Status **Active** PolicyStat ID **8992718**

Origination	2/20/2018
Approved	2/26/2021
Effective	2/26/2021
Next Review	2/26/2024

Owner	Stephanie Madrigal: Dir Clin Rsrch Admin/Ops
Category/ Chapter	Compliance
Applicability	OSF All Operating Units
Areas/Depts	Research

OSF HealthCare System Research Billing Policy

DEFINITIONS:

1. Centers for Medicare and Medicaid Services (CMS) Diagnosis Codes and Modifiers identify qualifying clinical trials and differentiate between routine/standard and investigational clinical services.
2. Conduct of Clinical Research includes intervening or interacting with participants, obtaining informed consent, obtaining identifiable private information or biological specimens, administering investigational procedures or products, and receiving an award through a grant/ contract.
3. Coverage Analysis (CA) is a detailed review of research items, services, procedures and Medicare billing rules to determine the appropriate payer/funding source for each.
4. Qualifying Clinical Trials (QCTs) are research projects that meet the Medicare Clinical Trial Policy criteria to receive Medicare coverage for routine/standard care items and services.
5. Third-Party Payers are institutions or companies that provide reimbursement to health care providers for services rendered to a third party (i.e., the patient).

PURPOSE:

To ensure appropriate billing of research-related charges by OSF HealthCare System (OSF) business units.

POLICY:

1. This policy applies to all OSF business units involved in clinical research billing and administration, including Research Administration, the Common Business Office (CBO), the

Patient Accounting and Access Center (PAAC), as well as individual principal investigators (PIs) conducting clinical research involving billable services at OSF.

2. OSF bills clinical services rendered during the course of a clinical research study to the appropriate sponsor, study account, third-party payer, or individual in compliance with applicable state and federal regulations.
3. Research participants and payers are not billed for services that are for research purposes that the sponsor is already paying for and are provided to research participants at no cost.
4. CMS Publication 100-04, Chapter 32, Section 68 and 69, is followed when billing Medicare for routine care services and/or medical devices provided in a clinical research study.
5. When a research study conducted at OSF includes billable services, no subject is enrolled until a CA is completed by Research Administration in consultation with appropriate business units and the PI.
6. The CA includes a QCT analysis in accordance with the criteria in CMS National Coverage Determination (NCD) 310.1, the Medicare Clinical Trial Policy or the Medicare Benefit Policy Manual Chapter 14, Medical Devices.
7. The CA includes an analysis of items and services identified in the study to determine which are considered routine or "standard of care."
8. The CA is updated when there are changes to procedures or terms during the course of a study.
9. New and updated CAs are reviewed and signed by the PI.
10. At the discretion of Research Administration, CAs signed by non-OSF PIs are submitted prior to receiving facility permission to conduct the clinical trial.
11. At the request of a non-OSF PI, Research Administration provides CA services for an agreed upon fee.

PROCESS:

Billing

1. PIs, departments, administrative units, and OSF entities coordinate activities to ensure services associated with research studies are billed appropriately and in compliance with relevant laws, regulations, contractual obligations, and the policy for *Claim Development and Submission Process (CC-115)*.
2. The PI or delegate is responsible for patient enrollment and/or completion using the research functionality in the EMR and notifies Research Administration upon research participants being enrolled and/or completing research related encounters.
3. Research Administration, the CBO or the PAAC appends the appropriate codes, modifiers, National Clinical Trials number (NCT #), and other identifiers to claims when billing Medicare for routine care services and/or medical devices provided in a clinical research study, including:
    a. Diagnosis Code V70.7 (ICD 9) or Z00.6 (ICD 10)
    b. Condition Code 30

c. Condition Code 53
d. Q0 for lines that contain an investigational item
e. Q1 for lines that contain a routine service
f. NCT #
g. Investigational Device Exemption number (IDE #) for device studies, if applicable
h. Premarket Approval number (PMA #) for device studies, if applicable
i. Humanitarian Device Exemption number (HDE #) for device studies, if applicable

Coverage Analysis

1. The Research Administration Clinical Research Business Office (CRBO):
    a. Obtains the documents needed to conduct the CA from the study team, which include but are not limited to:
        i. research study protocol, including the schedule of events
        ii. informed consent document, including attachments and amendments
        iii. clinical trial agreement (CTA) or notice of grant award, including attachments and amendments
        iv. FDA status of the investigational item (IND, IND exemption, IDE)
        v. sponsor proposed budget
    b. Conducts a QCT analysis according to the criteria in CMS National Coverage Determination (NCD) 310.1, the Medicare Clinical Trial Policy or the Medicare Benefit Policy Manual Chapter 14, Medical Devices.
    c. Incorporates Local Coverage Determinations (LCDs) into the CA in the absence of a CMS NCD.
    d. Conducts an "items and services analysis", including a billing grid that outlines services required by the protocol and designates whether each service is research related or routine/standard of care.
        i. Reviews relevant research documents and nationally recognized treatment guidelines, peer reviewed literature, and hospital treatment guidelines to identify which items are experimental (for research purposes only) and which are considered treatment for the condition being studied.
        ii. Consultsthe PI or medical department head when there is incomplete information or no national standard available.
        iii. Removes services designated as "research related" from participant third-party payer invoices.
        iv. Includes services designated as routine/standard of care on participant third-party payer invoices.
    e. Obtains the review and approval signature of the PI to validate the CA.
    f. Reviews and approves the CA.

g. Creates a one-page analysis document to outline reasoning when it is determined that a full CA is not needed for a research project.

2. The PI or delegate "notifies" Research Administration of amendments or sponsor changes to the research in order to update the CA by submitting a Change of Research Form.

Monitoring and Enforcement

1. Research Administration conducts periodic quality assurance monitoring to evaluate compliance with this policy and related procedures.
2. This policy is consistently enforced through appropriate corrective and/or disciplinary measures when violations are identified.
3. Corrective measures for violation of this policy include, but are not limited to:
    a. suspension of study activities
    b. suspension of billing to participants and third-party payers
    c. reassignment of claims from billing entities to research accounts
4. Disciplinary measures are determined in accordance with the *Positive Discipline Policy (601).*

Employee Reporting

1. OSF Mission Partners (MPs) report good faith concerns of potential violations of law or regulations pertaining to the billing of research related charges by OSF business units in accordance with the following OSF Policies:
    a. Integrity Line Policy (CC-107)
    b. False Claims Prevention and Whistleblower Protections (CC-109)
    c. Whistleblower Protection (HR-130)
    d. False Claims Prevention: Federal and State False Claims and Whistleblower Laws (HR-142)

REFERENCES:

1. *Claim Development and Submission Process (CC-115).* OSF HealthCare System Policy. PolicyStat ID 996008. Retrieved September 5, 2017
2. *False Claims Prevention and Whistleblower Protections (CC-109).* OSF HealthCare System Policy. PolicyStat ID 996021. Retrieved September 5, 2017
3. *Whistleblower Protection (HR-130).* OSF HealthCare System Policy. PolicyStat ID 2014202. Retrieved September 5, 2017
4. *False Claims Prevention: Federal and State False Claims and Whistleblower Laws (HR-142).* OSF HealthCare System Policy. PolicyStat ID 1876365. Retrieved September 5, 2017
5. *Integrity Line Policy (CC-107).* OSF HealthCare System Policy. PolicyStat ID 996054. Retrieved September 5, 2017
6. *Positive Discipline Policy (HR-601).* OSF HealthCare System Policy. PolicyStat ID 1817040. Retrieved September 5, 2017

7. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination Manual (NCDM). Routine Costs in Clinical Trials section 310.1. Retrieved July 14, 2017 from https://www.cms.gov/
8. Medicare Claims Processing Manual. Chapter 32 – Billing Requirements for Special Services, Sections 68 – Investigational Device Exemption (IDE) Studies & 69 – Qualifying Clinical Trials. Retrieved October 23, 2017 from https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c32.pdf
9. Medicare Benefit Policy Manual. Chapter 14 – Medical Devices. Retrieved October 23, 2017 from https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c14.pdf
10. Medicare Benefit Policy Manual. Chapter 16 – General Exclusions From Coverage, Section 40 – No Legal Obligation to Pay for or Provide Services. Retrieved October 23, 2017 from https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c16.pdf

This policy is in effect for OSF Healthcare System, OSF Healthcare Foundation and all OSF Healthcare System subsidiaries and affiliates, except as limited in the header or body of this policy. For purposes of this policy, the terms "subsidiaries" and "affiliates" mean facilities or entities wholly owned or wholly controlled by OSF Healthcare System. The hospitals covered by this policy are:

		Name as listed with Medicare:
X	OSF St. Mary Medical Center	ST MARY MEDICAL CENTER
X	OSF Saint Francis Medical Center	SAINT FRANCIS MEDICAL CENTER
X	OSF Saint James – John W. Albrecht Medical Center	SAINT JAMES HOSPITAL
X	OSF St. Joseph Medical Center	ST JOSEPH MEDICAL CENTER
X	OSF Saint Anthony's Health Center	OSF HEALTHCARE SYSTEM
X	OSF Saint Anthony Medical Center	SAINT ANTHONY MEDICAL CENTER
X	OSF St. Francis Hospital & Medical Group	ST FRANCIS HOSPITAL
X	OSF Holy Family Medical Center	OSF HEALTHCARE SYSTEM
X	OSF Saint Elizabeth Medical Center	Ottawa Regional Hospital & Healthcare Center
X	OSF Saint Luke Medical Center	OSF HEALTHCARE SYSTEM
X	OSF Saint Paul Medical Center	Mendota Community Hospital
X	OSF Heart of Mary Medical Center	OSF HEALTHCARE SYSTEM
X	OSF Sacred Heart Medical Center	OSF HEALTHCARE SYSTEM
X	OSF Little Company of Mary Medical Center	OSF HEALTHCARE SYSTEM

Attachments

CA Decision Document Template

Coverage Analysis Template

Approval Signatures

Step Description	Approver	Date
Education/Communication Step	Stephanie Madrigal: Dir Clin Rsrch Admin/Ops	2/26/2021
Executive Steering Committee	Ronda Long: Coord Clinical Policy	2/26/2021
President, OSF Healthcare	Sister Diane Marie: President-Sister	2/9/2021
System Chief Medical Officer	Ralph Velazquez: System CMO	2/9/2021
Regulatory/Policies Council	Marci Fletcher: Resource Document Spec	2/4/2021
Executive Director, Research Administration	Stephanie Madrigal: Dir Clin Rsrch Admin/Ops	2/4/2021
Notification	Michael Bailey: Coord Clinical Research	2/3/2021