Weill Cornell Medicine

Research Billing Compliance Handbook

COMPLIANCE AND PRIVACY OFFICE

Revised January 2023

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INTRODUCTION

Weill Cornell Medicine ("WCM") is committed to ensuring that research is conducted in compliance with good clinical practices and in an ethical manner that protects the rights and welfare of the research participants.

The Compliance and Privacy Office ("CPO") at WCM provides guidance and ensures that research-related services are billed appropriately and in accordance with Medicare's National Coverage Decision for Clinical Trials.

This Research Billing Compliance Handbook will:

- Distinguish between Research Billing Compliance and General Billing Compliance.
- Provide the current Centers for Medicare and Medicaid Services ("CMS") and WCM policies for billing research-related services.
- Offer instructions on appropriately billing research-related services for clinical trials and other research studies involving clinical services.
- Provide guidance on identifying common research service coding and documentation errors.

Information contained in this guide is subject to change as billing procedures are continually revised. This guide will be updated annually as regulations change or WCM procedures are updated.

Please ensure that the information provided in this handbook is communicated to employees involved in research studies. Research patients must clearly understand which clinical services are payable by the research study and which will be submitted to their insurance and/or personally become their responsibility (i.e., co-payments and/or insurance deductibles). Research participants must be aware of the services that are or may become their responsibility, and this should be communicated to research participants via the Informed Consent Form ("ICF").

BILLING COMPLIANCE

Weill Cornell Medicine faculties engaged in clinical practice have specific legal requirements regarding how their professional services are billed. General billing compliance is challenging because regulatory requirements governing professional fee reimbursements are complex and subject to frequent modification.

The University has established a Billing Compliance Oversight Committee and adopted a Compliance Plan (the "Plan") to address billing for professional services, including billing regulations for supervising post-graduate trainees. The Plan sets forth a comprehensive compliance program to ensure a consistent interpretation and effective application of Medicare, Medicaid, and other third-party payor billing requirements relating to professional fee reimbursement.

RESEARCH BILLING COMPLIANCE

The purpose of the research billing compliance program is to help ensure that clinical services associated with a clinical research study are monitored to verify that the services are not billed inappropriately or in duplicate to a patient or third-party payer and that there is a general understanding of and adherence to all regulations governing medical billing practices related to clinical research, including but not limited to the CMS National Coverage Decision. Compliance with research billing policies and regulations helps to:

- Reduce billing risks between research and routine standard-of-care services.
- Reduce the risks of inappropriately billing research participants and/or third-party payers.
- Ensure consistency of clinical service payment responsibility across all study documents.
- Ensure there is an appropriate recovery of clinical research study costs.

WHY IS RESEARCH BILLING COMPLIANCE IMPORTANT?

- It is the law--CMS developed the Clinical Trial Policy in response to President Clinton's June 7, 2000, executive memorandum.

- Medicare "double billing"--billing the research participant or third-party payer for items or services already paid for by the grant or research sponsor is considered fraud.
- It is essential to determine "routine/standard of care" versus "research only" items and services.

RESEARCH-RELATED SERVICES COVERED BY MEDICARE

The Medicare program is a federal health insurance program designed to pay for medically necessary diagnostic and therapeutic health care services for a specific beneficiary's illness or injury-related care. Medicare provides coverage for medically necessary routine/standard of care services rendered to Medicare beneficiaries enrolled in a research protocol provided the same services are not paid for or otherwise provided by research sponsors.

The Medicare program does not reimburse or subsidize research for "research's sake." Nor does it cover the cost of items or services paid for by another party, such as those provided by the research sponsor.

The billing of Medicare (and Medicaid or other third-party payers) for items and services rendered to research participants must be carefully reviewed to ensure its appropriateness. That is, billing must be in accordance with CMS fee schedules used to reimburse physicians and/or other providers on a fee-for-service basis.

Research protocols often combine routine/standard-of-care and research protocol-driven services. This complicates the billing process and increases the risk of potential billing errors, which can result in the submission of inadvertent false claims. To avoid compliance risks, when initiating the study's budget and terms, researchers and their staff must be familiar with the regulations, WCM policies, and procedures related to research billing and understand how they apply to the research study.

Documentation requirements for research patients

Research participants' clinical documentation should include the clinical research study's name, the name of the research sponsor, and the assigned Institutional Review Board ("IRB") approved protocol number. This documentation must be provided if requested for a medical review by Medicare and/or

a third-party insurance payer. A copy of the participant's signed ICF must also be made available if requested for medical review.

To help attain this information, a list of studies the patient is enrolled in can be found in the patient's medical chart under the tab 'Research Studies.' Information for each study will be listed, which includes the title and type of study, the start date, IRB, and the National Clinical Trial number ("NCT").

SERVICES RENDERED TO RESEARCH PARTICIPANTS

Routine/Standard of Care

Medicare's Coverage Decision for Clinical Trials states that the definition of standard of care includes research protocol items and services that are ordinarily covered outside of a trial in accordance with coverage guidelines and are provided for any of the following reasons:

- Direct clinical management of the patient
- Conventional care
- Clinically appropriate monitoring of the effects of the investigational item or service
- Services required for prevention, diagnosis, or treatment of complications
- Provision/administration of an investigational item or service (e.g., infusion administration services and supplies)

Examples of routine/standard-of-care services may include blood tests to measure tumor markers, office visits for follow-up of a chronic condition, or imaging tests for implanted devices. In some clinical trials, the sponsor may agree to pay for all services, including those customarily considered standard-of-care. These services should not be billed to the patient and/or the patient's insurance in those cases.

Research Protocol-Driven Services

Protocol-driven services are those explicitly rendered for data collection and would not be provided if the patient was not enrolled in the study. These services are performed simply because of the protocol requirement and not because the patient's medical condition warrants it.

Research protocol-driven items or services can be:

- An investigational item or service (whatever is being studied).
- Items or services rendered solely for research purposes (i.e., data collection).
- Items or services rendered solely to determine trial eligibility.
- Items or services paid for by the grant or research sponsor.
- Items or services promised "free" in the ICF because the sponsor has made special arrangements, such as using an outside lab or providing investigational equipment.

CLINICAL TRIAL BILLING POLICY

The Compliance Plan addresses the parties responsible for overseeing the research patient billing activity of all clinical trials conducted at WCM regardless of payer.

The Clinical Trial National Coverage Determination issued by CMS is the principal billing rule for services rendered during a clinical research study. The policy is intended to encourage Medicare beneficiaries to participate in clinical trials without penalties. As of September 2000, Medicare explicitly authorized payment for routine/standard-of-care costs and costs associated with medical complications from participation in a qualifying clinical trial.

CMS Guidelines

Medicare is considered the "Gold Standard" by which many third-party payors base their coverage decisions, including coverage for clinical research services.

"Medicare covers the routine costs of qualifying clinical trials, as well as reasonable and medically necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicare rules apply."

COVERAGE ANALYSIS

WCM Policy

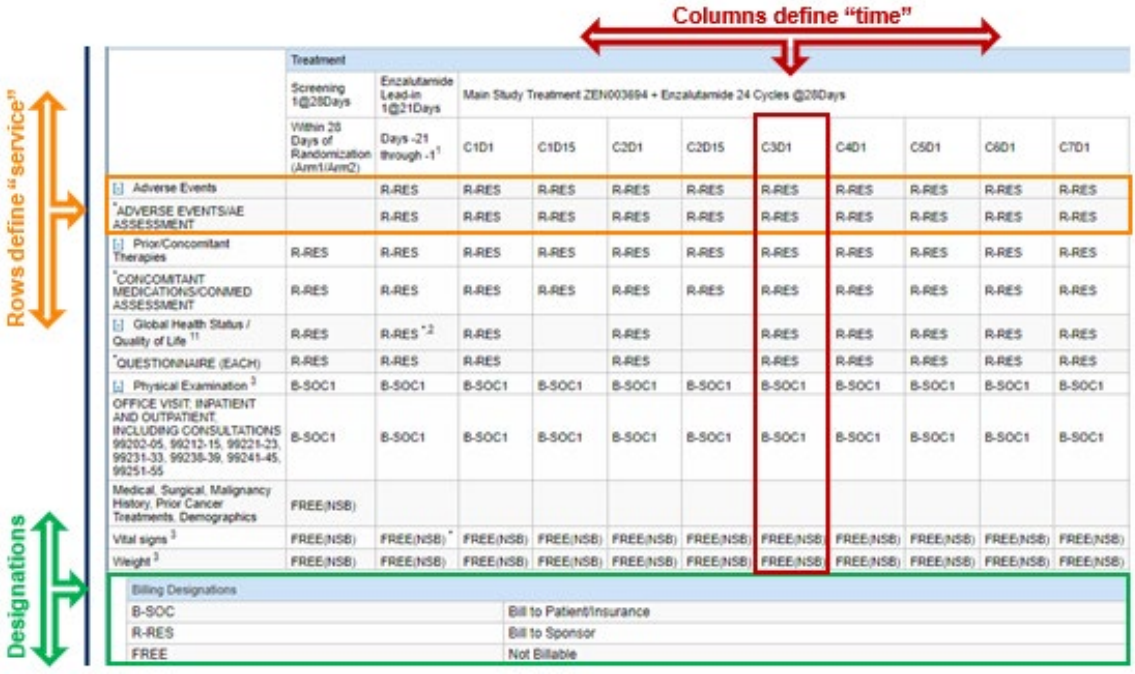
Weill Cornell Medicine policy requires completing a coverage analysis of research-related patient services in conjunction with the initial IRB submission and again at the time of renewal. The coverage analysis involves a review of the protocol requirements to determine if study-related services are billable to the patient's insurance as medically necessary routine/standard-of-care or if the services are billable to the study sponsor.

Principal Investigators ("PIs") must generate a coverage analysis for each IRB application, and the analysis should be updated accordingly when any protocol changes occur. The coverage analysis form is intended to replicate the patient services schedule of events as stated in the research protocol and/or informed consent and, in general terms, the service provider and payment responsibility. Completing the coverage analysis requires a thorough understanding of the protocol and funding and consideration of whether the clinical services are medically necessary routine/standard of care and would have been rendered to the patient regardless of enrollment in the research study. It also requires knowing to what extent the sponsor pays for clinical services.

The Department Compliance Liaison (for the PI) and/or a CPO manager are responsible for reviewing and approving the coverage analysis once the calendar is complete and the budget has been approved. Therefore, research billing compliance personnel must know how to read a coverage analysis, which is defined by columns of time vs. rows of services. The figure below depicts an example of a portion of a completed coverage analysis.

The compliance designee will review the coverage analysis and the study protocol with particular attention to the schedule of events, the IRB application, informed consent, and budget, when applicable. Once the coverage analysis is approved by the Department Compliance Liaison (for the PI) and/or a CPO manager (on behalf of the department), this information is used to create a billing grid that facilitates the routing of research charges for billing in the Practice Management System ("Epic").

- Studies originating <u>before</u> 7/1/2021 should have included the submission of a Human Research Billing Analysis Form ("HRBAF"). Since the use of the HRBAF has been phased out, those still active studies will continue to use the HRBAF for the lifecycle of the research study.
- Studies originating <u>after</u> 7/1/2021 require a coverage analysis to be generated in the clinical trials management system, OnCore.



	Treatment										
	Screening 1@28Days	Enzalutamide Lead-in 1@21Days	Main Study Treatment ZEN003694 + Enzalutamide 24 Cycles @28Days								
	Within 28 Days of Randomization (Arm1/Arm2)	Days -21 through -1[1]	C1D1	C1D15	C2D1	C2D15	C3D1	C4D1	C5D1	C6D1	C7D1
[-] Adverse Events		R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES
*ADVERSE EVENTS/AE ASSESSMENT		R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES
[-] Prior/Concomitant Therapies	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES
*CONCOMITANT MEDICATIONS/CONMED ASSESSMENT	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES	R-RES
[-] Global Health Status / Quality of Life [11]	R-RES	R-RES *2	R-RES		R-RES		R-RES	R-RES	R-RES	R-RES	R-RES
*QUESTIONNAIRE (EACH)	R-RES	R-RES	R-RES		R-RES		R-RES	R-RES	R-RES	R-RES	R-RES
[-] Physical Examination [3]	B-SOC1	B-SOC1	B-SOC1	B-SOC1	B-SOC1	B-SOC1	B-SOC1	B-SOC1	B-SOC1	B-SOC1	B-SOC1
OFFICE VISIT, INPATIENT AND OUTPATIENT, INCLUDING CONSULTATIONS 99202-05, 99212-15, 99221-23, 99231-33, 99238-39, 99241-45, 99251-55	B-SOC1	B-SOC1	B-SOC1	B-SOC1	B-SOC1	B-SOC1	B-SOC1	B-SOC1	B-SOC1	B-SOC1	B-SOC1
Medical, Surgical, Malignancy History, Prior Cancer Treatments, Demographics	FREE(NSB)										
Vital signs [3]	FREE(NSB)	FREE(NSB) *	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)
Weight [3]	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)	FREE(NSB)

Billing Designations	
B-SOC	Bill to Patient/Insurance
R-RES	Bill to Sponsor
FREE	Not Billable

The **column** headings are service intervals defined by the investigator (days, weeks, months, cycles, etc.) to reflect the planned timing/interval of when services will be rendered after enrollment in the study. The **row** headings are service categories defined and organized by the PI. Individual CPT codes

accompany services listed under each row heading. The grid **billing designation** codes are added to complete the grid. Currently, three codes are used, defined below.

- **B-SOC** indicates that the service is medically necessary, routine/standard-of-care, and may be billed to the patient or their insurance. It is essential to ensure the patient is aware of their responsibility to pay, even though this is specified in the informed consent. Depending on individual patient circumstances, an Advanced Beneficiary Notice (ABN) might be required for Medicare patients, and a Notification of Non-Covered Services might be needed for other patients. Notification is essential for transparency and protection from surprise billing from an out-of-network provider at a participating hospital.
- **R-RES** indicates that the research sponsor or private or internal funds pay for services designated in the protocol or contract, and these are not to be billed to the patient or their insurance.
- **Free** would be listed for services or products provided directly by the study sponsor and, therefore, not billable. For example, a laboratory service would be designated as "Free" if the protocol requires that labs are sent to a central lab facility and paid for by the sponsor (and no direct billing to the research account at WMC or the patient/insurance will take place). Another example is when the sponsor provides the study drug "free of charge."
    - **Free/NSB** would be listed for services that are 'not separately billed'; services that are bundled ('vitals' when done outside the physical examination).

WHAT IS A QUALIFYING CLINICAL TRIAL?

A qualifying clinical trial is a trial that MUST satisfy the three "necessary requirements" AND be deemed CMS to have the 7 "desirable characteristics."

The three (3) "necessary requirements" are:

1. The study must investigate an item or service in a Medicare benefit category.
2. The study must enroll patients with diagnosed diseases rather than healthy volunteers.
3. The study must have therapeutic intent – it must not be designed solely to test the safety or toxicity of the investigational item or service.

The seven (7) "desirable characteristics" are:

1. The principal purpose of the trial is to test whether the intervention potentially improves the participants' health outcomes.
2. The trial is well-supported by available scientific and medical information or intended to clarify or establish the health outcomes of interventions already in common clinical use.
3. The trial does not unjustifiably duplicate existing studies.
4. The trial design is appropriate to answer the research question being asked in the trial.
5. The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully.
6. The trial complies with Federal regulations relating to protecting human subjects.
7. All aspects of the trial are conducted according to the appropriate standards of scientific integrity.

NOTE: CMS does not allow PIs to self-certify that the seven (7) desirable characteristics are present. CMS always identifies specific clinical trials with these characteristics, referred to as "Deemed Trials."

Qualifying Clinical Trials: "Deemed Trials"

Clinical trials deemed by CMS to have the seven (7) desirable characteristics are:

- Trials funded by certain government agencies: National Institute of Health (NIH), Center for Disease Control ("CDC"), Agency of Healthcare Research and Quality ("AHRQ"), CMS, Department of Defense ("DOD"), and the Veterans Administration("VA").
- Trials funded by centers or cooperative groups that receive funding from the government agencies noted above.
- Trials conducted under an Investigational New Drug application ("IND") reviewed by the FDA.
- Drug trials exempt from having an IND under 21 CFR 312.2(b)(1).

DEVICE TRIAL

Medicare coverage for Investigational Devices and services "related to" the use of those devices is limited to those being studied by the FDA-approved clinical trial. Examples of services "related to" the use of the devices are hospital stay, the surgeon's and anesthesiologist's fees, and other professional/technical fees for services required during the device's implantation (are included in this definition).

FDA categorizes all Investigational Device Exceptions (IDE) into two categories:

Category A: Innovation devices for which the 'absolute' risk of the device has not been established (i.e., initial questions of safety and effectiveness have not been resolved). Centers for Medicare and Medicaid Services does not cover Category A devices under Medicare because they do not satisfy the statutory requirement that Medicare pays for devices determined to be reasonable and necessary. The study designed for this type of device would most likely examine the safety and effectiveness of this device.

Category B: Non-experimental and/or investigational devices where the incremental risk is the primary risk in question (i.e., underlying questions of safety and effectiveness of that device have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA approval for that device type. Centers for Medicare and Medicaid Services will cover Category B devices if they are considered reasonable and necessary and if all other applicable Medicare coverage requirements are met.

However, there is an exception that falls outside these two categories. The exception is devices determined to be reasonable and necessary for rare diseases where it would be challenging to gather enough clinical evidence to meet the FDA standard for safety and effectiveness. This regulatory pathway was created for humanitarian medical devices intended to benefit patients in diagnosing and treating rare diseases that affect ≤ 8,000 individuals in the United States annually.

CMS Policy on Device Trial Billing

The Center for Medicare and Medicaid Services does not cover Category A devices because they do not satisfy the statutory requirement that Medicare pays for devices determined to be reasonable and necessary. However, they will cover Category B devices if considered reasonable and necessary, and all other applicable Medicare coverage requirements are met.

Medicare's approval process for device trials involves a two-part authorization request from the PI of the study to the fiscal intermediary (National Government Services/NGS).

HOW ARE RESEARCH PATIENTS BEING FLAGGED IN ONCORE?

Weill Cornell Medicine policy mandates that each research study participant who signs an ICF must be registered in OnCore. The study team must add the date of consent and upload the signed ICF to OnCore for the central registration team to review. After that, the registrar enters eligible and 'on study dates' if the consent is valid.

If the participant consented to a study with billing services, that participant's medical chart is flagged in Epic, creating a patient-study association ("study record"). This association will allow study-related information and/or activity to be documented, encounters and/or orders to be linked, and ultimately study-related charges to be routed to the research workqueues to be reviewed. This "study record" can be found in the patient's medical chart under the tab 'Research Studies' and includes the study title, the type of study, the start date, IRB, and NCT number.

RESEARCH IDENTIFIERS USED FOR RESEARCH BILLING

Weill Cornell Medicine policy requires that the correct research modifier and research diagnosis code be appended to all claims billed to the patient and/or their insurance.

The CPO monitors research participants' billing activity for all routine/standard-of-care services associated with clinical trials conducted at WCM to ensure they are submitted with the correct modifier and diagnosis code.

All research services must be posted with a valid CPT code and linked to the appropriate fee schedule (No dummy code (99999) OR $0.00 fee should be posted in Epic).

Research Modifier ("BG")

BG (Billable to Grant) is a modifier used in the Epic system to identify those services paid by the sponsor/study. This is an internal modifier unique to WCM to prevent a bill associated with the charge from being released to the patient or patient's insurance.

Research Modifiers ("Q1" and "Q0")

The Q1 modifier is used to identify items and services that constitute medically necessary routine/standard of care or treatment of complications arising from a Medicare beneficiary's participation in a Medicare-covered clinical trial. The Q1 modifier serves as the provider attestation that the service meets the Medicare coverage criteria (i.e., was furnished to a beneficiary participating in a Medicare qualifying clinical trial and represents routine/standard patient care, including complications associated with qualifying trial participation).

The Q0 (numeral 0 versus the letter o) modifier is used for investigational clinical service provided in a clinical research study that is in an approved clinical research study. Investigational clinical services are those items and services being investigated as an objective within the study. Investigational clinical services may include items or services approved, unapproved, or otherwise covered (or not covered) under Medicare.

Research Diagnosis Code ("Z00.6")

The research diagnosis code Z00.6 is used to identify a participant in a clinical trial and is appended as a secondary diagnosis code (or in the primary position if the participant is a healthy control group volunteer). All claims submitted with the modifier Q1 or Q0 require using the diagnosis code Z00.6.

Mandatory reporting of National Clinical Trial ("NCT") Identifier Numbers on Medicare Claims

Effective January 1, 2015, CMS requires WCM to include NCT identifier numbers on all claims forms for items and services provided in clinical trials. The NCT number is used only if the clinical services are associated with the clinical trial. Center for Medicare and Medicaid Services uses the NCT number to identify all items and services provided to beneficiaries during their participation in a clinical trial, clinical study, or registry. Epic has been updated with the NCT numbers for each corresponding protocol with billable clinical services.

RESEARCH BILLING COMPLIANCE REPORTING

Quarterly Report

The CPO will re-establish the Research Billing Compliance Quarterly Report to ensure that all research billing activities at WCM are monitored and properly documented. This report will be distributed with the General Billing Compliance Quarterly Report to each Department Administrator and Billing Compliance Liaison.

The following items will be included in the Research Billing Compliance Quarterly Report:

- The total number of active studies
- The total number of active studies with billing risk
- The number of PIs associated with those studies at risk
- The total number of research participants identified in OnCore

- The total number of all research enrollments associated with active and closed studies
- A summary page that contains information about research audit results and actions taken/pending by the Department to ensure compliance with the Research Billing Compliance Policies.

The purpose of the Research Billing Compliance Quarterly Report will be to facilitate a reconciliation process. For closed studies with open enrollments in OnCore, verification regarding the closure of the study will be required from the department. Departments should reconcile the list of all active studies and confirm studies with billing compliance risk (studies with clinical services vs. studies with no clinical services). Departments should also confirm the enrollment of active research participants against the WRB-HS.

A quarterly meeting will be conducted with the department's Compliance Liaison, Department Administrator, and Compliance Leader. The department's compliance team will be asked to review the report thoroughly along with the required actions for discrepancies and discuss any questions and/or concerns with their Billing Compliance Manager during their Quarterly Report Meeting.

Annual Report

The quarterly reports, with the addition of active research information, will be compiled and summarized in the annual report.

RESEARCH BILLING COMPLIANCE MONITORING

Annual Research Billing Compliance Risk Assessment

For those studies identified as having billing risk, compliance reviews will be conducted on an ongoing basis in one of the following manners:

- Random verification that the coverage analysis/billing grid identifies all items/services and distinguishes financial responsibility for all study-related services as outlined in the schedule of events in the study protocol.

- Random confirmation that grant funds are used according to appropriate fee schedules.
- Prospective routine and random audits of select departmental principal- (PI) and co-principal investigators.
- Retrospective review of all billing for a selected study or a single research subject within a selected study.
- A probe review based on an alleged issue or concern, e.g., via the hotline or other report, insurance, sponsor, patient inquiry, or a pattern of payment denials.

The compliance office will prioritize each PI's active clinical research studies with participants who received clinical services to identify studies with billing compliance risk. Regardless of the review manner listed above, a formal, systematic audit review will be conducted on a sample of research studies to verify a consistent interpretation and effective application of study-related charges and to ensure that designated research billing systems are being utilized to the full extent and in adherence to all regulations governing medical billing practices related to clinical research. This is achieved through centrally reviewing research study administrative documentation in OnCore, tracking trends and reconciling enrollment WRB-HS, and performing a concordance review of OnCore coverage analysis with the study protocol, the IRB application, informed consent, and budget, when applicable.

Errors identified during an audit review include:

- Misdirected research billing--Research billed as SOC OR SOC billed as Research
- Modifier--Research Modifier Missing OR Incorrect
- Diagnosis--Research Diagnosis Code Not Used OR Not Correct
- NCT number--Research NCT Not Used OR Not Correct
- Research Related Services Rendered BUT Not Billed/Posted
- Research Service Posted With a $0.00 Charge
- Patient not flagged as Research in Epic

A summary of compliance findings, including risks, identified, the root cause of deficiencies or violations, and recommendations for corrective actions, is compiled and sent by the CPO to the

department(s) impacted, the Compliance Leader and Liaison, as well as the Joint Clinical Trials Office ("JCTO").

The department will be required to respond to any identified risks by providing a management response, a plan of action for resolution, and a timeline for completion. Immediate and preventive corrective actions are monitored, and the seriousness and complexity of the deficiencies dictate the nature of the follow-up.

WHAT CAN BE DONE TO ENSURE COMPLIANCE WITH RESEARCH BILLING REQUIREMENTS?

- Determine whether your clinical trial qualifies for Medicare coverage for the routine care costs associated with the clinical trial.
- Review all research documents for consistency (coverage analysis with the study protocol, the IRB application, informed consent, and budget).
- Ensure consistency of payment terms across the research documents.
- Ensure documentation to support each service billed appropriately.
- Ensure audit requirements are met:
    - Participants are entered in OnCore.
    - All paper and electronic documentation include protocol name and number.
    - Confirm no zero-dollar charges, and Q0, Q1 and BG modifiers are used correctly.
    - Verify the use of Z00.6 diagnosis code in conjunction with Q0 and Q1 modifiers.

CONTACT INFORMATION

If you have questions or concerns about Research Billing Compliance, please contact:

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REFERENCE LINKS IN TEXT

WCM Compliance Plan: https://compliance.weill.cornell.edu/sites/default/files/2021-01_wcm_annual_compliance_program_fy22.pdf

CMS Fee Schedules: https://www.cms.gov/medicare/physician-fee-schedule/search/overview

Clinical Trials Policy/Clinical Trials National Coverage Determination:
https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=1&fromdb=true

Medicare's Coverage Decision for Clinical Trials/Qualified Clinical Trials:
https://www.cms.gov/Medicare/Coverage/ClinicalTrialPolicies/Downloads/Finalnationalcoverage.pdf

Surprise Medical Bills:
https://www.dfs.ny.gov/consumers/health_insurance/surprise_medical_bills

Humanitarian Medical Devices: https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/humanitarian-device-exemption

National Clinical Trial (NCT) Identifier: https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Downloads/Mandatory-Clinical-Trial-Identifier-Number-QsAs.pdf

CMS Manual: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals