Improving Research Billing Outcomes:

The Real Impact of Coverage Analysis Choices

Before We Kick-Off Today's Event…

1

We will be recording today's webinar. **24-hours following the event**, you will receive an email with a link to the recording, as well as a Certificate of Attendance.

2

If at any time during today's broadcast you would like to **submit questions to our speakers**, please ask them in the Q&A section on your screen.

3

We'll answer audience questions at the end of the presentation. **Please submit your questions as you have them.**

Today's Speakers

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Polling Question #1

The Jefferson Enterprise

Key Facts

- Philadelphia's second largest employer
- NCI-Designated Cancer Center
- 10 Colleges
- 4 Schools

Institutional Data

- **18** Hospitals
- **3,876** Licensed Beds
- **3,500** Physicians and Licensed Practitioners
- **42,700 +** Employees
- **6.2 Million** Outpatient Visits
- **$172 Million** Sponsored Research Awards

Jefferson Clinical Research Institute (JCRI)

A centralized research administrative office providing business operations support and clinical operation support to clinical research studies across the enterprise.

Business Operations Primary Functions

1. Contract Negotiations
2. Coverage Analysis
   - Outsourced to WCG
3. Budget Negotiation
4. Post-Award Account Management
   - Accounts Payable
   - Accounts Receivable
5. Clinical Research Billing Review

The Jefferson Enterprise

Started in 2015

- No Electronic Health Record
- No Clinical Trial Management System (CTMS)

2
Hospitals

300
Clinical Research Study Financial Accounts

$8.2 Million
Annual Accounts Receivable

Current State

- Epic serves as Electronic Health Record
- Oncore for CTMS

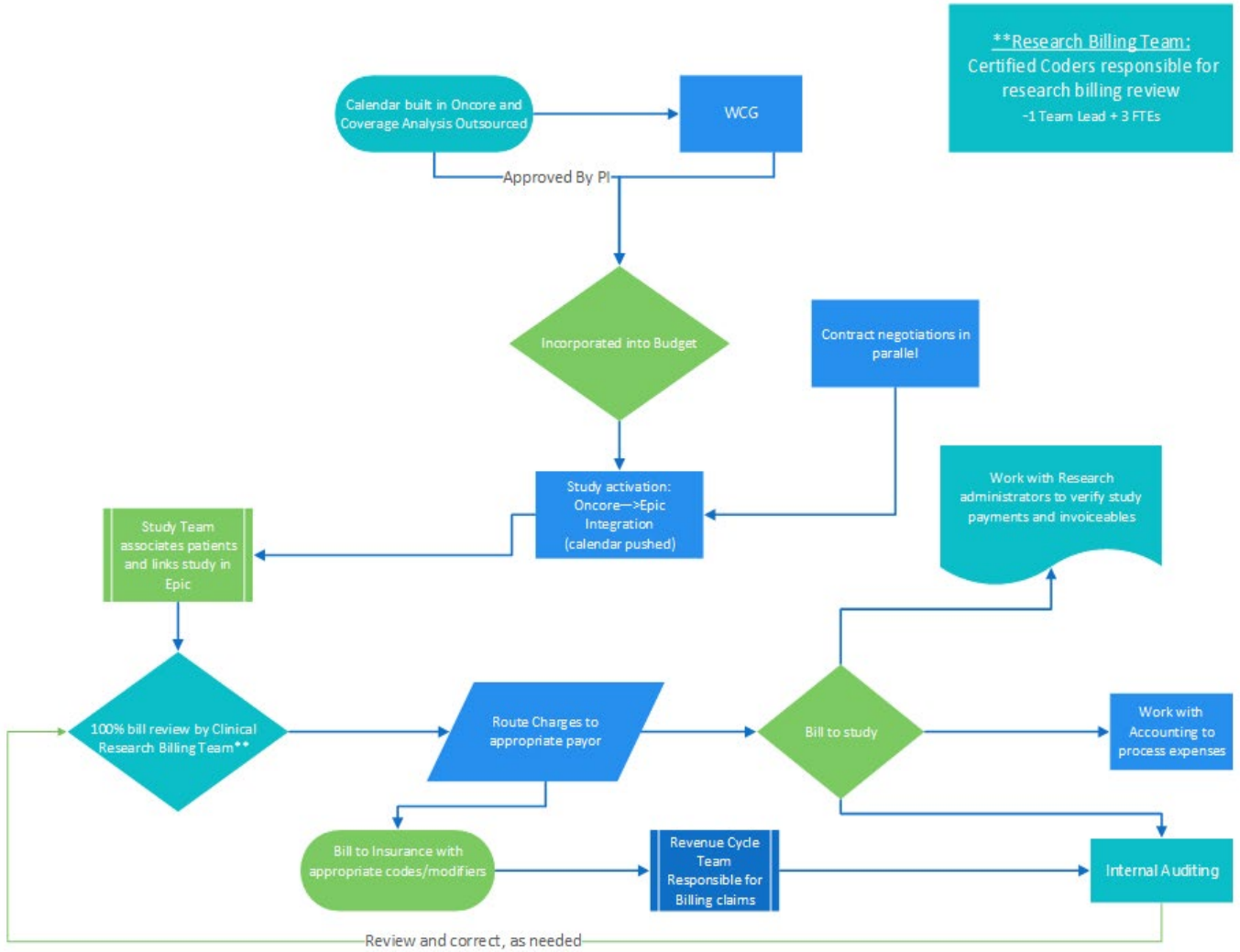
18
Hospitals

779
Clinical Research Study Financial Accounts

847
Clinical Research Studies Requiring Research Review

$18.2 Million
Annual Accounts Receivable

Jefferson Clinical Research Billing Process



Polling Question #2

Overview of Topic:

The Practical Impact of Coverage Analysis

Objectives

1. Discuss challenging research billing scenarios
2. Provide possible front-end solutions to avoid these scenarios
3. Demonstrate the considerations that need to be taken into account

Scenarios

Challenges in Implementing a Coverage Analysis

Scenario 1

A coverage analysis and budget are finalized for a new study. The screening visit contains several items that are paid for by the sponsor but also several items that are billed to insurance including radiological imaging and lab work.

Challenges

- Increased complexity for research billing review
  - Differentiate between regular clinical care and the research study visit
- Window issues for imaging/biopsies
  - Standard of care(SOC)/Invoice(INV)

	Code	Screening Day-28 to Day-1
Informed Consent	INCON	1
Inclusion/Exclusion Criteria	INCEX	1
Complete Physical Examination	99205	SOC
Limited Physical Examination	99212	
Vital Signs (additional to vitals at examination)	T9200	X
Single 12-Lead ECG (includes tracing, interpretation and report)	93000	SOC*
ECOG Performance Status	S0042	SOC*
Tumor Imaging	RDC-TA	SOC/INV
RECIST v1.1	S0145	1
Concomitant Medications	CONMD	1
Adverse Events	ADEVT	1
Clavien-Dindo assessment	S0905	
Serum Pregnancy Test	84702	SOC/INV
Urine Pregnancy Test	84703	
Urinalysis	81001	SOC*
Hematology	85025	SOC*
Serum Chemistry	80053	SOC*
Magnesium	83735	1
Phosphate	84100	1
Amylase	82150	1
Lipase	83690	1
Creatinine clearance	82575	INV
Lipid Panel	T0065	1
Coagulation: INR	INR	SOC*
Coagulation: aPTT	85730	SOC*
TSH	84443	SOC*
Free T4	84439	SOC*
Free T3 (or total T3)	84481	SOC*
C-Reactive Protein	86140	SOC*
HIV test	86689	SOC*
Hepatitis B (HbcAb and (HbsAg) and Hepatitis C	80074	SOC
Hepatitis B: HBsAb	86706	SOC*
EBV test	86664	1
Lactate Dehydrogenase (LDH)	83615	SOC*
Central Laboratory: Blood Draw and Sample Collection of Specimens	36415	1
Central Laboratory: Lab Handling and Shipping	99000	1
Phone Call	98967	

Avoiding a “Screen Failure”

There are several ways that Screening assessments may be approached in the CA:

The Standard
Analyze Screening items and add SOC windows/split designations

The Window Shatterer
Anything that may have an SOC window is to be paid for by the Sponsor

The All or Nothing
Everything that is performed at Screening is to be paid for by the sponsor

The Not Included in the Above List

Polling Question #3

Scenario 2

A newly negotiated budget and coverage analysis for a new study requires outpatient chemotherapy intravenous (iv) infusion. There is an investigational agent and a standard of care (SOC) chemotherapy being administered during the same outpatient visit. The sponsor is providing the investigational drug at no cost and paying for its administration. The SOC chemotherapy and its administration are deemed billable to insurance.

Challenges

- Research Billing complexities
  - Which IV admin charges are with which chemotherapy agent?
  - Who pays for the ancillary costs? (saline, pre-medications)
- If charges are split incorrectly, it could lead to denied claims
  - May be possible but challenging and additional work on revenue cycle teams

Procedure	Study Src	Qty
SODIUM CHLORIDE PER 500 ML		1
SODIUM CHLORIDE 0.9 %		20
SODIUM CHLORIDE PER 500 ML		1
SODIUM CHLORIDE 0.9 %		20
SODIUM CHLORIDE PER 500 ML		100
26096375-HC THER/PROPH/DIAG IVP EA AD		2
26096368-HC THER/DIAG CONCURRENT INF		1
33196411-HC CHEMO IV PUSH ADDL DRUG		1
33596413-HC CHEMO IV INFUSION 1 HR		1
IRINOTECAN PER 20 MG		12
ATROPINE PER 0.01 MG		25
ATROPINE PER 0.01 MG		25
LEUCOVORIN 100 MG RECON SOLN 1 EACH VIAL		2
LEUCOVORIN 200 MG RECON SOLN 1 EACH VIAL		4
LEUCOVORIN CALCIUM PER 50 MG		7
DEXAMETHASONE PER 1 MG		12
PALONOSETRON PER 25 MCG		10
BEVACIZUMAB-BVZR 25 MG/ML SOLUTION 4 ML VIAL		30
94096372-HC THER/PROPH/DIAG INJ SC/IM		1
26096372-HC THER/PROPH/DIAG INJ SQ/IM		1

SOC IV: A (Hopefully Not) New Hope

There are several ways that Screening assessments may be approached in the CA:

Analyze each infusion on its own

- May result in both SOC and research infusions at the same visit
- If there are multiple infusion billing designations, this should be discussed with study team/billers

Make all infusions SOC

- This may cause billing issues if the drug is not considered SOC
- Some sites apply NCD 310.1 infusion coverage across all drugs in a trial

Make them pay!

If one infusion is research-related and/or sponsor paid, they all should be

Don't forget about pre-medications!

Scenario 4

A new study is designed so that part of the eligibility criteria requires a patient be scheduled to undergo a procedure that requires an inpatient admission. The inpatient admission is therefore deemed billable to insurance in the CA and budget. The sponsor has offered to pay for a procedure occurring later in the admission and the subsequent 2 night stay after the procedure.

Challenges

- Under inpatient billing, there are rules and regulations that require charges to be on claims
- System limitations-may or may not have the ability to create a workaround for split billing
    - Workarounds can cause confusion or downstream implications for registration, clinicians, coding and billing staff
- Don't want to accept money from sponsor for items we can't separate from a claim

To SOC or not to SOC

Sponsor Paid Hospitalization

- There is one all-encompassing approach to a research-related hospitalization. Everything is research
  - Potential billing implications
  - Workarounds exist. They aren't recommended, but they do exist
  - The one time where extra negotiation time is actually worth it

The Flip Side

- What if the sponsor is offering payment for the procedure during an SOC hospitalization?
- The initial CA will typically include the sponsor payment
  - Billing implications should be reviewed
  - Consider declining sponsor payment or requesting the sponsor pay for the entire hospitalization
- All or nothing is the ideal scenario, but may not always be possible

Polling Question #4

Scenario 5

A new study has been negotiated where some of the lab work is being billed to the sponsor and some are being billed to insurance. This is allowable from a billing perspective and relatively simple to review…..so what's the problem?

Logistics

- Capitation issues
- Depending on patient population and payor makeup, patients may be REQUIRED to go to an outside lab for lab work to be completed
  - Possible additional visits for patients
  - Challenges with fitting within protocol timelines
  - Increased administrative burden working with outside organizations
    - Increased costs
    - 3rd party billing
- Importing results back to EHR?

	Screening Day-28 to Day-1	Cycle 1 Day 1	Cycle 2 Day 1
Hematology	SOC	SOC	SOC
Serum Chemistry	SOC	SOC	SOC
Magnesium	1	1	1
Phosphate	1	1	1
Amylase	1	1	1
Lipase	1	1	1
Creatinine clearance	INV		
Lipid Panel	1		
Coagulation: INR	SOC	SOC	SOC
Coagulation: aPTT	SOC	SOC	SOC
TSH	SOC	SOC	
Free T4	SOC	SOC	
Free T3 (or total T3)	SOC	SOC	
C-Reactive Protein	SOC	SOC	SOC
HIV test	SOC		

Lab-gistics

1 If these situations are frequent, make a policy around these tests.

- Put this policy on signed letterhead

2 It's your site's responsibility to share your coverage determinations with the outside facility.

- Important to keep CA designations as simple as possible
- If one of the protocol required labs cannot be billed at your site, consider making all labs research

3 This is a very common problem across sites. Many sites struggle with this and develop policies around lab billing.

4 If an outside facility is used for any research designation protocol test, make sure you are getting (and actually using) pricing from the outside facility.

Site Considerations

Risk Tolerance

- How far are you and your institution willing to go?
- Trust in staff

Ability to Negotiate

- Sponsors push to bill
- Knowledge in billing conditions
- Documentation
- Risk Tolerance (Full-circle)

Logistical Concerns

- Staffing resources
- Patient pay or makeup (capitation)
- Patients' geographical locations
- Physical locations
- Study timelines/ requirements

Audience Questions

Thank you for attending!

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