Applicability: UW Medicine

Policy Title: Budgeting and Billing Requirements for Clinical Research Using UW Medicine Faculty, Facilities or Services

Policy Number: COM-101

Superseded Policies: Policy 1: Budgeting and Billing Requirements for Clinical Research Using UW Medicine Faculty, Facilities or Services
Policy 3: Clinical Research Subject and Study Reporting Requirements

Date Established: April 25, 2005

Date Effective: June 1, 2015

Dates Revised: November 1, 2006; May 1, 2008; June 1, 2013; June 1, 2015

Next Review Date: June 1, 2018

PURPOSE AND SCOPE
The purpose of this policy is to identify when clinical research studies require pre-implementation review by the School of Medicine Clinical Research Budget and Billing office (CRBB), and to establish standards for accurate budgeting and billing related to services that accompany clinical research.

This policy applies to the following:
- All clinical research utilizing the services of a member of UW Physicians (UWP), regardless of the site of practice;
- All clinical research studies that involve services, items or tests provided by a facility that bills through UW Medicine Patient Financial Services (PFS), or CRBB, whether the services are billed to study subjects, study budgets or both. See Attachment A: Billing Entity by Site of Practice.

POLICY PRINCIPLES/STATEMENT
Complex federal and private payer rules govern the conditions under which clinical services, items and tests associated with a research study can be billed to study sponsors, study subjects and/or their insurers. Accurate research billing depends on planning and collaboration between the study team and a wide variety of individuals and offices before, during and after the study is initiated.

For purposes of this policy, individuals who are billed for services associated with a research study are patients or participants in research studies, and are generically referred to as “study subjects.”
DEFINITIONS

1. **Active billing period**: The time period marked by the first and last dates that the study subject will receive billable study-related services.

2. **Billing ended**: The date on which there are no further study-related services that could generate a UWP, PFS or CRBB billable charge to either a study subject or the study budget.

3. **Billing Grid**: A document that lists the study-related billable clinical services, items or tests included in a study protocol. The billing grid identifies what practice sites are planned for study visits; what services, items or tests will be provided; and indicates whether the study sponsor or study subject will be billed.

4. **Category A and B investigational device coverage rules**: Medicare’s policy that defines coverage of investigational device studies for Medicare beneficiaries. The rules also define coding requirements for claims billed to Medicare in the context of these studies. Under these rules, Medicare may provide coverage for certain research-related clinical services, items, or tests that are provided to study subjects for studies that meet certain conditions and after Medicare pre-authorization is obtained.\(^1\)

5. **Clinical Research Budget and Billing (CRBB)**: The centralized UW School of Medicine support office that serves as a resource to assist faculty and staff in budgeting, billing, and Medicare coverage analyses for clinical research projects.

6. **Clinical Trials Policy (CTP)**: Medicare’s policy defining coverage of clinical research for Medicare beneficiaries. Under this policy, Medicare may provide coverage for routine costs for certain (deemed qualified) research studies. The policy also defines coding requirements for research services, items, and tests billed to Medicare in the context of these studies.\(^2\)

7. **Cost Transfer Invoicing (CTI)**: A process by which departments charge the costs of services or supplies between University of Washington (UW) budget entities.

8. **Effort**: For the purposes of sponsored projects, effort is the time faculty spends on all of their university activities, including research, instruction, administration, service and clinical activity.

9. **Enrollment**: The point at which an individual has signed the informed consent document and has satisfied all requirements to participate in a given research study. Enrollment status characterizes the subject’s relationship in a study at a given time, and is one of the following: consented, enrolled or off-study.

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\(^2\) See: [http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=18&amp;nbncdw=2&amp;ncd%2bCoverageselection=Both&amp;nb%3bArticleType=All&amp;nb%3bPolicyType=Final&amp;nb%3bState=Washington&amp;nb%3bKeyword=Clinical%252Btrials&amp;nb%3bLookUp=Title&amp;nb%3bForKeyWordSearchType=And&amp;nb%3bwhere=index&amp;nb%3bmid=38&amp;nb%3bbc=gAAAAABAAAAA]
10. **Expanded Care (E):** The Medicare CTP includes coverage for items or services required for the provision of the investigational item or service (for example, administration of a non-covered chemo-therapeutic agent); the clinically appropriate monitoring of the effects of the investigational item or service; the reasonable and necessary care arising from the provision of the investigational item or service, such as the prevention, diagnosis or treatment of complications; and/or in certain cases the investigational item or service itself. In the Medicare Category A and B investigational device coverage rules, this includes services provided in preparation of use of the device; for the prevention, diagnosis or treatment of complications; services provided contemporaneous with the device and necessary to use the device, such as the provision of the investigational item or service; and necessary aftercare services that are incident to recovery from the use of the device, including the clinically appropriate monitoring of the effects of the device.

11. **Healthcare:** Any care, service, or procedure provided by a healthcare professional.

12. **Industry-funded:** Research and development activities that are funded (monetary or non-monetary) by commercial agencies and organizations.

13. **Inpatient admission:** When a physician or other qualified provider submits an order to place the patient in a bed with the category “inpatient”, typically but not always involving two or more overnight stays.

14. **Investigational item or service:** A Food & Drug Administration (FDA) approved or unapproved item or service which is the subject of and/or provided during the research study. In the Medicare CTP, investigational items or services are categorized as expanded care or non-covered research depending on the type of study and whether the item or service is otherwise covered outside of the study. For Medicare Category A and B investigational devices, coverage depends on the category of the device and whether it has been pre-approved by Medicare.

15. **Medicare coverage analysis:** The process by which it is determined whether a research protocol qualifies for coverage under Medicare’s CTP or Investigational Device Exemption (IDE) rules, allowing study services to be billed to Medicare. A completed coverage analysis is also a key element in the creation of a study’s billing grid.

16. **Non-covered research-only:** Clinical services provided in the context of the clinical research study that are not used for the direct clinical management of the study subject and should not be billed to the study subject’s insurer or other third-party payer.

17. **Patient:** An individual who receives or has received healthcare. (For purposes of this policy, individuals who are billed for services associated with a research study are patients or participants in research studies, and are generically referred to as “study subjects.”)

18. **Principal Investigator (PI):** The investigator with overall responsibility for the conduct of a particular research study.
19. **Professional fee:** The billable charge for a professional service that has not been identified as Faculty Effort under the terms of the sponsor agreement. Services identified as clinical research study effort for other institutional reporting purposes may not be billed as professional fees.

20. **Professional services:** Care, services and/or procedures provided by a physician or other non-physician healthcare professional (for example, diagnosis, therapy, surgery, consultations, and home, office and hospital visits).

21. **Routine Costs:** A term used by Medicare to describe the types of clinical services, items or tests it will cover under the CTP for qualified clinical trials. Routine costs must be provided in either the experimental or the control arm of a clinical trial; otherwise generally available to Medicare beneficiaries (for example, there exists a benefit category); not statutorily excluded from Medicare coverage; and not excluded from Medicare coverage by a National or Local Coverage Decision.

As defined by the Centers for Medicare & Medicaid Services (CMS), routine costs in clinical trials include:

a. Items or services that are typically provided absent a clinical trial (for example, conventional care);

b. Items or services required solely for the provision of the investigational item or service (for example, administration of a non-covered chemo-therapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and

c. Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service, in particular, for the diagnosis or treatment of complications.

The following are excluded from CTP coverage:

a. The investigational item or service itself, unless otherwise covered outside of the clinical trial;

b. Items and services provided solely to satisfy data collection and analysis needs which are not used in the direct clinical management of the patient; and

c. Items and services customarily provided by the research sponsors free of charge for any study subject.

22. **Sponsored project.** Any project receiving external support (including research, scholarly work, training, workshops and services) that has defined performance requirements.

23. **Study-related services.** The clinical services, items and/or tests that are called out in the study protocol, calendar of events and/or billing grid. CMS requires identification of all study-related services which it defines as routine costs on study-related Medicare claims, including conventional care services.
24. **Study subject.** (Also referred to as, “subject”, “human subject” and “research participant”). For purposes of this policy, these terms refer to an individual who is either directly participating in a research study, or whose identifiable private information is being used in a research study. The UW Institutional Review Board applies two regulatory definitions of human subjects for purposes of determining whether a research activity is considered human subjects research (see [http://www.washington.edu/research/hsd/glossary/#iv_H](http://www.washington.edu/research/hsd/glossary/#iv_H)).

25. **Third party payer.** An entity, other than a patient who receives charges for clinical services, that is responsible for some portion of the payment to the provider (for example, a hospital, clinic, physician, healthcare professional) for the services. Third party payers include insurers, healthcare service contractors, health maintenance organizations, employee welfare benefit plans, and state or federal health benefit programs.

26. **Usual care.** Medically reasonable and necessary items and/or services used in the direct clinical management of a study subject which would be provided absent the research study. From the National Institute of Health’s (NIH) perspective, these are expenses that would be incurred even if the research did not exist. NIH expects third party payers or the study subject to pay these costs.

**POLICY**

For all clinical research studies covered by this policy as described in the PURPOSE AND SCOPE section:

1. Each clinical research study must be:
   a. Conducted pursuant to the study’s Medicare coverage analysis and approved billing grid that serve as guides for appropriately directing and coding charges to the study account, the study subject, or the subject’s third party payer; and
   b. Reviewed by CRBB to approve the coverage analysis and billing grid in advance of opening the study to subject accrual.

2. For industry-funded research projects contracted through the UW, a study budget must also be submitted to CRBB, reviewed, negotiated and approved prior to execution of the research contract.

3. Clinical services, items or tests billed to study sponsors, study subjects, and/or study subjects’ third party payer must be fully documented in the medical record. These services must be consistent with:
   a. Applicable billing rules of the third party payer that is billed;
   b. UW Medicine procedures that establish safeguards to prevent billing errors; and
   c. Any grant provisions or contractual obligations entered into by UW Medicine or study sites.

4. Potential costs to the study subject or subject’s third party payer associated with participating in the research study must be:
   a. Clearly disclosed and agreed to by the study subject; and
b. Represented consistently across all study-related documents, including the protocol, grant, contract, budget, billing grid and Informed Consent Form.

5. All study subjects must:
   a. Be registered as patients of every UW Medicine hospital and/or site where study services will be delivered, under the procedures applicable at each site;
   b. Have appropriate information about their research participation documented in their medical record in accordance with the policies of the study site;
   c. Have their initial study enrollment and subsequent enrollment status changes reported within one business day, using the tools and procedures established by the UW School of Medicine/CRBB. Specific reporting methods and/or additional requirements may be established by the clinical sites of practice where the study is conducted.
   d. Have every UW Medical Center, Harborview Medical Center and Seattle Cancer Care Alliance Emergency Department (ED) or inpatient admission reported to CRBB when the encounter may include study-related clinical services, items or tests, unless otherwise directed. Study-related hospital inpatient admissions and ED visits must be reported within one business day of the subject’s admission.

6. CRBB must be informed when all study subjects have received all services in the study billing grid and study billing has ended.

REGULATORY/LEGISLATION/REFERENCES

PROCEDURE ADDENDUM(s) REFERENCES/LINKS
- Attachment A: Billing Entity by Site of Practice
- Attachment B: Review & Reporting Requirements
- Attachment C: Using Epic to report subject enrollment and study information

Contacts and Resources
Clinical Research Budget & Billing (CRBB):
  Main Office: 206.543.7774, crbb@uw.edu
  Billing Phone: 206.543.9006, crbills@uw.edu
School of Medicine Compliance 206.685.0173
UW Human Subjects Division 206.543.0098
UW Medicine Compliance:
  Main Office: 206.543.3098, comply@uw.edu
  Toll-free line: 855.211.6193
  Anonymous Compliance Hotline: 206.616.5248, 866.964.7744
UW Physicians Compliance 206.221.3345
ROLES AND RESPONSIBILITIES
Each UW Medicine faculty, staff and trainee is responsible for understanding and adhering to UW Medicine’s policies and procedures, participating in required training, fulfilling recordkeeping requirements, reporting compliance concerns, seeking clarification when questions arise and responding in a timely manner to requests for information associated with audits or investigations.

- The PI has primary accountability for all aspects of the clinical research projects operating under his/her name. The PI may delegate responsibility for the procedures required by this policy to appropriately qualified members of the study team.

- CRBB provides centralized support for PIs and is responsible for maintaining operations and researcher training programs to support proper budgeting and billing in clinical trials.

- Study-site personnel (including patient service representatives, billers, coders, clinic administrators and service providers) are responsible for maintaining procedures and working with the PI and study team to ensure that services for patients enrolled in research studies are scheduled, coded, billed and recorded in accordance with instructions from the study team, seeking clarification when questions arise.

- Offices that bill facility and professional fees are responsible for establishing business practices and systems that support compliance with research billing policies and procedures.

- Compliance officers in UW Medicine, the UW School of Medicine and the practice plans work closely with CRBB, study-sites and operational departments to develop procedural safeguards; receive and investigate allegations of noncompliance; conduct audits; and participate in the development and delivery of compliance training.

AUTHORITIES

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APPROVALS

UW Medicine Executive Compliance Committee 6/1/2015 Endorsed By Date