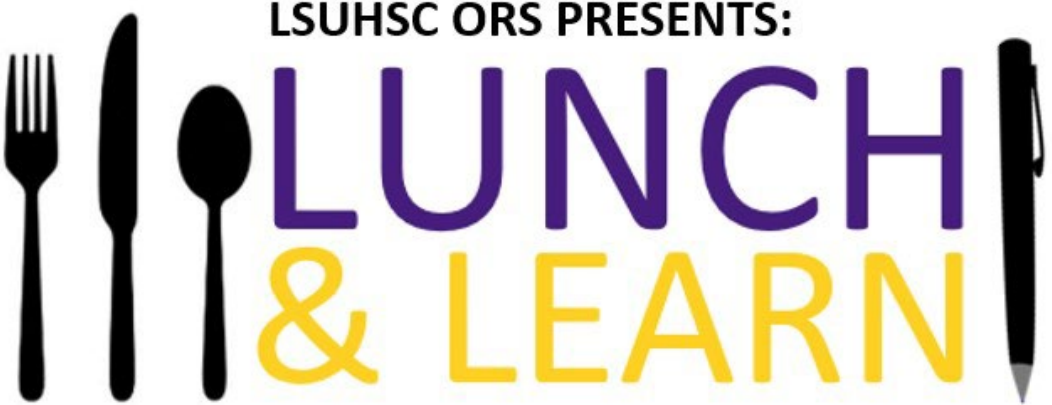
LSUHSC ORS PRESENTS:



Research Billing in EPIC

May 1, 2024

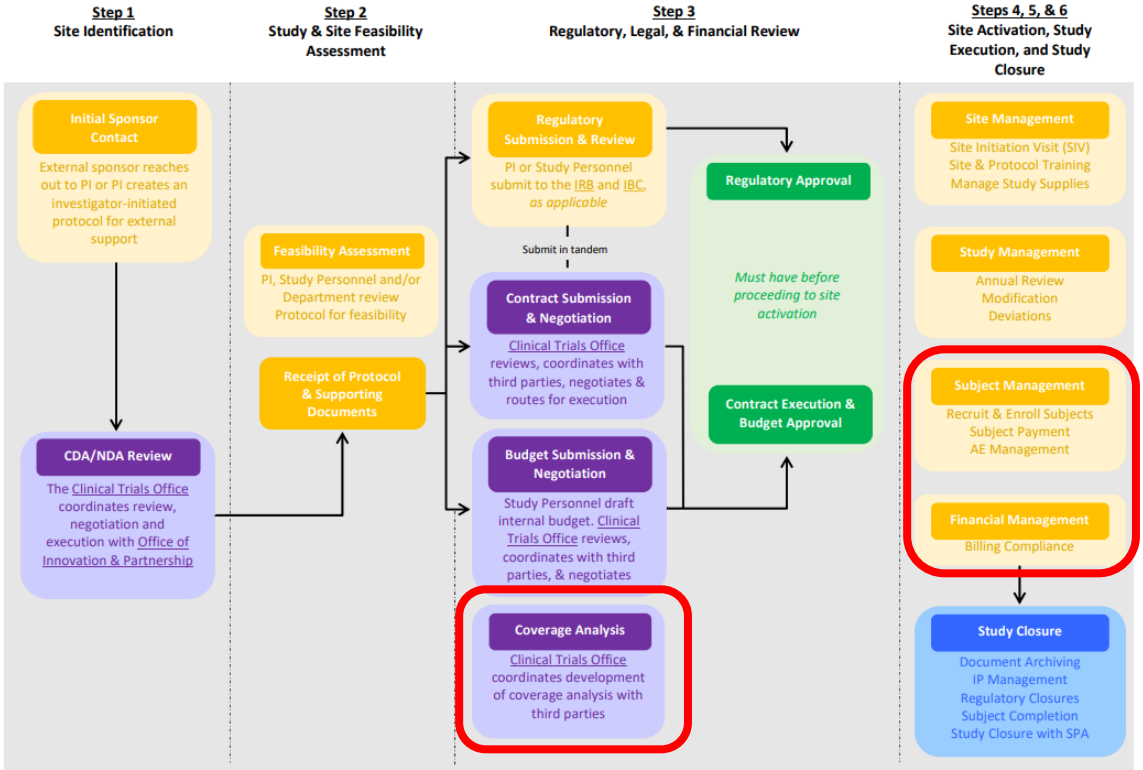
Brianne Voros, MS, CCRP

Email: bvoros@lsuhsc.edu

Objectives

- Discuss the importance of the MCA in the context of Research Billing Compliance
- Review Linking to Research Studies in Epic
- Describe the process for Research Billing Review in Epic

Lifecycle of a Clinical Trial



Components of Research Billing in EPIC

1. Medicare Coverage Analysis (MCA)
2. Standard of Care Processes that affect Research Billing Compliance
3. Linking to Research Study in EPIC
4. Research Billing Review

What is a 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.

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

LSUHSC CTO Training - Medicare Coverage Analysis for Clinical Research

Understanding the MCA …and Why It Is IMPORTANT

- The **Principal Investigator (PI)** has the ultimate responsibility for achieving research billing compliance….. but the full support of the study team is needed to do so successfully.

- The PI has primary responsibility to understand and comply with rules for billing Medicare, Medicaid and third-party payors for services, drugs, devices, tests and procedures rendered in the clinical research context.

- Other site personnel (including patient service representatives, billers, coders, clinic administrators, etc.) are responsible for working with the Principal Investigator and study team to ensure that services for patients enrolled in research studies are scheduled, coded, billed and documented appropriately.

Risks Associated with Research Billing Non-Compliance

1. Billing for services that are already paid by the sponsor (double billing)
2. Billing for services promised free in the informed consent
3. Billing for services that are for research-purposes only
4. Billing for services that are part of a non-qualifying clinical trial and do not qualify for coverage

Federal False Claims Act

- Federal False Claims Act (FCA) establishes liability for anyone who submits a false claim for payment to the government
  Specific intent not required

- False Claims Act applies to clinical research activities and failure to comply with the rules may lead to fines and penalties

- Under the False Claims Act, those who knowingly submit, or cause another person or entity to submit false claims for payment of government funds, are liable for three times the government's damages plus civil penalties of $10,781 to $21,563 **per** false claim.

- Study documents and MCA must be aligned to assure compliance with clinical trial billing rules and the regulations that protect human subjects

For Immediate Release….
Research Billing Non-Compliance in the Headlines

PRESS RELEASE

Florida Research Hospital Agrees to Pay More than $19.5 Million to Resolve Liability Relating to Self-Disclosure of Improper Billing for Clinical Trial Costs

Thursday, January 4, 2024 | For Immediate Release

The Scripps Research Institute To Pay $10 Million To Settle False Claims Act Allegations Related To Mischarging NIH-Sponsored Research Grants

Friday, September 11, 2020 | For Immediate Release

PRESS RELEASE

Emory University To Pay $1.5 Million To Settle False Claims Act Investigation

Wednesday, August 28, 2013 | For Immediate Release

PRESS RELEASE

Duke University Agrees to Pay U.S. $112.5 Million to Settle False Claims Act Allegations Related to Scientific Research Misconduct

Monday, March 25, 2019 | For Immediate Release

Department of Justice

FOR IMMEDIATE RELEASE
THURSDAY, APRIL 14, 2005
WWW.USDOJ.GOV

CIV
(202) 514-2007
TDD (202) 514-1888

UNIVERSITY OF ALABAMA-BIRMINGHAM WILL PAY U.S. $3.39 MILLION TO RESOLVE FALSE BILLING ALLEGATIONS

The 3 C's of Research Billing Compliance

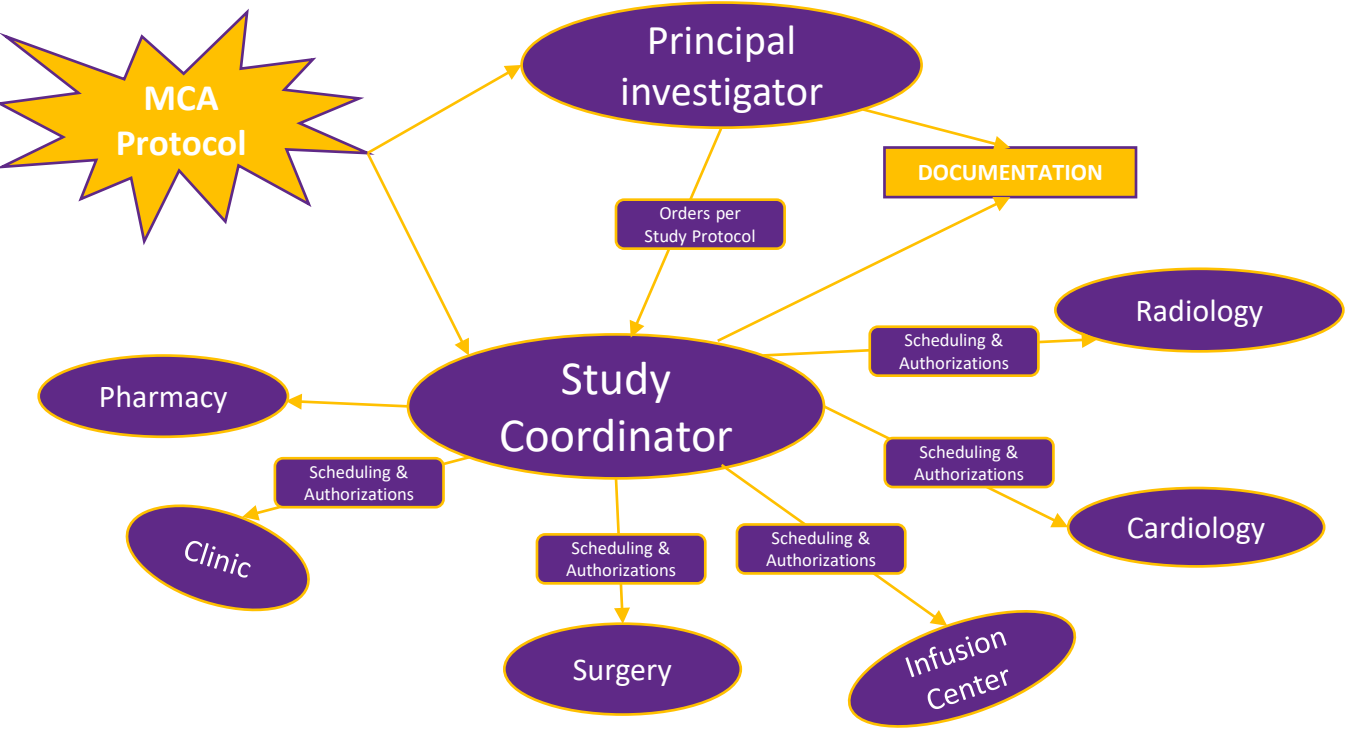
1. Coordination of study information across multiple study documents
2. Communication of relevant study information to the billing process
3. Cooperation among departments and offices that may not usually work together

The 3 C's of Research Billing Compliance

1. Information that must be coordinated and communicated to minimize compliance risks
   - What is billable and not billable
   - Who is enrolled in a research study
   - Which services are required by the protocol

2. Within an academic medical setting, many different parties are involved in developing study documents that have important information for billing:
   - University/Campus
   - School of Medicine
   - Medical Center
   - Physician Offices
   - Sub-contractors/Private Physician Groups

The PI and SC should be the Protocol EXPERTS for Non-Study Staff



The MCA is our cheat sheet to WHO pays WHAT

Research Billing Terms & Definitions

- **Study related**: A service/procedure that must happen for a research study and occurs after the subject has signed the research consent.
  - Study-related services may bill to insurance (designated as **M** on the MCA)

- **Routine Care Costs aka Standard of Care:** A study-related service that *also* happens as part of a subject's standard medical care *and* is not promised free from the sponsor is designated as M on the MCA. **M services bill to insurance.**
  - These costs may include doctor visits, hospital stays, and lab and imaging tests.

- **Research Sponsored (S)**: A study-related service that *only* happens for research, or is promised free from the sponsor (even if it is part of a subject's standard medical care) will be designated as S on the MCA. **S services must bill to the sponsor.**
  - These costs may include the investigational intervention (such as the drug being tested), extra doctor visits, electrocardiograms or blood draws, certain lab and imaging tests, and questionnaires performed solely for research purposes.

MCAs can be simple and easy to understand ….

S=Paid for by study and cannot be billed to insurance
INV=Invoiceable services paid by study
M=Routine cost in a qualifying clinical trial and can be billed to Medicare
M/S=Routine cost in a qualifying clinical trial and can be billed to Medicare. If not covered by insurance, will be covered by sponsor per Non-SOC below.
X=This is a non-billable item and will not generate a charge.
NC= This is not a billable charge.

VISIT SCHEDULE	CPT Code	MODIFIER TYPE	Baseline/ Screening (-90 days)	Surgery Visit	Post Surgery/ Discharge	Week 6 ±14 days	Month 3 ±30 days	Month 6 ±30 days	Month 12 ±60 days	Month 24 ±60 days	Unscheduled	COMMENTS
PROTOCOL RELATED ITEMS & SERVICES												
Informed Consent Process			S									
Eligibility Confirmation			S	S								
Demographics			S									
Medical History			S									
Physical Exam			M	M	S	S	S	S	S	S	S	Post Surgery/Discharge, per investigators discretion
Neurological Examination			S	S	S	S	S	S	S	S	S	Post Surgery/Discharge, per investigators discretion
X-ray (AP, lateral, flex/ext films)	72050		M	M	M	S	S	S	S	S	S	For Surgery Visit, Pre- and post-implant images will be collected using intra-operative fluoroscopy instead of standard x-rays. For Post Surgery/Discharge Visit, Neutral AP and Lateral X-ray only, per investigator's discretion.
Osteoporosis Assessment			S									
CT scan	72125		M		M				S	S		CT scan optional to rule out any bony abnormalities. For 12m and 24m, sagittal and coronal reconstructions are required
MRI	72156		M									MRI required for all patients, unless Inclusion #2b is determined using x-rays or CT
Surgical Procedure				M								For investigational portion of surgery, device is provided by sponsor.
Pregnancy Test	81025		M									Females of childbearing potential only.
Nicotine Intake			S			S	S	S	S	S		
VAS pain			S			S	S	S	S	S		
NDI			S			S	S	S	S	S		
SF-12 and EQ-5D-5L			S			S	S	S	S	S		
Satisfaction Survey									S	S		
Employment Status			S			S	S	S	S	S		
Adverse event assessment				S	S	S	S	S	S	S	S	
Concomitant medications			S	S	S	S	S	S	S	S	S	

…or MCAs can be very complex

	Treatment																									Follow Up									Comments
	Screening 1@21Days	Treatment Cycles 1-4 4 Cycles @56Days																								Long Term Safety Follow-up Visits								EOS	
	Screening	C1D1*	C1D7	C1D14	C1D28	C1D42	C1D56*	C2D1*	C2D7	C2D14	C2D28	C2D42	C2D56*	C3D1*	C3D7	C3D14	C3D28	C3D42	C3D56*	C4D1*	C4D7	C4D14	C4D28	C4D42	C4D56/E	Long Tel	Long Tel	Long Tel	Long Tel	Long Tel	Long Tel	Long Tel	Long Tel	EOS M	
Informed Consent	S(X)																																	This is not a billable item or service.
Inclusion/Exclusion Criteria	S(X)																																	This is not a billable item or service.
Demographics and baseline disease characteristics	S(X)																																	This is not a billable item or service.
Medical History	S(X)																																	This is not a billable item or service.
Prior And Concomitant Medications	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	This is not a billable item or service.
ECOG Performance Status	S(X)	S(X)					S(X)	S(X)					S(X)	S(X)					S(X)	S(X)					S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	This is not a billable item or service.
Height, Weight	S(X)	S(X)					S(X)	S(X)					S(X)	S(X)					S(X)	S(X)					S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	This is not a billable item or service.
Vital Sign Measurement	S(X)	S(X)					S(X)	60(X)					S(X)	60(X)					S(X)	60(X)					S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	This is not a billable item or service.
Electrocardiogram	S						S						S						S						S								S	A conventional care reference for this item could not be found following review of UpToDate and NCCN Guidelines. Therefore, this item is considered research-related and should be paid for by the sponsor.
- EKG (CPT-93005)	S						S						S						S						S								S	
Physical Examination	M1	M1					M1	M1					M1	M1					M1	M1					M1	M1	M1	M1	M1	M1	M1	M1	M1	A physical exam appears reasonable and necessary at this frequency for the clinical management of the patient in order to assess the patient's disease status, as well as to detect, monitor, and treat side effects of 212Pb-DOTAMTATE: fatigue, nausea (ICF p. 11). According to the NCCN Guidelines for Neuroendocrine and Adrenal Tumors (v4.2021), during follow-up this item is recommended every 12-24 weeks for 2 years (WD&D-3) and every 6-16 weeks for patients with Poorly Differentiated/Large or Small Cell Carcinomas or Unknown Primary (MS-32). Coverage at screening, during treatment, and during the first 100 days of follow-up is supported by NCD 310.1.
- EKA-EST, PATIENT-LVL IV (CPT-99214)	M1	M1					M1	M1					M1	M1					M1	M1					M1	M1	M1	M1	M1	M1	M1	M1	M1	
- EKA-EST, PATIENT-LVL V (CPT-99215)	M1	M1					M1	M1					M1	M1					M1	M1					M1	M1	M1	M1	M1	M1	M1	M1	M1	
Histopathology*	S(X)																																	This is not a billable item or service.
Pregnancy Test For WOCBP	S(INV)	S(INV)					S(INV)	S(INV)					S(INV)	S(INV)					S(INV)						S(INV)	S(INV)	S(INV)	S(INV)	S(INV)	S(INV)	S(INV)	S(INV)	S(INV)	There are no known effects of the study drug on pregnant mothers or unborn children (ICF, pg. 12). Therefore, this item should be considered research-related and paid for by the sponsor.
- URINE PREGNANCY TEST (CPT-81025)	S(INV)	S(INV)					S(INV)	S(INV)					S(INV)	S(INV)					S(INV)	S(INV)					S(INV)	S(INV)	S(INV)	S(INV)	S(INV)	S(INV)	S(INV)	S(INV)	S(INV)	
- HCG QUANTITATIVE (CPT-84702)	S(INV)	S(INV)					S(INV)	S(INV)					S(INV)	S(INV)					S(INV)	S(INV)					S(INV)	S(INV)	S(INV)	S(INV)	S(INV)	S(INV)	S(INV)	S(INV)	S(INV)	
Adverse Event Collection		S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	S(X)	This is not a billable item or service.
212pb-DOTAMTATE (IV)		NB(INC)						NB(INC)																										212Pb-DOTAMTATE will be provided by the sponsor (Protocol, p. 32). It should therefore be considered research-related.
212pb-DOTAMTATE Administration		M1						M1																										This item is required for the provision of IV medication used in the study. Coverage is supported by NCD 310.1.
- HC IV INFUSION, THERAPY - EA ADD'L HOUR (CPT-96365)		M1																																
- HC IV INFUSION, THERAPY - UP TO ONE HOUR (CPT-96365)		M1																																
Pre-AA Anti-emetic Medications†		M1																																This premedication is required by the protocol to be taken with the study drug to prevent infusion-related reactions (Protocol, p. 6). Coverage is supported by NCD 310.1.
Amino Acids		M1																																This premedication is required by the protocol to be taken with the study drug to minimize kidney toxicity (Protocol, p. 6). Coverage is supported by NCD 310.1.
AA Infusion		M1																																This item is required for the provision of IV medications used in the study. Coverage is supported by NCD 310.1.
- HC IV INFUSION, THERAPY - EA ADD'L HOUR (CPT-96365)		M1																																
- HC IV INFUSION, THERAPY - UP TO ONE HOUR (CPT-96365)		M1																																
PK Blood Samples*		S(SO)																																This item is for submission of a blood sample to a central lab for analysis (Protocol, p. 39). Therefore, it should be paid for by the sponsor.
PK Urine Collection*		S(SO)																																This item is for submission of a urine sample to a central lab for analysis (Protocol, p. 39). Therefore, it should be paid for by the sponsor.
Clinical Chemistry	M1	M1		M1	M1	M1	M1	M1					M1	M1					M1	M1					M1	M1	$	$	$	$	$	$	$	This item is provided at screening to serve as a baseline and during treatment to monitor for treatment-related complications such as high blood sugar (ICF pg. 11). Coverage at screening, during treatment, and during the first 100 days of follow-up is supported by NCD 310.1. According to the NCCN Guidelines for Neuroendocrine and Adrenal Tumors (v4.2021), CBC and serum chemistry should be monitored post-treatment for patients receiving 177Lu-Dotatate (NE-G 2 of 3). While it is possible a similar recommendation could be made for patients receiving 212Pb-DOTAMTATE, a conventional care reference could not be found following a review of NCCN Guidelines and UpToDate. Therefore, this item should be considered research-related and paid for by the sponsor during the 6 mo - 24 mo follow-up period.
- COMPREHENSIVE METABOLIC PAN 14 CHP (CPT-80053)	M1	M1		M1	M1	M1	M1	M1					M1	M1					M1	M1					M1	M1	$	$	$	$	$	$	$	
Hematology	M1	M1		M1	M1	M1	M1	M1		M1	M1	M1	M1	M1		M1	M1	M1	M1	M1		M1	M1	M1	M1	M1	$	$	$	$	$	$	$	This item is provided at screening to serve as a baseline and during treatment to monitor for treatment-related complications such as reduced number of white blood cells (ICF pg. 11). Coverage at screening, during treatment, and during the first 100 days of follow-up is supported by NCDs 310.1 and 190.15. According to the NCCN Guidelines for Neuroendocrine and Adrenal Tumors (v4.2021), CBC and serum chemistry should be monitored post-treatment for patients receiving 177Lu-Dotatate (NE-G 2 of 3). While it is possible a similar recommendation could be made for patients receiving 212Pb-DOTAMTATE, a conventional care reference could not be found following a review of NCCN Guidelines and UpToDate. Therefore, this item should be considered research-related and paid for by the sponsor during the 6 mo - 24 mo follow-up period.
- CBCW/ CBC W/PLT W/AUTOM DIFF (CPT-85025)	M1	M1		M1	M1	M1	M1	M1		M1	M1	M1	M1	M1		M1	M1	M1	M1	M1		M1	M1	M1	M1	M1	$	$	$	$	$	$	$	
Coagulation†	S(INV)																																	Coverage for this item is limited by NCD 190.17. Therefore, this item should be considered research-related and paid for by the sponsor.
- PROTHROMBIN TIME (CPT-85610)	S(INV)																																	
Virus Serology (HIV)	S																																	Coverage of this item is limited by NCD 210.7. Therefore, it should be considered research-related and paid for by the sponsor.
- HIV-1 DNA QUAL BY PCR (CPT-87535)	S																																	
Virus Serology (Hepatitis B)	S																																	Coverage of this item is limited by NCD 210.6. Therefore, it should be considered research-related and paid for by the sponsor.

Billing Designations

M	Bill to Patient/Insurance
S	Bill to Sponsor
NB	Not Billable

Supporting Designations

AN	As Needed Procedure
ICF	Promised free in Informed Consent
INV	Invoiceable item paid for by the study
NA	Bundled Service, Not Separately Billable
NC	No charge - this item is provided for by the sponsor
NR	Not Part of the Research Study
S/RC	Routine care performed for safety and paid for by the sponsor
SO	Send Out
X	This is an non billable item and cannot generate a charge

Lessons Learned

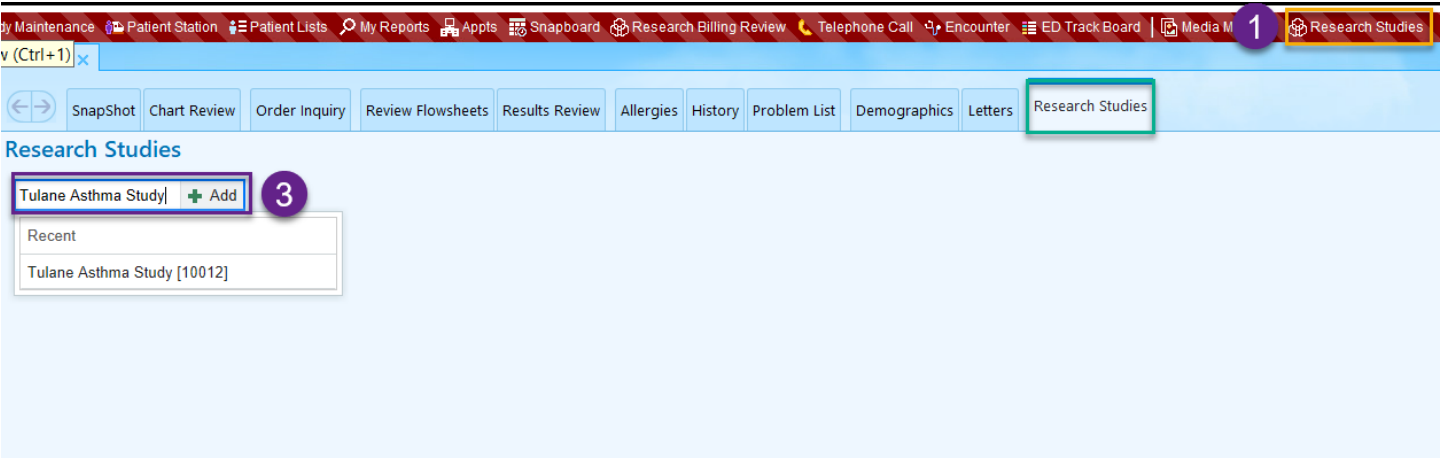
Never assume that RESEARCH means that everything required by the protocol is FREE

Let the normal processes that are currently in place for non-research patients continue to function for your research patients (i.e. prior authorizations, scheduling, etc.)

Utilize the current workflows of the clinic/hospital/support staff to implement the clinical trial.

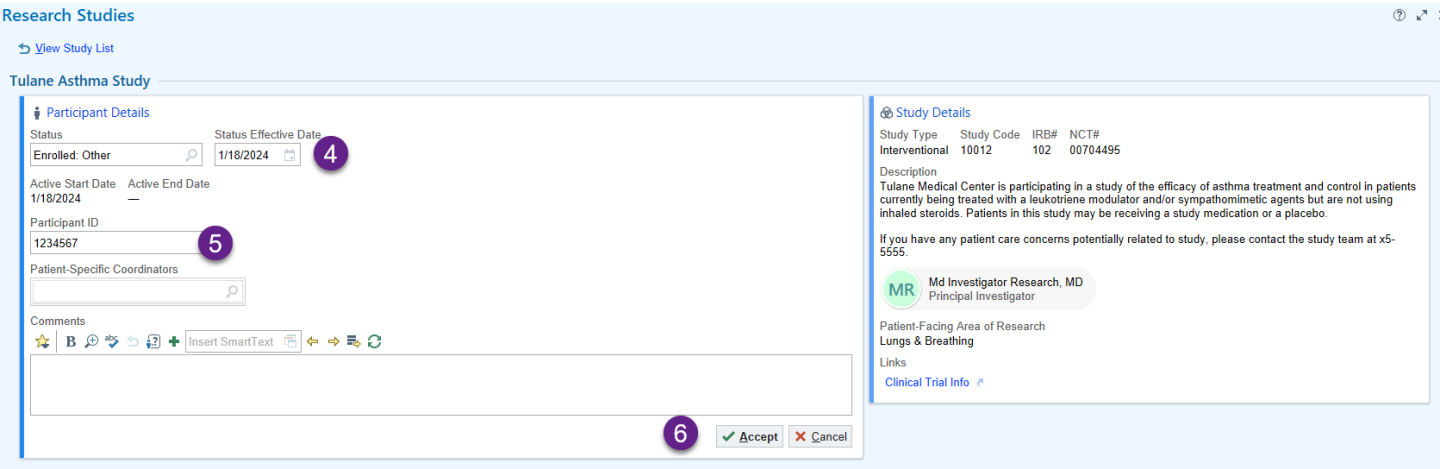
How do we IDENTIFY Patients in EPIC as Enrolled in Research?

Linking Patient to the Research Study



1. Click on the Research Studies button in the main toolbar.
2. Search for and select your patient to open their chart.
3. Within the Research Studies activity, search for the study in the Add study search field.

Linking Patient to the Research Study



4. Search for and select an active association status, such as In Screening, Consented, or one of the Enrolled options. Once selected, the Status Effective Date will auto populate with today's date. If you need to back chart (chart for events that happened in the past), change the Status Effective Date and the Active Start Date will automatically adjust.

5. Enter a participant ID if the patient's name is not used in the study and only an ID number.

6. Click Accept to save your changes.

Research Association Status Definitions

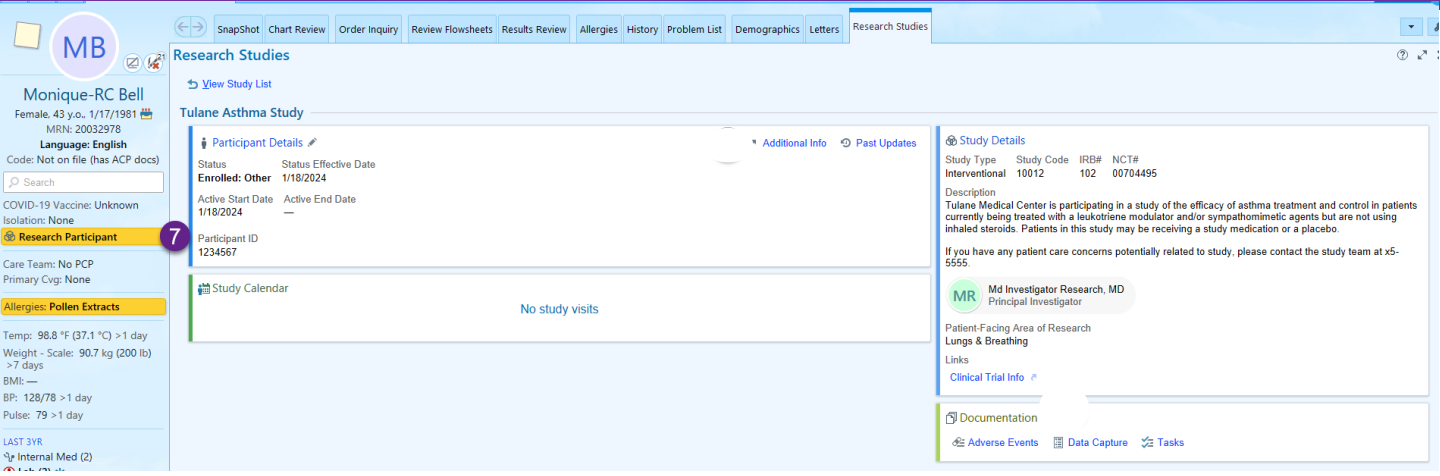
Pre-Consent

- **Identified** *subject is identified as meeting prescreening criteria but has not been approached*
- **Interested** *subject has been approached to participate but has not signed consent form*
- **Declined** *subject is not interested in participating*

After Consent

- **In Screening** *subject has consented to participate but has not completed screening phase*
- **Consented** *subject has consented to participate but has not started treatment*
- **Enrolled – Treatment Phase** *subject is on active treatment*
- **Enrolled – Follow Up Phase** *subject is still on trial but has completed treatment phase and in follow up*
- **Withdrawn**
- **Completed** *subject has completed all study visits and is no longer enrolled in trial*

Linking Patient to the Research Study

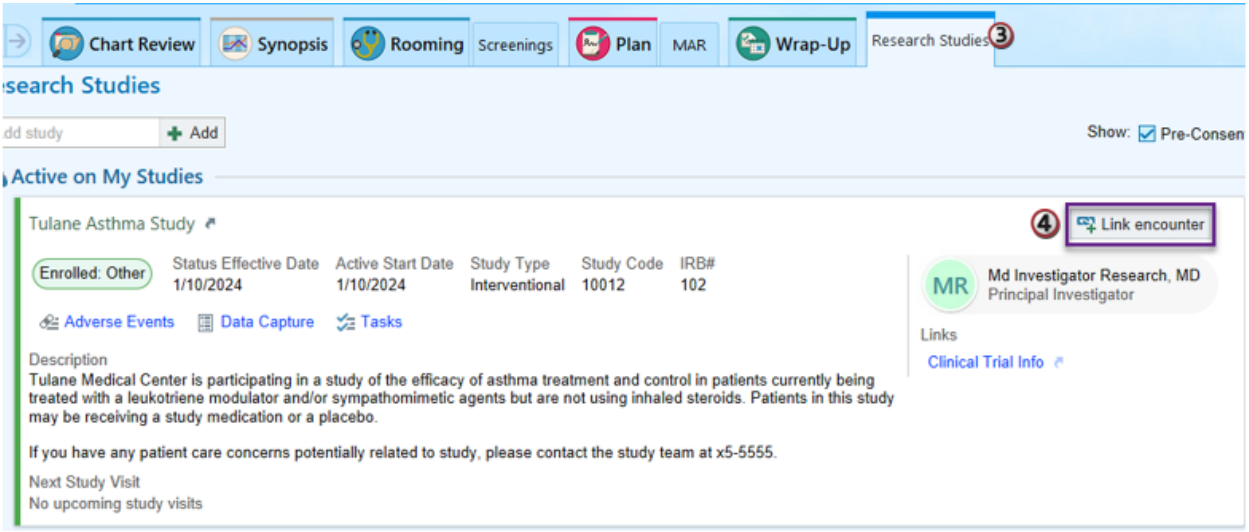


7. Notice a Research Participant banner will appear on the Storyboard. This will alert every provider that views the chart of the patient's participation in a research study.

8. You will be able to click on Participant Details hyperlink to view the study report, which will display study details, linked encounters and linked orders

Link Encounter to Study When in an Encounter

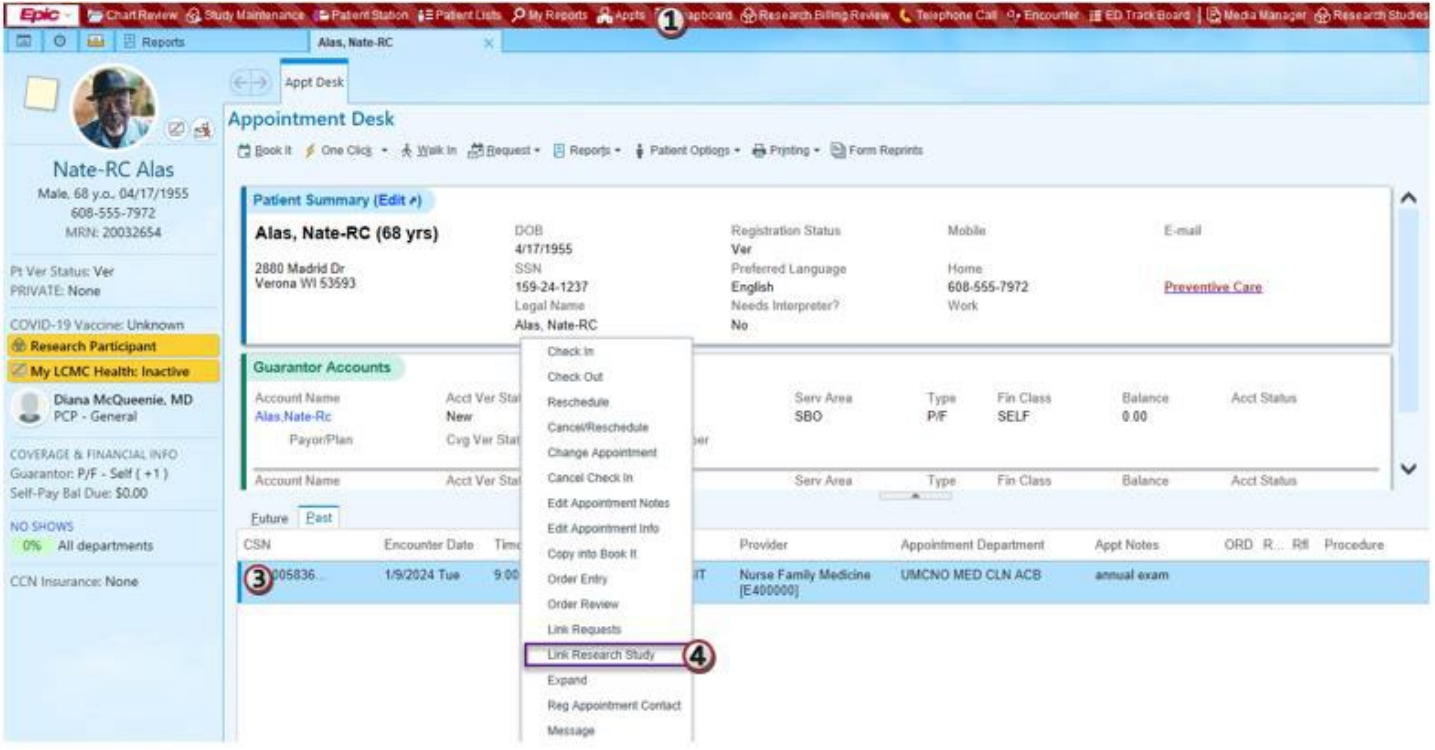
1. Click on the Research Studies button in the main toolbar.
2. Search for and select your patient to open their chart.
3. Within the Research Studies activity, search for the study in the Add study search field.



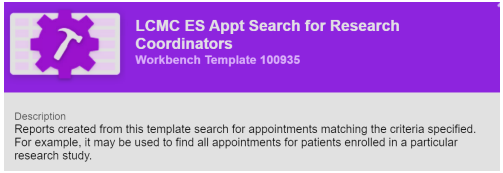
Link Upcoming Visits to Studies via Appointment Desk

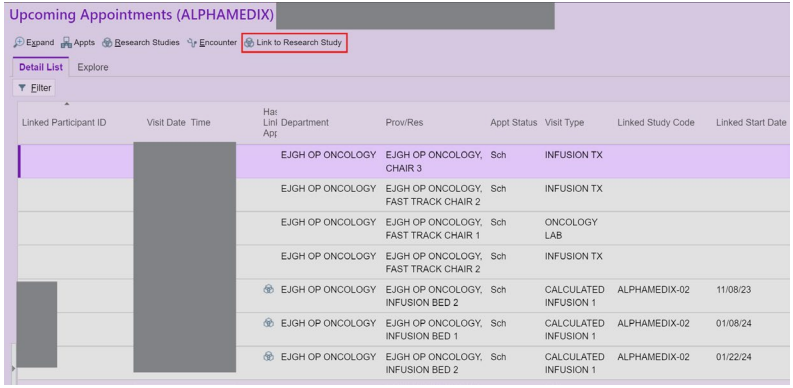
1. Click **Appts** on your main toolbar.
2. Look up your patient and click **Accept**.
3. Right-click the upcoming appointment.
4. Select **Link to Research Study** to confirm association or to link the appointment to the research study.
5. Click ✕Close when all updates for the encounter are complete.

Link Upcoming Visits to Studies via Appointment Desk



Reports for Linking Upcoming Visits to Studies

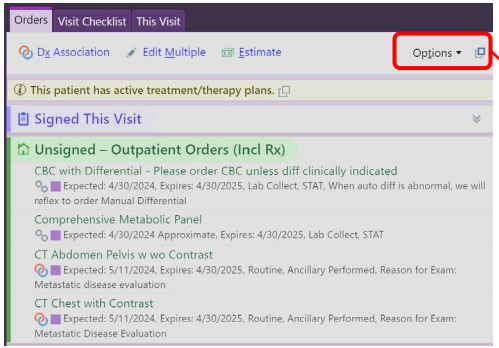


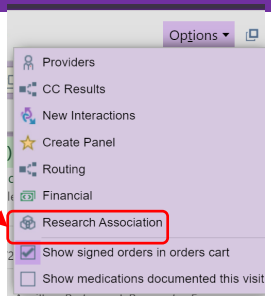


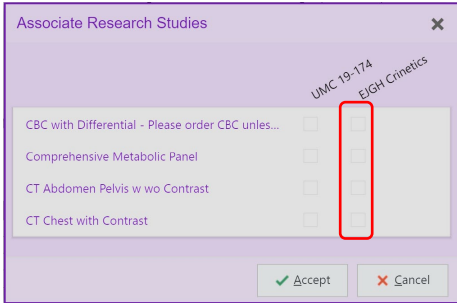
- Search in Reporting Workbench for **LCMC ES Appt Search for Research Coodinators.**
- Modify report with Study Code and Save Report as Favorite.
- Select visits to be linked and Click Link to Research Study.
- Can be used to link Past or Upcoming Appointments

Reach out to me if you need additional guidance on setting these up.

Linking Orders to Research Study When in an Encounter

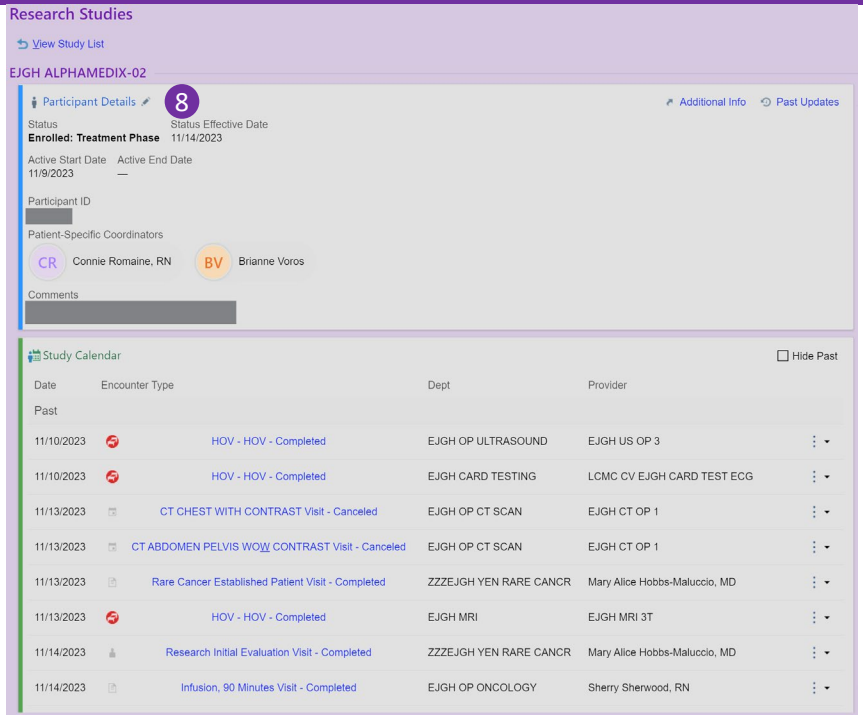






1. At the top of the Orders Panel, select Options.
2. Then Click Research Association.
3. In pop up, Select the check box next to the Order to Associate under the applicable study.

Linking Patient to the Research Study



Once linking begins, you will be able to click on the **Participant Details** hyperlink to view the study report, which will display study details, linked encounters and linked orders in the Study Calendar.

Professional Billing Charges

- Currently, Professional Billing Charges are billed outside of Epic through ACS (in most cases)

- Therefore, these charges are not captured in Epic. Because these charges may be reimbursed by the sponsor, some important safeguards are required to flag research patients when the billing report is sent to ACS.

This can be accomplished with the diagnosis code

***Z00.6**: Examination of participant in clinical trial*

This will FLAG the patient as enrolled in a clinical trial and prompt ACS to reach out to the Study Coordinator.

CMS – Z00.6 and Q0/Q1 Modifiers

CMS requires that the following diagnosis code be used on Medicare research claims to identify Medicare patients who are participating in a **Qualifying Trial**:

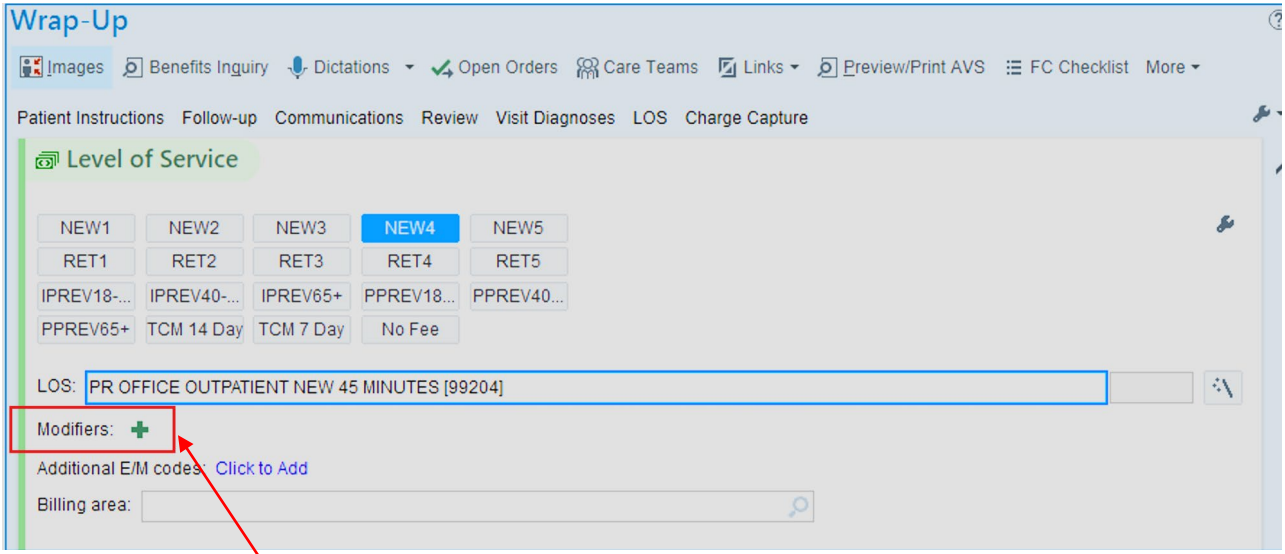
- Diagnosis code ***Z00.6: Examination of participant in clinical trial***

In addition, the claims must include one of the following modifiers to differentiate between routine and investigational clinical services:

- ***Q0*** ***– Investigational clinical service provided in a clinical research study that is in an approved clinical research study.***

- ***Q1*** ***– Routine clinical service provided in a clinical research study that is in an approved clinical research study.***

Coding Office Visits with Modifiers



- ***Q0 – Investigational clinical service provided in a clinical research study that is in an approved clinical research study.***
- ***Q1 – Routine clinical service provided in a clinical research study that is in an approved clinical research study.***

Best Practice

BestPractice Advisory -

DID YOU ADD Z00.6 TO YOUR VISIT DIAGNOSES?

This patient is
enrolled in a clinical trial.

Please consider:
1. Linking patient to research study
2. Ensuring that all orders are linked to the research study before signing visit.

Click HERE to provide feedback on this BPA

Remove the following orders?

Remove | Keep

Check with your Study Coordinator ☺
Expires: 5/9/2020, Routine, Lab Collect

Acknowledge Reason

See comments

✓ Accept

Putting it ALL together

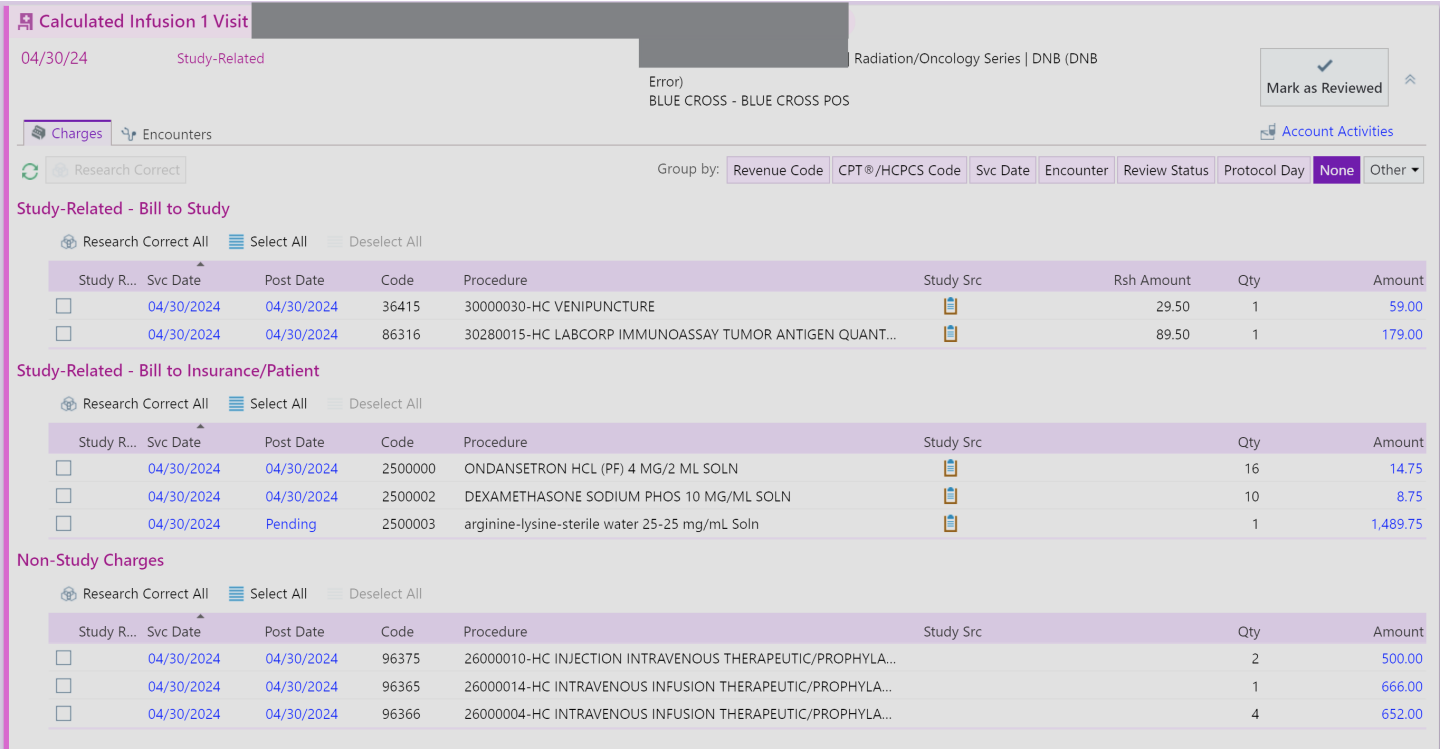
Research Billing Review Process

All charges linked to patients enrolled in a research study in Epic are flagged and reviewed to make sure they're billed appropriately through the Research Billing Review Process.

Each charge associated with a research patient falls into one of three buckets:

- **Non-research related**. These charges are billed to the patient or their insurance.
- **Research-related, bill to the study**. These are research charges that will be billed to the study or study sponsor.
- **Research-related, bill to the patient**. These are research-related charges that are billed to and paid by the patient or their insurance.

Research Billing Review Process



Important Takeaways

1. Understanding the MCA is the foundation of ensuring compliant research billing
2. Linking Patients, Orders, and Encounters on the front end saves a headache on the backend
3. Communication with all involved is KEY
4. Add Z00.6 diagnosis code with Q0/Q1 modifiers
5. Research Billing Non-Compliance jeopardizes our ability to continue doing research. We must work together to ensure that it is done correctly!

Resources

- LSUHSC CTO Training - Medicare Coverage Analysis for Clinical Research
- CITI Training - Clinical Trial Billing Compliance
- CMS.gov National Coverage Determination (NCD) - Routine Costs in Clinical Trials
- HCPCS Modifiers when Billing for Patient Care in Clinical Research Studies


QUESTIONS