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Billing Coverage Analysis (BCA)

Courtney D. Nightengale
SOM Clinical Trials Office
434-243-1927

Accreditation

- The University of Virginia School of Medicine and School of Nursing designates this live activity for a maximum of **1.5 *AMA PRA Category 1 Credits.™*** Physicians should claim only the credit commensurate with the extent of their participation in the activity.

- The University of Virginia School of Medicine and School of Nursing awards **1.5 contact hours** for nurses who participate in this educational activity and complete the post activity evaluation.

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Disclosures

- The speakers, Jessica Morris & Courtney Nightengale have no personal or professional financial relationships with a commercial entity producing healthcare goods or services.

- The planning committee members, Katie Rea, MSCR, BSN, RN, CCRC; Lori Elder, RN, BSN, CCRA, Amy Smith, MSHS Certificate ; Kimberly Underwood, BS, CCRC; and Maria Davenport, MPH, CCRP; have no personal or professional financial relationships with a commercial entity producing healthcare goods or services.

Activity Code: **150667**
Instructions for claiming credits/contact hours can be found here.

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CTO Finance Team

Our team will provide billing coverage analysis, site budget development (coming soon), research billing assistance, and invoicing (coming soon) to ensure proper billing of services.

- Team email: CTOfinsupport@uvahealth.org
- Team webpage: https://med.virginia.edu/clinicalresearch/research-resources/offices-supporting-clinical-research/clinical-trials-office/clinical-trials-billing-and-finance/
- Virtual Drop-in sessions every 2nd & 4th Wednesdays at 11 am: https://virginia.zoom.us/j/95034073584?pwd=QlMrYmNrM2crNm0rak1zOE0zWmZPdz09

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Presentation Overview

Topics:

- Billing Coverage Analysis (BCA) internal process
- Changes that require an updated Billing Coverage Analysis (BCA)
- Subject injury compensation
- Research billing compliance/Medicare's clinical trial policy
- Legal consequences

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Billing Coverage Analysis Internal Process

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What is a Billing Coverage Analysis?

A Billing Coverage Analysis (BCA) is a review of all procedures detailed in a study protocol to determine how each service and/or procedure at each visit time point should be billed to ensure institutional billing compliance. Medicare billing rules and guidelines are referred to during this determination process.

The BCA workflow involves the following steps:

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Step 1: Identify studies to undergo a BCA

When is a BCA required?

- A BCA is required for all research studies in which tests, procedures, services, and interventions associated with the study, could possibly generate Medical Center or University Physicians Group charges.

When is a BCA NOT required?

- If a trial only uses existing specimens or involves collecting data based on clinical progression
- A survey, retrospective or observational study that only includes a collection of forms.

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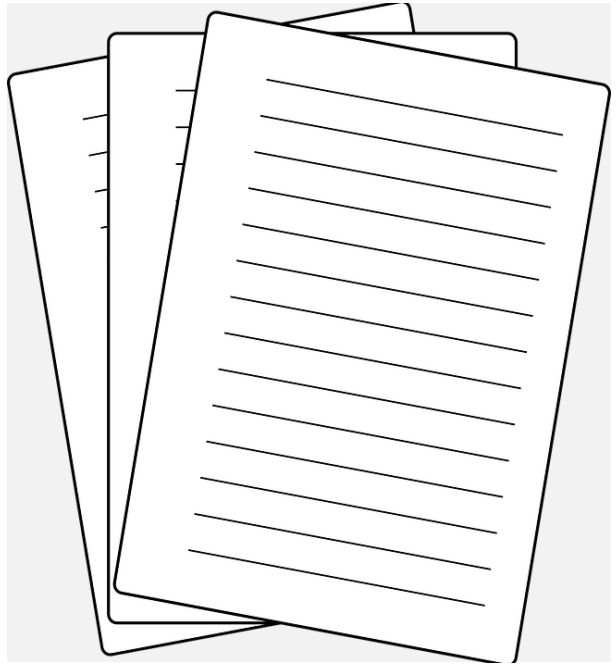
Step 2: Review research related document

- Protocol
- Consent(s)
- Budget/Sponsor Reimbursement Guide

Drafts are okay, but you must remember to send finalized documents to Courtney.



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Step 3: Identify standard of care vs. research costs

Standard of care costs

- Items or services in which the patient would receive regardless of their participation in a study

Research costs

- The investigational item or service itself (unless otherwise covered outside of the clinical trial)
- Items and services solely to satisfy data collection and analysis needs
- Items and services not used in the direct clinical management of the patient (*e.g.*, used to determine trial eligibility)
- Items and services provided by the research sponsors at no cost
- Items and services promised at no cost to the participant in the informed consent

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Step 4: Develop a study billing grid with coverage determination

CRC's should use the billing grid as a tool for coverage determinations when doing their billing review in Epic to ensure appropriate billing.

Coverage determinations:

- PT = Patient (This item will be conducted as standard of care, bill to the subject or the subject's insurance)
- ST = Study (This item has been deemed "research-specific", bill to the study's UVA worktag)

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Study Billing Coverage Analysis

Protocol Title:

IRB-HSR #:

Protocol version date:

NCT #:

Budget version date:

Investigator:

ICF version date:

Sponsor(s):

IND/IDE #:

Research Related Injury per ICF:

CTO Sumbission by:

I have reviewed the content of this document and agree that it is complete and accurate:

Date of signature:

Procedures	Screening Visit	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	End of Treatment Visit
Visit (Evaluation and Management CPT Codes)	ST	ST	ST	ST	ST	ST	ST	ST	ST	ST
Venipuncture			ST	ST	ST	ST				
Hematology	PT	PT	PT	PT	PT	PT	PT	PT	PT	PT
Chemistry	PT	PT	PT	PT	PT	PT	PT	PT	PT	PT
Pregnancy Test (If applicable)	PT			ST		ST		PT		
Brain CT Scan	ST				PT					ST
Blood Biomarkers (Central lab)			ST	ST	ST	ST				
Study Drug (Provided by sponsor)		ST	ST	ST	ST	ST	ST	ST	ST	

PT = Patient (This item will be conducted as standard of care, bill to the subject or the subject's insurance)

ST = Study (This item has been deemed "research-specific", bill to the study's UVA worktag)

**If the Billing Coverage Analysis is based on a preliminary study budget and the final version includes changes in sponsor compensation for study services and/or procedures, it is the responsibility of the investigator to provide the final budget to the SOM CTO. Changes may require modification & re-signing of the Billing Coverage Analysis.

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Step 5: Study billing grid is sent to study team for review and comments

- CRC should review billing grid thoroughly with the PI.
- Make comments and changes.

Step 6: Study billing grid is sent back to Courtney for final review and approval

- Courtney will review study team's changes.

Step 7: Final BCA is uploaded to CRConnect-BCA step, where the PI reviews and signs the BCA

- Study team can print a copy for their records from CRConnect.
- Study team can't enroll study participates until BCA is signed by PI.

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Hard stops in the internal BCA process

- ICF doesn't have the correct injury compensation language
- NCT# (ClinicalTrials.gov) is missing (If applicable-can't bill insurance without it)

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Changes that Require an Updated BCA

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An update is required when…

- Principal investigator changes
- Sponsor changes
- There is a change in the protocol, ICF, and /or budget that effects the billable charges
- Study team notifies Courtney of changes.

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Subject Injury Compensation

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Local injury language changes/updates:

- Our institution's injury language can't be changed, nor can additional language can added. The sponsors must agree to use the local injury language verbatim in the ICF.
- If the sponsor refuses to accept our local injury language, any sponsor changes will need to be escalated to general counsel for review by Courtney or HSR-IRB. ***This will cause significant delays***. The contract between UVA and the sponsor is the place for fine-tuned language about negligence and allocation of responsibility. Not the consent form. Therefore, there is no need for the sponsor to change or add anything to our local injury language in the consent form.
- Option #2 language is no longer an option

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Research injury language in the ICF

<u>Option # 1:</u> *Commercial sponsor pays for injuries regardless of insurance type. This option is required if the study has a commercial sponsor.*

You do not give up any legal rights, such as seeking compensation for injury, by signing this form. If you feel you have been injured as a result of this study, you may contact the Principal Investigator or the IRB (phone numbers are located near the end of this form). If you are hurt as a result of being in this study, there are no plans to pay you for lost wages, disability, or discomfort. The sponsor will reimburse the reasonable cost of necessary and appropriate emergency and/or acute medical care for injury or illness that is determined by the principal investigator and sponsor to be directly related to the study. Injury related to the study does not include the normal progression of any disease or any underlying pre-existing medical conditions.

To pay medical expenses, the sponsor will need to know some information about you like your name, date of birth, and, if you have health insurance coverage through Medicare, your Medicare Beneficiary Identifier (MBI). This is because the sponsor must check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

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No longer an option-Option # 2: *Commercial sponsor pays for those with Medicare/Medicaid, those who are uninsured and those with commercial insurance if the commercial insurer does not pay.*

If you feel you have been injured as a result of this study you may contact the Principal Investigator or the IRB (phone numbers are located near the end of this form). If you are hurt as a result of being in this study, there are no plans to pay you for lost wages, disability or discomfort. The sponsor will reimburse the reasonable cost of necessary and appropriate emergency and/or acute medical care for injury or illness that is determined by the principal investigator and sponsor to be directly related to the study if you are (a) uninsured, (b) insured by Medicare/Medicaid, or (c) insured by commercial (non-government) insurance but your injury or illness is not covered by your commercial insurance. Injury related to the study does not include the normal progression of any disease or any underlying pre-existing medical conditions.

To pay medical expenses, the sponsor will need to know some information about you like your name, date of birth, and, if you have health insurance coverage through Medicare, your Medicare Beneficiary Identifier (MBI). This is because the sponsor must check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

Option # 3: *There is no sponsor, or the sponsor is a government agency such as the NIH.*

You do not give up any legal rights, such as seeking compensation for injury, by signing this form. If you feel you have been injured as a result of this study, you may contact the Principal Investigator or the IRB (phone numbers are located near the end of this form). If you are hurt as a result of being in this study, there are no plans to pay you for medical expenses, lost wages, disability, or discomfort. The charges for any medical treatment you receive will be billed to your insurance. You will be responsible for any amount your insurance does not cover.

IMPORTANT: Our institution's injury language can't be changed, nor can additional language can added.

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Research Billing Compliance/Medicare's Clinical Trial Policy

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Research billing rules

- Do not bill for services the sponsor is already paying for (double billing)
- Do not bill for services that were promised at no cost to the participant in the ICF
- Do not bill for services that are for research purposes only
- Only bill for services that have no external funding source and are medically necessary

Resources:

- Medicare Clinical Trial Policy Memo: https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&ncaid=186
- Medicare Clinical Trial Policy (National Coverage Determination 310.1): https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=1&ncdver=2&fromdb=true
- Medicare Secondary Payer: https://www.cms.gov/medicare/coordination-benefits-recovery/overview/secondary-payer
- False Claims Act:

  Civil Division | The False Claims Act (justice.gov)

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Legal Consequences

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Most recent settlement related to improper billing for clinical trial costs

H. Lee Moffitt Cancer Center & Research Institute Hospital Inc. (Moffitt), a non-profit cancer treatment and research center based in Tampa, Florida, has agreed to pay $19,564,743 to resolve its civil liability under the False Claims Act for improper claims submitted to federal healthcare programs for certain patient care items and services provided during research studies that were not eligible for reimbursement. Specifically, Moffitt billed federal healthcare programs for items and services provided as part of clinical trial research that should have been billed to non-government trial sponsors.

Article: Office of Public Affairs | 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 | United States Department of Justice

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Settlements involving clinical trials

- Rush University Medical Center paid $1 million to resolve its liability for inappropriate clinical trial charges submitted to Medicare and Medicaid for services and items provided by Rush and its staff to patients enrolled in oncology clinical trials.
- Tenet USC Norris Cancer Hospital settled its civil monetary penalty liability with the Office of Inspector General (OIG) for $1.9 million after self-disclosing overbilling with oncology trials as a “reportable event” pursuant to its corporate integrity agreement requirements. Tenet disclosed that it improperly received government reimbursement for (1) items or services that were paid for by clinical research sponsors or grants under which the clinical research was conducted; (2) items or services intended to be free of charge in the research informed consent; (3) items or services that were for research purposes only and not for the clinical management of the patient; and/or (4) items or services that were otherwise not covered under Medicare’s Clinical Trial Policy.
- The University of Alabama at Birmingham agreed to pay $3.39 million to resolve its liability in two whistleblower actions brought against it alleging that false claims were submitted to the Medicare program and the National Institutes of Health in connection with clinical trials for researcher time spent on patient care when no patients had been seen and for double-billing both Medicare and the sponsor of the research grant for the same items/services. The whistleblowers were a physician formerly employed by the university and the affiliated faculty practice plan and a research compliance officer from the university.
- Emory University agreed to a $1.5 million settlement in a False Claims Act case for falsely billing Medicare and Medicaid for services the clinical trial sponsor agreed to pay (and, in some cases, actually did pay, resulting in double payment to Emory for the same service). This case was brought by a whistleblower who was a former research finance manager at Emory.


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EPIC RESEARCH BILLING REVIEW

Jessica Morris

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Activity Code: **150667**

Instructions for claiming credits/contact hours can be found here.

OBJECTIVES

- Study Activation in Epic
- Associating Patients with Research Study
- Linking Encounters & Orders
- Grant Pricing Request Form
- Research Dashboard Reports
- Performing Research Billing Review
- Types of Charges
- Types of Modifiers
- Research Corrections
- Investigational Device Billing Review
- Manual Corrections
- Common Errors
- Available Resources

WHY RESEARCH BILLING REVIEW?

- Every Clinical Trial **MUST** be Reviewed According to Medicare Clinical Trials National Clinical Decision (NCD) if Medicare is to be Billed
- Study Patients Generate Billable Charges when Seen in Provider Based Clinic and/or Orders for Tests, Evaluations, & Procedures are Performed
  - Venipuncture, CMP, Echo, CT Chest with Contrast, Cardiac Catheterization
- Linking Encounters & Orders to Research Study to Prevent Charges Covered by Research Study from Being Billed Directly to Insurance/Patient

REQUIRED FOR STUDY ACTIVATION IN EPIC

- PI Signed Billing Coverage Analysis
- NCT Number
- Grant Pricing Request Form
- Work tag
- Study Should be **ACTIVATED** Prior to Study Patient's Being Scheduled for Visits, Evaluations, Procedures
- **DON' T DELAY!** Reach out to the Clinical Trials Office if NOT Able to Locate study in Epic

ASSOCIATING PATIENT TO RESEARCH STUDY

- Study Team is Responsible for Associating Patient with Research Study
- Capturing Research Status, Date of Consent, Study Patient Number, Comment
- Recent Epic Upgrade
  - Status Effective Date, Active Start Date

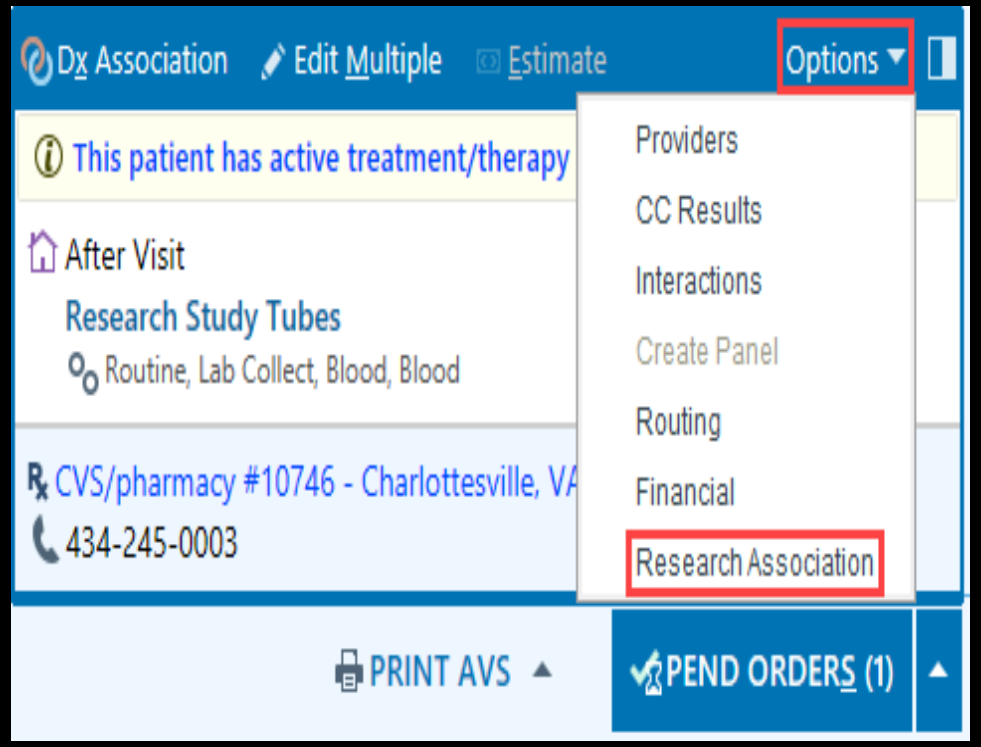
LINKING ENCOUNTER TO RESEARCH STUDY

- Study Team's Responsibility to **LINKED** Encounter to Research Study Prior to the Date of Service
- Successful Linking Results in **'DO NOT BILL'** Status & Account pulls for Research Billing Review
- Patient Station in Chart
- My Patients with Appointments in the Next 14 Days
- Upcoming/Current Admissions for Patients on Study
- **ALWAYS** Link Encounter Prior to Date of Service
- Closed Encounters can be Linked by Creating an Addendum

LINKING ORDER TO RESEARCH STUDY

- Orders **MUST** be Linked when Order Placed
- Critical to Link Orders in Addition to Encounters to Ensure Charge(s) Pull for Research Billing Review
- Radiology and Cardiology Orders – Need to Ensure **Both Encounter & Order Linked**
- Orders Linked to Research Will Have 'DNB' Do Not Bill Status Resulting in Charges pulling for Research Billing Review Rather than Being Billed Directly to Insurance/Patient

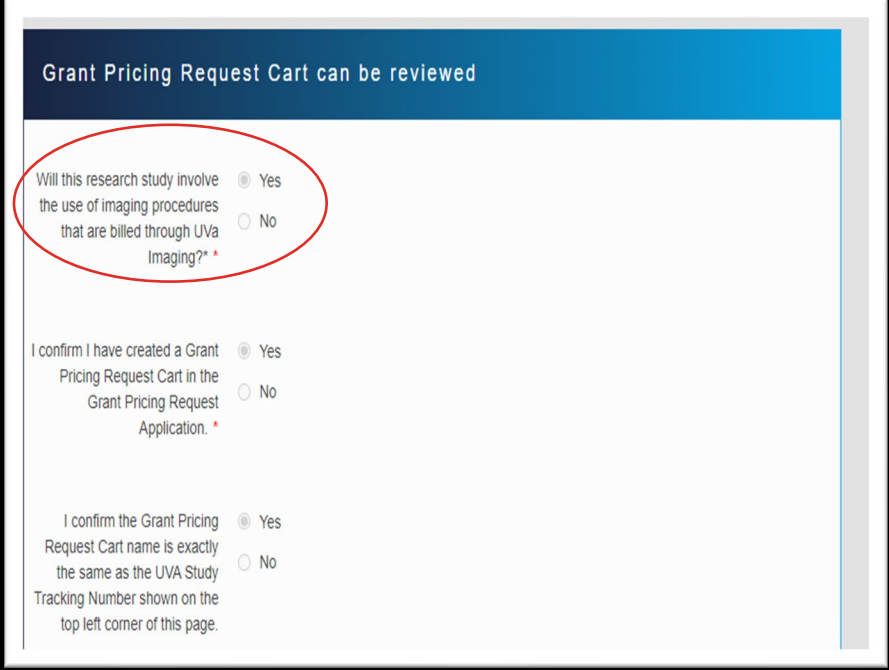
LINKING ORDER TO RESEARCH STUDY



ENCOUNTER & ORDERS LINKED IN ERROR

- Medical Chart Review/Data Collection or No Billable Services Covered by Research Study
- Typically Linked by Scheduling or Registration
- Results in Account Pulling for Research Billing Review
- Charges Cannot be Billed to Insurance/Patient until Research Billing Review is Complete
- **UNLINK** Encounter to Remove Account from Research Billing Review

GRANT PRICING REQUEST FORM



- Study Team Creates Cart with Services Covered by Research Study
- Locate Pricing for Service by Searching by CPT Code, Epic Code, or Procedure Description
- If Study Team Affirms Imaging Billed through UVA Imaging
- Uploaded to CRConnect by Clinical Trials Office

UVA IMAGING BILLING

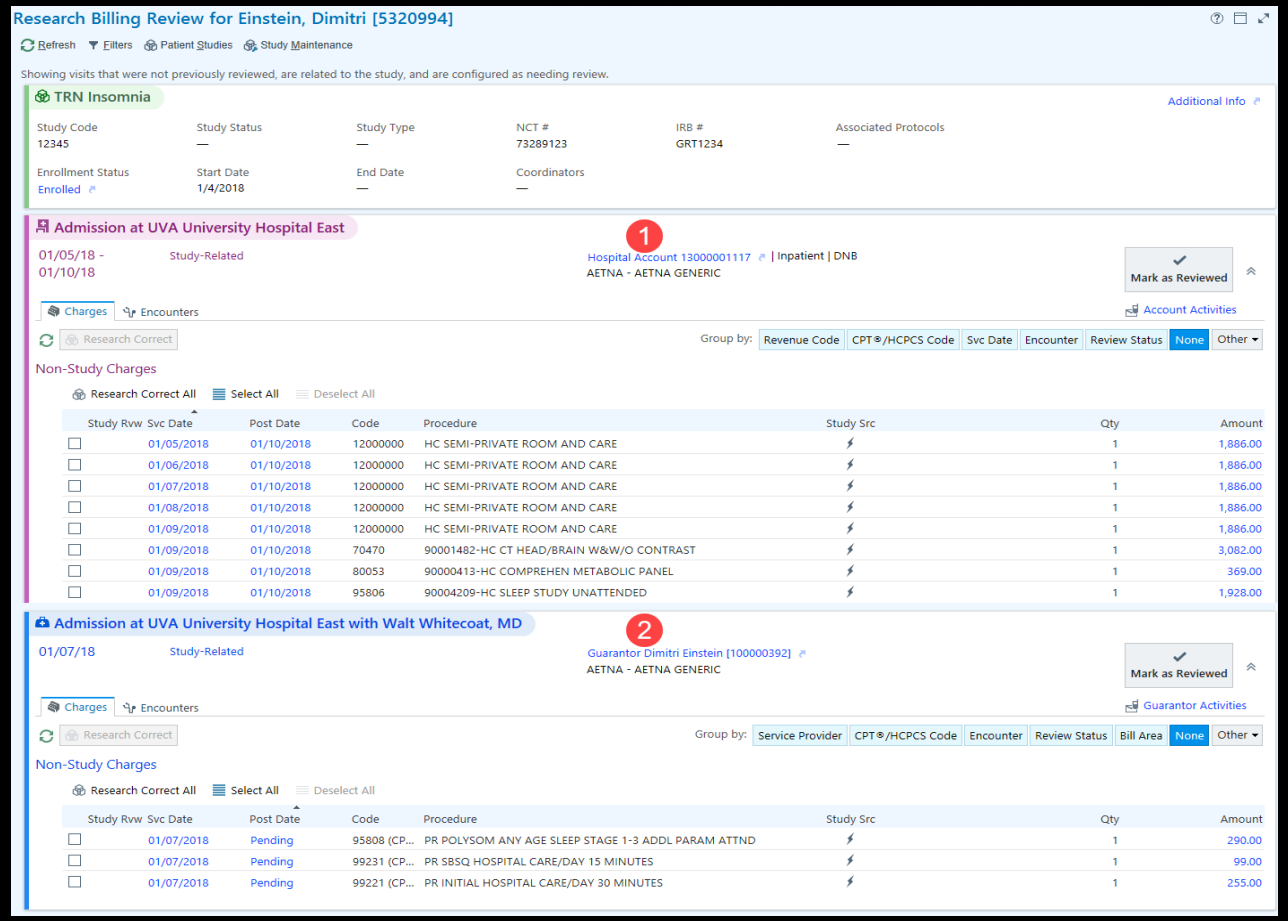
- Technical Charges for Imaging Invoiced Directly to the Department to bill HSR IRB#
- Location for UVA Imaging include Fontaine, Zion Crossroads, Ivy, Northridge
- Professional Charges are Reviewed in Epic
- Imaging on Research Scanners are **NOT** Billed through UVA Imaging
- Technical Charges for Imaging Performed at the Hospital, Emily Couric Clinical Cancer Center, Education Resource Center Billed through Epic

RESEARCH BILLING DASHBOARD

- Located on Research Home Dashboard
- Patients Needing Research Billing Review Report
- My Patients with Appointments in the Next 14 Days Report
- Upcoming/Current Admission for Patients on Study
- Previous Admissions

PERFORMING BILLING REVIEW

- Frequency of Billing Review
- Date of Service
- Current Billing Designation of Charge(s)
- Modifier Applied Correctly
- Research Correction
- Research Price



TYPES OF CHARGES

Pink Banner

- HB – Hospital Bill
- Technical Charge for Service
- Billed through Patient Financial Services

Blue Banner

- PB – Professional Fee
- Professional Charge for Service
- Billed through University Physicians Group

REVIEW OF HB & PB CHARGES FOR SERVICE MUST MATCH

Example:

- ✓ HB charge for Echo CPT 93306 Reviewed as Study Related, Bill Insurance with Routine Modifier Applied
- ✓ PB Charge for Echo CPT 93306 should ALSO be Reviewed as Study Related, Bill Insurance with Routine Modifier Applied

EPIC BILLING DESIGNATION

- Bill to **STUDY**
- Study Related, Bill Insurance with **MODIFIER**
- Non-study Related, Bill Insurance

MODIFIERS –STUDY RELATED, BILL INSURANCE

Routine

- Applied for Services Reviewed as Study Related and Billed to Insurance

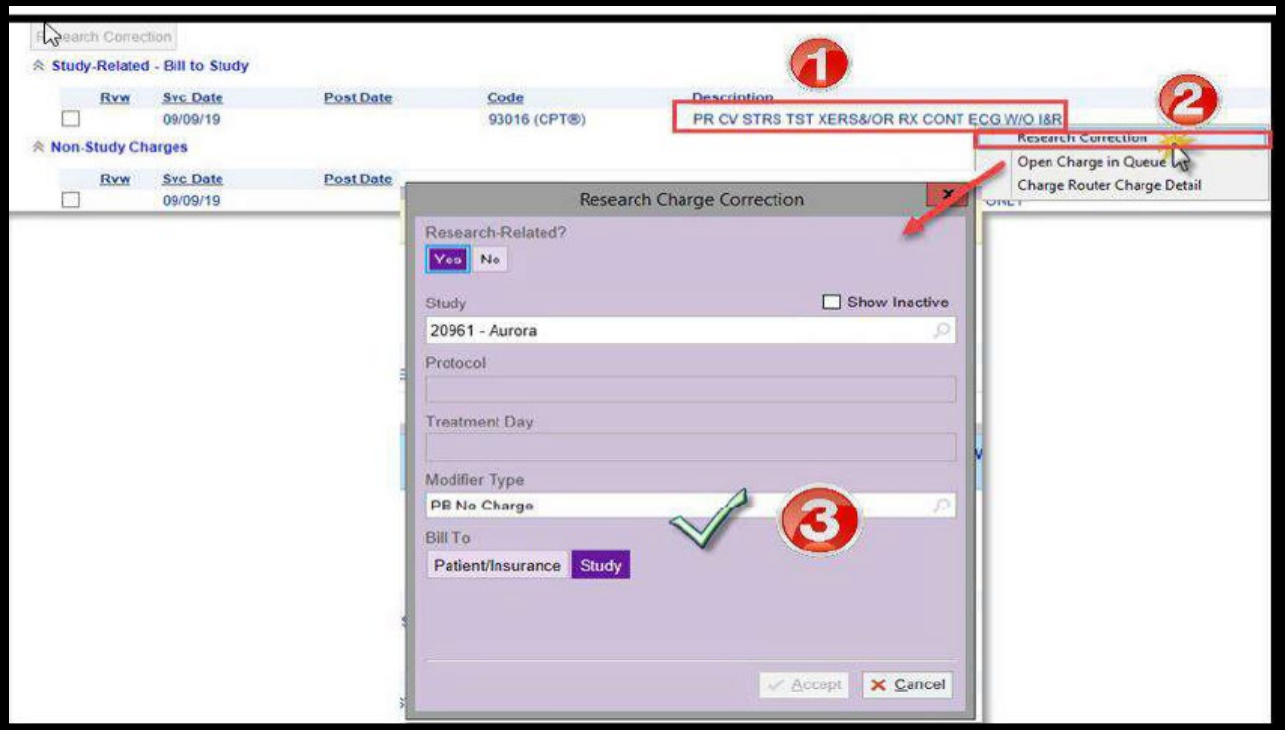
Investigational/Device

- Applied **only** to Investigational Device Charge Reviewed as Study Related and Billed to Insurance

PB NO CHARGE MODIFIER – PROFESSIONAL CHARGES BILL TO STUDY

- Only Applied to Professional Charges
- Federally Funded Research Study as Grant Cannot be Billed Twice for Same Service
- Imaging where Professional Read not required
- Must Bill to Study
- **ALWAYS** Examine Bill to designation after Applying PB No Charge Modifier as Bill to Status Reverts Back to Bill Insurance/Patient

CONFIRMING BILL TO DESIGNATION FOR PB NO CHARGE MODIFIER



RESEARCH CORRECTION

- Select Charge(s) Needing Correction
- Research Correction Button
- Accept
- Complete Review
- Research Corrections Occurring During 2nd Tier Review Result in Account Requiring **RE-REVIEW** by Study Team

DEVICE RESEARCH BILLING REVIEW

- Study Team Provides Device Specifications
- Confirms How the Device will be **BILLED**
- Confirms Where Procedure Performed and Department Billing Staff Who Should be Notified to Establish IDE billing Process
- Status of Request to Palmetto GBA (Recognize the participation of UVA and the study investigators and approve Part A and Part B claims Medicare study patients)
- NCT Number

DEVICE RESEARCH BILLING REVIEW

- MC Finance Generates Epic Code with Corresponding Price Associated with FDA IDE#
  - ❖Bill at Clinical Cost OR Bill with $0.01 Place Keeper
- Inform Applicable Teams of Scheduled Procedures
- Notify of Device Implantation
- Review Device Charge under **Revenue Code 0624**
- Apply **Investigational/Device Modifier** to Device Charge Reviewed as Study Related, Bill Insurance

QUIRKS OF BILLING REVIEW

- Outpatient Charges Lumped in with Admission Charges
- Room & Care Charge Reviewed as Bill to Service Requires **ALL** Services on that Date of Service to be Billed to Research Study
- HB Charge and PB Charge May not Pull for Billing Review Together
- PB Charge for Service May have **Different Date of Service**
- $0.00 Balance Accounts Need Billing Review
- Re-review of Charges May Require Team to Utilize Hyperlinks to Complete Billing Review

Manual Corrections

Performed After Charges have been Billed

Why?

- Study Team Linked-Late Encounter & Charges Billed to Insurance/Patient in Error
- Patient Reaches out to Disputed Claims
- Revenue Integrity Request
- Collections

LATE-LINKED ENCOUNTER

- Email HSR IRB#, Patient Name, MRN, Date of Service, Services Needing Correction to Bill to Study
- Correction Requests through Patient Financial Services, University Physicians, and UVA Imaging
- HB & PB Charges will Pull for Research Billing Review for Study Team to Make Corrections During Billing Review
- Ensure Charges are Reviewed with Correct Billing Designation

ERRORS DURING RESEARCH BILLING REVIEW

- Reviewing HB and PB Charge for Service with Different Billing Designations
- Point of Care Testing, Contrast, CDSM NDSC NOT Reviewed with Billing Designation of Imaging
- Medication Administration NOT Reviewed with Billing Designation of Medication
- Failure to Apply Modifier
- Applying Incorrect Modifier

RESEARCH BILLING RESOURCES

- Epic Learning Library Research Tip Sheets
- Drop-in Hours Every 2nd & 4th Wednesday 10-11AM
- Schedule Training/Refresher Session
- Direct Support

‘TO TRANSFORM HEALTH & INSPIRE HOPE FOR ALL VIRGINIANS AND BEYOND’

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