at no cost by the sponsor and is therefore Non-Billable (NB).
- IV administration services associated with the study drug are considered routine patient care and are billable to insurance.
- Administration services are supported by Medicare National Coverage Determination (NCD) 310.1, allowing coverage for administration of investigational agents.
- Appropriate research modifiers (Q0/Q1) are applied to distinguish sponsor-provided items from routine care services.

# Practical Use: Example 4

## Bundled Labs

Do not rely on test names alone.

Sponsors may bundle additional or expanded labs within a CMP that are not part of a standard CMP.

These labs should be identified and analyzed separately for coverage and billing purposes.

Items and Services	Protocol Location	CPT/ HCPCS Codes	Screening	Treatment			EOT Visit	Analysis
				Cycle 1	Cycle 2	Cycle 3+		
			-28 to -1D	±3D <sup>1</sup>			+7D <sup>2</sup>	
<b>Local Labs</b>								
Comprehensive Metabolic Panel <sup>6</sup>	Prot. P. 31-34	80053	R	S(Q1)	S(Q1)	S(Q1)	R	<b>Screening, EOT Visit, Safety Follow-up:</b> This item is paid for by the sponsor (Sponsor Budget). <b>Treatment:</b> A CMP once per cycle, prior to an infusion, is reasonable and necessary to monitor the patient's cancer during treatment.
GGT <sup>6</sup>	Prot. P. 31-34	82977	R	R	R	R	R	<b>Screening, Treatment, EOT Visit, Safety Follow-up:</b> This item is paid for by the sponsor (Sponsor Budget).
Direct Bilirubin <sup>6</sup>	Prot. P. 31-34	82248	R	R	R	R	R	<b>Screening, Treatment, EOT Visit, Safety Follow-up:</b> This item is paid for by the sponsor (Sponsor Budget).
LDH (lactate dehydrogenase)	Prot. P. 31-34	83615	R	R	R	R	R	<b>Screening, Treatment, EOT Visit, Safety Follow-up:</b> This item is paid for by the sponsor (Sponsor Budget).
Magnesium <sup>6</sup>	Prot. P. 31-34	83735	R	R	R	R	R	<b>Screening, Treatment, EOT Visit, Safety Follow-up:</b> This item is paid for by the sponsor (Sponsor Budget).
Phosphorus <sup>6</sup>	Prot. P. 31-34	84100	R	R	R	R	R	<b>Screening, Treatment, EOT Visit, Safety Follow-up:</b> This item is paid for by the sponsor (Sponsor Budget).

# Questions?



## Helpful Links

# CMS National Coverage Determination (NCD 310.1)

- **Routine Costs in Clinical Trials (NCD 310.1 – Official CMS Page)**  
<https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=1&fromdb=true>  
[\[cms.gov\]](#)
- **Medicare Clinical Trial Policy Overview (CMS)**  
<https://www.cms.gov/medicare/coverage/approved-facilities-trials-registries/clinical-policies> [\[cms.gov\]](#)

# Investigational Device Exemption (IDE) Coverage

- **Medicare Coverage Related to IDE Studies (CMS)**  
<https://www.cms.gov/medicare/coverage/investigational-device-exemption-ide-studies> [\[cms.gov\]](#)
- **CMS-Approved IDE Studies (Category A & B Listing)**  
<https://www.cms.gov/medicare/coverage/investigational-device-exemption-ide-studies/approved>  
[\[cms.gov\]](#)

# Helpful Links

## Billing & Coding Requirements (NCD 310.1 + IDE)

- **Clinical Trials Coverage and Billing Guide (Noridian MAC)**  
<https://med.noridianmedicare.com/web/jea/topics/claim-submission/clinical-trials-coverage-and-billing-guide>  
[\[med.noridi...dicare.com\]](https://med.noridianmedicare.com)
- **Billing & Coding of Routine Costs (Novitas MAC)**  
<https://www.novitas-solutions.com/webcenter/portal/MedicareJH/pagebyid?contentId=00080347>  
[\[novitas-so...utions.com\]](https://www.novitas-solutions.com)
- **Mandatory Reporting of NCT Number on Claims (CMS Q&A)**  
<https://www.cms.gov/medicare/coverage/coverage-with-evidence-development/downloads/mandatory-clinical-trial-identifier-number-qsas.pdf> [\[cms.gov\]](https://www.cms.gov)