Clinical Research Billing & Compliance
SESSION 2:

How to Begin Building a Coverage Analysis & Tools to Use to Get There

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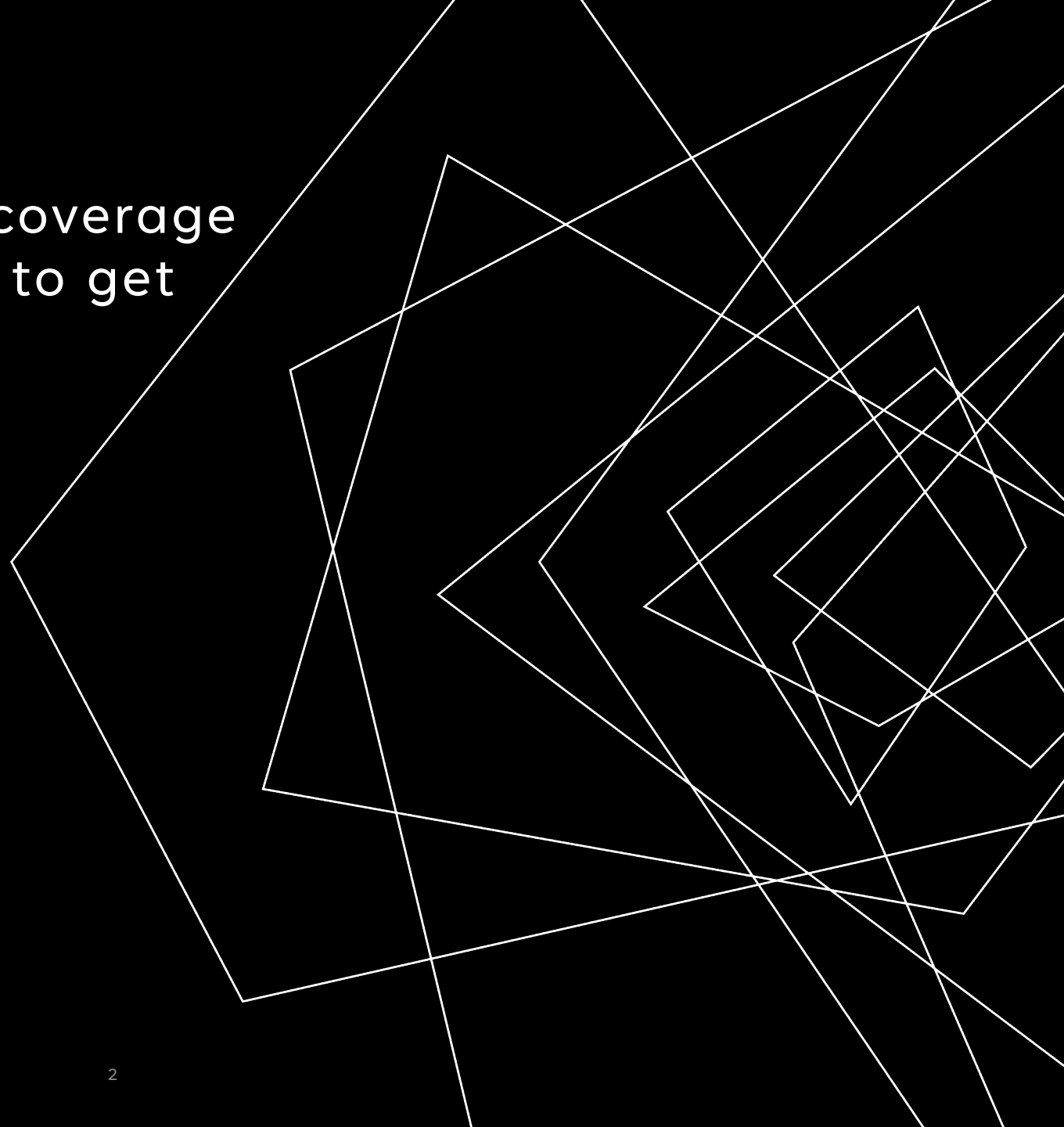
How to begin building a coverage analysis and tools to use to get there.

Objectives:

Process for developing a CA

Understand Routine Costs



WHAT DOES A COVERAGE ANALYSIS INCLUDE

Billing and Service Codes

Required Medicare research modifiers

Designated Funding Source

Technical and Professional charges(Hospital & Physician)

Where do we start?

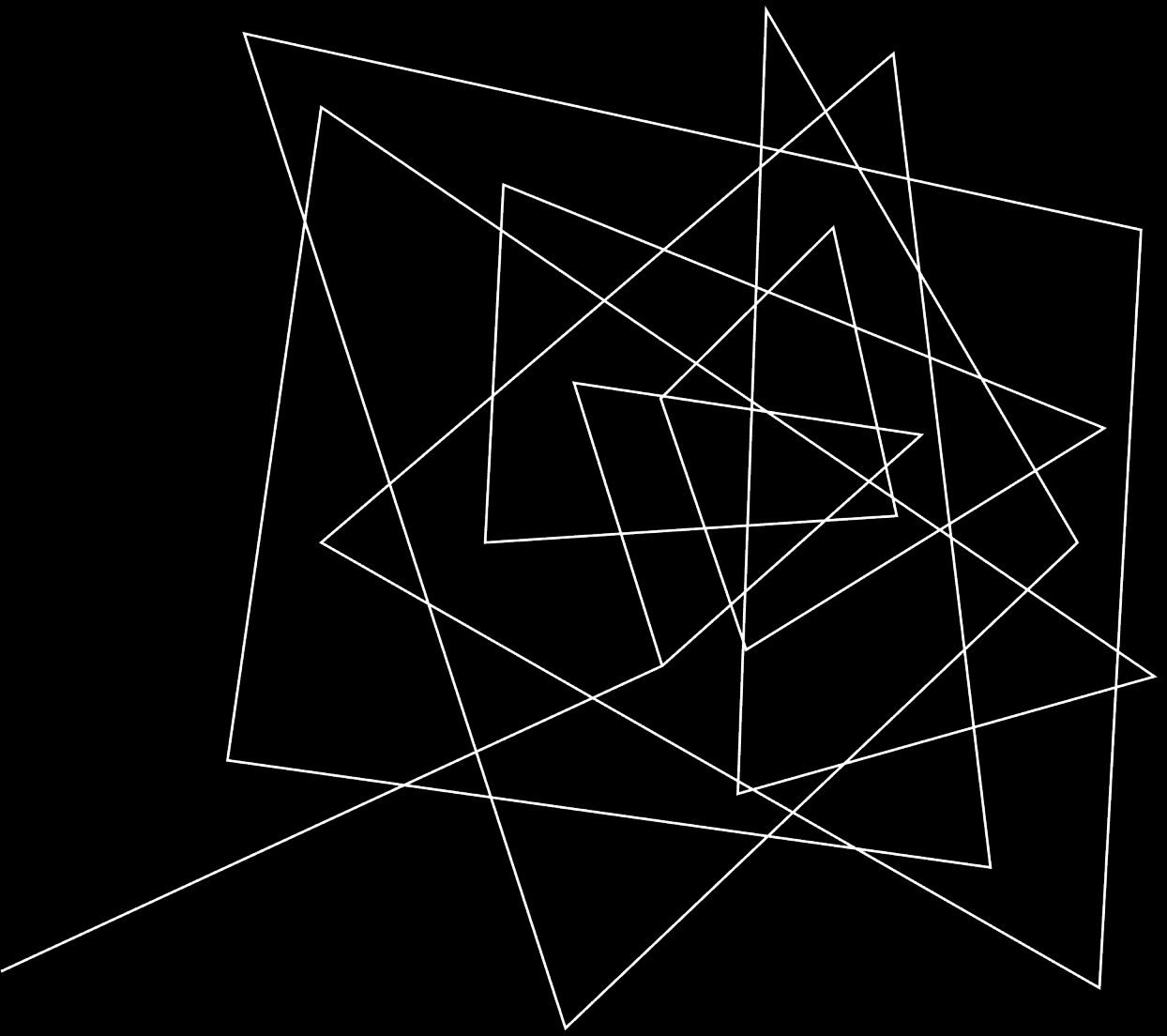
*Gather all of the relevant documents:

Protocol, CTA and budget, ICF, Drug Brochure, lab manual, Case Report Forms, and IND number

What to watch for

*Don’t rely solely on the sponsor’s schedule of benefits

*Don’t rely solely on the sponsor’s budget



CA GRID PROCESS

Read the protocol

*Footnotes

*Sections specific to interventions

*Appendices

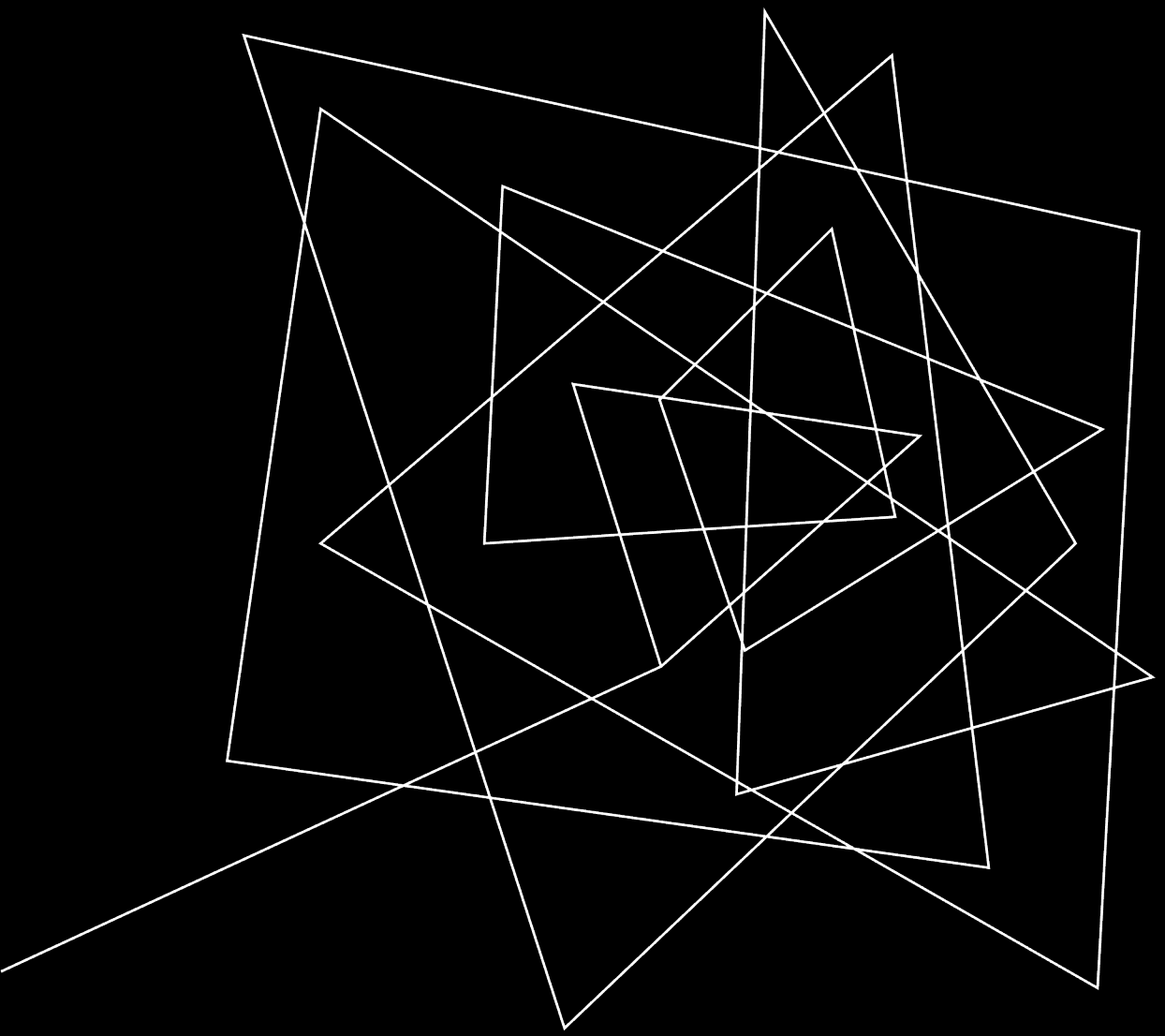
Know equipment supply/requirements and where processing is to occur

Think logically

*Visit schedule

*Services

*Effort



Study Number

Study Title

This Medicare coverage analysis is intended as a general guideline for use in determining which items and services are billable to Medicare based upon current benefit policies, coverage determinations, coverage decisions, and federal guidelines. All items and Services that are billable to Medicare must be supported by medical necessity.

Study Identifying Information and Documents Received

Identifier	Additional Information
Protol Version	
Principal Investigator	
Clinical Department	
Study Sponsor	
FDAIND/IDE Number	
IRB	
ICF Appproval Status and Version	
Clinical Trial Agreement and Version Received	
Sponsor Budget Version	
Clinicaltrials.gov	NCT

Study Number			
Study Title			
This Medicare coverage analysis is intended as a general guideline for use in determining which items and services are billable to Medicare based upon current benefit policies, coverage determinations, coverage decisions, and federal guidelines. All items and Services that are billable to Medicare must be supported by medical necessity.			
Investigation Item or Service Analysis			
Question	Answer		
What is the investigational item or Service?			
What is the FDA status of the investigational item or service?			
If FDA approved, is the investigational item or service being used off-label?			
Qualifying Clinical Trial Analysis			
Question	Yes	No	Comment
Does the investigational item or service fall into a Medicare benefit category?			
Deos the study include therapeutic intent as a primary objective?			
Does the study enroll patient with diagnosed diseases?			
Is the study a deemed trial?			
Is the study a qualifying clinical trial?			

		Eligibility	Treatment					Follow Up			
ASSESSMENT	CPT	Screening	If Eligible, Baseline	SFSID (0 Hour)	24 Hours	48 Hours	72 Hours	96, 144, 192, 240 Hours	120, 168, 216 Hours	Q48 Hours (Days 12-28)	Day 30 (+/- 5 days)
Informed Consent	na	1									
Inclusion & Exclusion Criteria	na	1									
Demographics & Medical History	99201-99205 99211-99215	1									
Concomitant Medications	na	1	1	1	1	1	1	1	1		1
Abdominal Examination	na	1									
Height	na		1								
Weight	na		1				1				1
Vital Signs including SpO2 and FiO2	na	1	1	1	1	1	1	1	1		1
Determine Presence of SIRS	na	1									
Serum Lipase (analyzed at local lab)	83690	1									
CMP_	80053		1		1	1	1		1		1
LDH (analyzed at local lab)	83615		1		1	1	1		1		1
Triglycerides (analyzed at local lab)	84478		1		1	1	1		1		1
Total Cholesterol (analyzed at local lab)	82465		1		1	1	1		1		1
CPK (analyzed at local lab)	82550		1		1	1	1		1		1
Serum Procalcitonin (analyzed at local lab)[a]	84145		1		1	1	1		1		1
CBC+diff+Platelets (analyzed at local lab)[a]	85025	1			1	1	1		1		1
Blood and Urine Sample for Biomarkers (IL-6 and Urine NGAL) (analyzed at central lab)			1		1	1	1		1		1
Blood Sample for											

Routine costs in clinical trials

* “Items or services that are typically provided absent a clinical trial (e.g., conventional care);

* “Items or services required solely for the provision of the investigational item or service (e.g., administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and

* “Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service-in particular, for the diagnosis of treatment of complications.”

CONVENTIONAL CARE

Clinical guidelines provide objective support for determining if an item or service is conventional care

- Professional association guidelines
- Peer reviewed literature
- Significant textbooks
- Disease associations
- NIH recommendations

Administration of investigational item

Could be in the form of Surgery, Infusion, Injection, etc.

Example: Drug X supplied by Sponsor requires intravenous administration
-Drug X: Not covered
-IV administration: Covered

Detecting or preventing complications

Known potential side effects or complications

- Protocol
- Informed Consent
- Product Label

Relationship to the patient’s disease or condition

Record your Reasoning

EKG performed to assess cardiac function.
The study drug is known to have potential cardiac toxicities(protocol, p 46). This test is covered under NCD 310.1 to detect complications.

“All other Medicare rules apply.”

This means that any other Medicare rule that exists which would not cover an item or service outside a research study applies inside a research study.

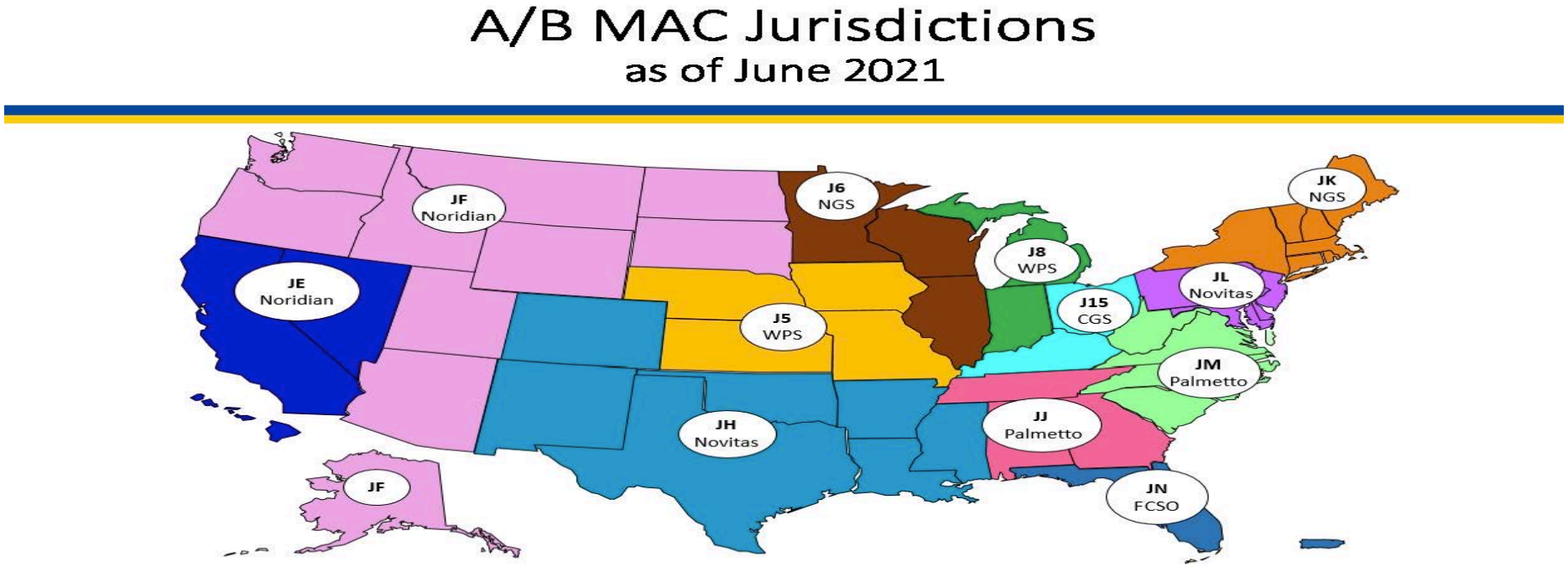
Statutes and Regulations

NCD’s and LCD’s

Medicare Manuals

“Services that are excluded from coverage include routine physical examinations and other services that are not reasonable and necessary for the diagnosis or treatment of an illness or injury.”

MEDICARE ADMINISTRATIVE CONTRACTORS (MAC)



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