Clinical Research Support Office

UNIVERSITY OF KENTUCKY
CLINICAL RESEARCH SUPPORT OFFICE
BILLING INTEGRITY UNIT

Clinical Trials Billing Guide

ROLES AND RESPONSIBILITIES

Each UK staff involved in handling claims reviews, budget preparations, and overall financial management of a clinical trial is responsible for understanding and adhering to the state and federal rules and regulations, as well as the UKHC reimbursement policies and procedures. Staff conducting clinical trials and responsible for the financial and operational management of such trials, is required to comply with the federal rules for reimbursement, and for health care related claims as set forth under the Uniform Grants Guidance, the False Claims Act, CMS, and the state's Medicaid program, among others.

The Principal Investigator (PI) has primary accountability for all aspects of the clinical trials operating under his/her name. The PI may delegate responsibility for the required procedures to appropriately qualified members of the study team.

The Clinical Research Support Office (CRSO) offers the initial forecasting of charges for clinical trials, known as the Medicare Coverage Analysis (MCA). This is a tool to guide the teams during their charge segregation and to aid billing compliance; however, because the MCA is not patient specific, the detailed billing, coding, and documentation for health care related claims is the responsibility of each team conducting the clinical Trials and UKHC.

The CRSO is not a centralized department for the financial management, charge segregation, or first tier review of claims for all clinical trials. The CRSO manages the OnCore system, including the development of a detailed calendar of events, and the Medicare Coverage Analysis (MCA). The financial responsibility, including the development and negotiation of budgets and charge review, are not under the CRSO purview.

This is intended as a guide for billing in clinical trials, based on the current Centers for Medicaid and Medicare Services (CMS), the Uniform Grant Guidance, the U.S. Food and Drug Administration (FDA), and the False Claims Act, among others. This guide does not include specific third party insurance requirements, such as prior authorization. This guide does not include specific KY Medicaid billing requirements – please consult with the UKHC billing and coding experts to determine the State Medicaid program coverage and limitations in clinical trials.

Clinical Research Support Office

Equity and No Legal Obligation to Pay Provisions – All clinical trials must comply with these provisions, no exceptions allowed by federal law

Exclusions are forbidden:

Medicare has no obligation to pay for items and services if a provider treats Medicare beneficiaries differently from non-Medicare patients, or if other situations trigger Medicare exclusions. The provision outlines limited situations (such as patient indigence) when waiving charges for non-Medicare patients will not disturb Medicare coverage.

No Legal Obligation to Pay:

This provision under the Medicare Benefit Manual addresses scenarios such as billing Medicare for a service while not billing non-Medicare patients for the same service. This provision of the manual operates to prohibit billing Medicare for the same service that is provided free to non-Medicare beneficiaries. In such a case, Medicare has no legal obligation to pay for the service, and the provider also cannot charge the Medicare beneficiary.

Equity:

The Special Edition Article issued by CMS, clarifies that if a provider does not charge a non-Medicare enrollee for a research study service, then the Medicare enrollee must also receive that same study service free. If the provider does not pursue collections against the research subject after the patient's insurance denies coverage, CMS argues that the provider's actions disallow billing for the same service for Medicare patients enrolled in the study.

CMS utilizes the CTP's "free of charge" rule which prohibits billing Medicare for "items and services customarily provided by the research sponsors free of charge for any enrollee in the trial." This provision of the CTP has generally been understood to apply to situations in which the sponsor pays outright for a specific service. If the sponsor pays outright for the service, then Medicare cannot be billed for the service.

Collections for those patients with denied claims under clinical trials:
CMS does not stop with the sponsor's obligation in the clinical trial agreement to pay for services denied coverage, but applies the "free of charge" category to any instance in which the provider does not pursue collection against an enrollee.

CMS provision: "If private insurers deny the routine costs and the provider of services does not pursue the non-Medicare patients for payment after the denials (even though the non-Medicare patient has the ability to pay), Medicare payment cannot be made and the beneficiary cannot be charged for the routine costs."

Investigator Initiated Studies:

Using a patient-by-patient approach for billing during an unfunded/underfunded study could disallow Medicare billing if the provider does not pursue collections against one non-Medicare enrollee, where insurance will not cover a scheduled service. According to the Special Edition Article's "clarification," not pursuing collections against non-Medicare patients enrolled in a research study operates to prohibit the

provider from billing the same service to a Medicare patient enrolled in the research study, unless the provider did not pursue collections against the non-Medicare patient pursuant to the provider's "indigence policy".

1.- Coverage

CMS (Medicare) allows for reimbursement of Routine Costs in Clinical Trials under three policies:

1. Clinical Trial Policy (CTP) – National Coverage Determination (NCD) 310.1

The CTP is a National Coverage Determination (NCD) that allows payment of routine items/services, and payment of the investigational item/service if it is normally covered outside of the trial. Such services must meet specific medical necessity requirements in the statutes, regulations, and manuals, and specific medical necessity criteria defined by (NCDs) and Local Coverage Determinations (LCDs), if any apply to the reported service. For every service billed, the specific sign, symptom, or beneficiary complaint that makes the service reasonable and necessary must be documented for all clinical trials that qualify for coverage.

Note: Medicare does not pay for medically unreasonable and unnecessary services and supplies to diagnose and treat a beneficiary's condition.

Some examples include:

- Evaluation and management services exceeding those considered medically reasonable and necessary
- Excessive therapy or diagnostic procedures
- Unrelated screening tests, examinations, and therapies for which the beneficiary has no symptoms or diagnoses, except for certain screening tests, examinations, and therapies, as limited or expanded under the National and/or Local Coverage Determinations, and
- Unnecessary services based on the diagnosis of the beneficiary

2. Investigational Device Exemption (IDE) Policy

CMS added criteria for coverage of IDE studies and changed from local Medicare Administrative Contractor (MAC) review and approval of IDE studies to a centralized review and approval of IDE studies.

- An approval for a Category A (Experimental) IDE study will allow coverage of routine care items and services furnished in the study, but not of the Category A device, which is statutorily excluded from coverage.
- An approval for a Category B (Non experimental/investigational) IDE study will allow coverage of the Category B device and the routine care items and services in the trial. The listing is available on the CMS Approved IDE Studies webpage.

3. Coverage with Evidence Development (CED):

Medicare may issue an NCD that requires participation in certain clinical trials, **longitudinal studies, or registries for coverage** of an item/service and routine and related items/services.

- CMS released an updated guidance document on November 20, 2014, that describes coverage with evidence development (CED). CMS, as part of the national coverage determination (NCD) may determine coverage of an item or service only in the context of a clinical study.
- All CED studies are listed on the Centers for Medicare & Medicaid Services' (CMS') CED Website.
- Under CED, routine costs of an approved clinical trial in both the treatment arm and the control (standard of care or placebo) arm are paid. Routine costs include all items and services that are otherwise generally available to Medicare beneficiaries (i.e., there exists a benefit category, coverage is not statutorily excluded, and there is not a national non-coverage decision),provided in either the experimental or the control arms of a clinical trial.

Medicare Billing Table

Medicare coverage of clinical trials, prospective studies, and registries			
	CTP	**IDE**	**CED**
CMS approval required	No – must qualify under NCD 310.1	Yes –each specific study approved by FDA before 1/1/2015, requires MAC approval; for each specific study approved by FDA after 1/1/2015, requires CMS approval	Yes – requires CMS approval for each specific study
Public notification	No – provider determines qualification	Each specific study approved by FDA after 1/1/2015 appears on CMS IDE Website	Each specific study approved by CMS appears on CMS CED Website
Routine services (Q1)	Covered if otherwise coverable by Medicare in qualified study	Covered if study is approved by CMS and otherwise coverable by Medicare	Covered if study is approved by CMS and otherwise coverable by Medicare
Investigational item/ service (Q0)	Covered if otherwise coverable by Medicare in qualified study	Covered if study is Category B, and approved by CMS	Covered if study is approved by CMS

2.- Billing Medicare and Medicare Advantage

- Medicare will reimburse qualifying clinical trial claims on behalf of MA members and will waive the Part A and the Part B deductibles. MA plans are responsible for the remaining original Medicare coinsurance, minus the plan's normal member copays for the incurred types of service.
- Clinical trial coding requirements for Medicare Advantage claims are the same as those for regular Medicare fee for service claims. However, for Medicare Advantage plans, we must not bill outpatient clinical trial services and non-clinical trial services on the same claim.
- If covered outpatient services unrelated to the clinical trial are rendered during the same day/stay, the provider must split-bill so that ONLY the clinical trial services are contained on a single claim and billed as fee-for service (this allows the Medicare claims processing system to not apply deductible when the patient is found to be in a managed care plan). Any outpatient services unrelated to the clinical trial should be billed to the managed care plan.

3.- Claims Reporting Requirements:

The NCT identifier number is required for all trial/registry/study-related claims if it qualifies per the CTP, is an IDE study, or is a CED study.

- All clinical Trials registered on ClinicalTrials.gov are assigned an NCT identifier number. All clinical trials that include billable charges should report the NCT# on all related claims as long as the patient is a study participant.
- For all patients in a clinical trial who have completed their active treatment, and are being seen yearly for observation, the National Clinical Trial (NCT) identifier number is not needed.
- If patients are in an observation-only trial (where the trial is looking at care trending and has no bearing on treatment decisions) the NCT identifier number is not required.
- If the treating UKHC physician orders lab tests/scans, and these are not required by the study (not included in the schedule of events or the billing grid) and the patient is still in a clinical trial, the NCT number is not reported.
- If the UKHC treating physician orders labs required by the study protocol, and also orders additional labs, the Q1 modifier is required on the study-required labs but not for the additional labs.
- The Q1 modifier is applied on all line items.
- A claim does not require the NCT# for a clinical trial patient who has been admitted to the hospital for a problem not related to the clinical trial (i.e., sepsis, heart attack).
- Pediatrics and Children's Oncology Group (COG) trials: Medicare indicates that these billing and compliance policies apply to all Medicare beneficiaries regardless of age.
- The Z00.6 diagnosis code needs to be reported in the secondary position on the hospital and professional claim when billing for items/services related to a Qualified Clinical Trial or approved study, regardless of whether all services on the claim are related to the clinical trial or not.
- Condition Code 30 means "Qualified Clinical Trial". It must appear on the hospital inpatient or outpatient claim when billing for items/services related to a Qualified Clinical Trial, regardless of whether all services on the claim are related to the clinical trial or not – this is for institutional claims.

4.- Humanitarian Device Exemption

- Humanitarian Use Device (HUD): a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year (Section 3052 of the 21st Century Cures Act (Pub. L. No. 114-255).
- Humanitarian Device Exemption (HDE): a marketing application for an HUD (Section 520(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)). An HDE means the device is exempt from the effectiveness requirements of Sections 514 and 515 of the FD&C Act and is subject to certain profit and use restrictions. HDE claims are not guaranteed payment, and many are denied. The 0624 revenue code should be used, along with applicable clinical trial coding, when the HDE has been reviewed and approved as a clinical trial meeting medical necessity.
- "Under section 520(m)(6)(A)(i) of the FD&C Act, an [Humanitarian Use Device] HUD is only eligible to be sold for profit after receiving an HDE approval if the device is intended for the treatment or diagnosis of a disease or condition that either:
    - occurs in pediatric patients or in a pediatric subpopulation, and such device is labeled for use in pediatric patients or in a pediatric subpopulation in which the disease or condition occurs; OR

    - Occurs in adult patients and does not occur in pediatric patients or occurs in pediatric patients in such numbers that the development of the device for such patients is impossible, highly impracticable, or unsafe." - U.S. Department of Health and Human Services, FDA
- Medicare has no specific rules, regulations or instructions with regard to HUDs. Medicare does not require nor is there any process for obtaining prior approval for HUDs. Furthermore, Medicare does not perform "prior authorizations" for insertion of these devices.
- Additionally, coverage under general Medicare rules (see Social Security Act, Section 1862 (a)(1)(A) Medically Reasonable & Necessary) indicates most HUDs are not covered by Medicare.
- Claims for HUDs must support that the services were reasonable and necessary.
- Given the complexities of determining whether a device is reasonable and necessary when it has not been proven effective for its intended use, the coverage analysis cannot provide specific coverage information; therefore billing decisions must be made in coordination between UKHC and the study teams to determine specific billing compliance. Additional information on the Centers for Medicare & Medicaid Services (CMS) beneficiary notice initiative may be found at https://www.cms.gov/Medicare/Medicare-General-Information/BNI

5.- Billing Rules for Time and Effort – Uniform Grant Guidance

For federal sponsored clinical trials:

Professional charges cannot be charged to a study fund where the investigator has effort assigned, but technical charges should be captured appropriately.

- **Paying employees based on budgets, not effort** – Federal grant rules require employees to be reimbursed based upon actual recorded effort on grants, not merely budgeted amounts.
- **Cost objectives** – Effort must be recorded towards specific cost objectives, not just to the grant in general. For example, a single grant may have three different cost objectives.
- **T/E Percentages** – This is a similar theme to the concept that an employee's time is allocated based on percentages of grant funding. For instance, 13.5% to one grant and 27.7% to another grant.
- **Recording T/E appropriately** – Staff, study teams and other supporting employees must record the actual time they spent on different cost objectives.
- **100% means 100%** – The total of time charges must always equal 100% of your time. You cannot charge time exceeding 100% of your time. Even if you work overtime you could not say that you spent 80% of your time on one particular federal project and 40% of your time on a privately funded project.
- **False Claims Act** – Incorrectly charging time to federal awards means that you are making a false claim against the government, which carries criminal penalties.

6.- Documentation in the EHR system

Medical Necessity: When services provided to patients are based solely upon "medical necessity" the documentation must support the medical necessity and must be clear and legible as set forth by CMS; however, this does not guarantee that the service may be a covered service. The billing components, including the limitations of coverage, for third party insurances, Medicaid, and Medicare still apply.

Medical Necessity is not applicable to an experimental treatment or the investigational item; nor can it be furnished primarily for the convenience of the attending physician, or other provider.

6.1. Medical Necessity applies to insurance companies and the Commonwealth of Kentucky's Medicaid Program

The "medically necessary" definitions for private insurances are found within the contracts between the patients and the insurance companies, or between health plans and providers. They can be subject to state regulation and there is some variation in them. For example, in Kentucky, the statutory provisions under KRS 205.520 Federal Statutes [42 C.F.R. 440.230, 441 Subpart B, 42 U.S.C. 1396d(r)] and 907 Ky. Admin. Regs. 3:130:

The determination of whether a covered benefit or service is medically necessary or clinically appropriate, shall:

(a) Be based on an individualized assessment of the recipient's medical needs; and

(b) Comply with the requirements established in this paragraph. To be medically necessary or a medical necessity, a covered benefit shall be:

1. Reasonable and required to identify, diagnose, treat, correct, cure, palliate, or prevent a disease, illness, injury, disability, or other medical condition, including pregnancy;

2. Appropriate in terms of the service, amount, scope, and duration based on generally-accepted standards of good medical practice;

The American Medical Association (AMA) provides a definition that has been adopted by many private insurances, as follows: Health care services or products that a prudent physician would provide to a patient for preventing, diagnosing, or treating an illness, injury, disease, or its symptoms in a manner that is:

- In accordance with generally accepted standards of medical practice;
- Clinically appropriate in terms of type, frequency, extent, site, and duration; and
- Not primarily for the economic benefit of the health plans and purchases or for the convenience of the patient, treating physician, or other health care provider.

7.- What is the False Claims Act, and why is it important for both health care claims and federal grants?

The False Claim Act is a federal law that makes it a crime for any person or organization to knowingly make a false record or file a false claim regarding any federal health care program. This includes any plan or program that provides health benefits, whether directly, through insurance or otherwise, which is funded directly, in whole or in part, by the United States Government or any state healthcare system. "Knowingly" includes having actual knowledge that a claim is false or acting with "reckless disregard" as to whether a claim is false.

On February 16, 2018, the University of North Texas settled with the Department of Justice for more than $13 million based upon a self-reported failure to accurately measure, track, and pay researchers for effort spent

on certain federally sponsored research. This is one of the larger settlements for inaccurate federal grant effort reporting and would have possibly been larger had it been based upon a qui tam investigation rather than a self-report by the university.

For reporting time and effort: Research institutions that accept federal grant monies from National Institutes of Health, National Science Foundation, and others are required to comply with technical and detailed effort reporting rules and regulations. Researchers may inaccurately report effort devoted to research activities for reasons including inadequate reporting infrastructure or misunderstanding about how to apply effort reporting rules. Failure of institutions to reliably and accurately track researcher efforts can result in overpayment of researchers and could subject the institution to significant False Claims Act ("FCA") liability.

Common billing errors:

- Billing for services not rendered
- Billing Medicare (or other payers) for free items/services
- Billing for non-reimbursable items/services (non-qualifying or research driven)
- Billing without proper codes, modifiers, NCT # or incorrect payer
- Billing Medicare without approval for device studies
- Waiving/paying /reimbursing subject co-pay and/or deductible obligations
- Billing for items not supported by required documentation
- Documentation of medical necessity for the patient
- Documentation of study participation, as required