RB.052.A Clinical Trials

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Thank you for being a valued provider for members in one or more of our health plans: Jefferson Health Plans Medicare Advantage, Jefferson Health Plans Individual and Family Plans, Jefferson Health Plans CHIP, and/or Jefferson Health Plans EverWell (our Medicaid plan).

PRODUCT VARIATIONS

This policy applies to the Jefferson Health Plans Medicare Advantage line of business.

Application of Claim Payment Policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Payment may vary based on individual contract.

POLICY STATEMENT

For members enrolled in Jefferson Health Plans Medicare Advantage who participate in a qualifying clinical trial covered under Medicare National Coverage Determination (NCD) 310.1 – Routine Costs in Clinical Trials, Original Medicare is responsible for payment of covered routine clinical trial items and services, including reasonable and necessary services used to diagnose or treat complications resulting from participation in the clinical trial.

Providers must bill Original Medicare for services for which Original Medicare retains payment responsibility and must follow applicable CMS clinical trial billing requirements.

For qualifying clinic members' services for which Original Medicare retains payment responsibility, Jefferson Health Plans is responsible for applicable Medicare Advantage plan liabilities, including the difference between Original

Medicare cost-sharing and the member's applicable in-network cost-sharing, in accordance with CMS requirements.

For clinical trial services for which CMS assigns payment responsibility to the Medicare Advantage plan, Jefferson Health Plans covers applicable Medicare-covered services in accordance with applicable CMS coverage requirements, member benefits, and provider contract requirements.

Covered routine costs under NCD 310.1 include items and services that would otherwise be covered by Medicare outside of the clinical trial; items and services required solely for the provision of the investigational item or service, clinically appropriate monitoring, or prevention of complications; and reasonable and necessary items and services used to diagnose or treat complications arising from participation in the clinical trial.

Under NCD 310.1, routine costs do not include:

- The investigational item or service itself, unless otherwise covered outside of the clinical trial.
- Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the member; and
- Items and services customarily provided by the research sponsor free of charge to any enrollee in the trial.

Separate Medicare coverage and payment requirements may apply to clinical studies outside of NCD 310.1, including CMS-approved Investigational Device Exemption (IDE) studies and services covered under Coverage with Evidence Development (CED). Providers must follow the applicable CMS coverage and billing requirements for these services.

POLICY GUIDELINES

Services must meet applicable Medicare coverage requirements and be medically necessary. The medical record must contain documentation supporting the member's participation in the qualifying clinical trial and the medical necessity of the services provided.

For qualifying clinical trial services covered by Original Medicare under NCD 310.1, providers must submit claims to Original Medicare in accordance with applicable CMS clinical trial billing requirements. Institutional claims must include, as applicable:

- Condition Code 30.
- Diagnosis Code Z00.6 in the primary or secondary position.
- The applicable 8-digit National Clinical Trial (NCT) number; and
- Modifier Q0 or Q1, as appropriate, on outpatient clinical-trial-related services.

Modifier Q0 identifies an investigational clinical service provided in a qualifying clinical research study. Modifier Q1 identifies a routine clinical service provided in a qualifying clinical research study. Q0 and Q1 are applicable to outpatient claims and are not applicable to inpatient institutional claims.

Claims for clinical trial services for which Jefferson Health Plans retains Medicare Advantage payment responsibility must be submitted to Jefferson Health Plans in accordance with applicable CMS coverage, coding, and billing requirements.

The inclusion of a code, modifier, diagnosis code, NCT number, or billing instruction in this policy does not, by itself, establish coverage or payment responsibility. Coverage and reimbursement are subject to member eligibility, benefit limitations, medical necessity, provider contract terms, and applicable Medicare requirements.

CODING

Note: The Current Procedural Terminology (CPT®), Healthcare Common Procedure Coding System (HCPCS), and the 10th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10) codes that may be listed in this policy are for reference purposes only. Listing of a code in this policy does not imply that the service is covered and is not a guarantee of payment. Other policies and coverage guidelines may apply. When reporting services, providers and facilities should code to the highest level of specificity using the code that was in effect on the date the service was rendered. This list may not be all inclusive.
CPT® is a registered trademark of the American Medical Association.

CPT Code	Description
N/A	

ICD-10 Codes	Description
Z00.6	Encounter for examination for normal comparison and control in clinical research program

HCPCS Modifier	Description
Q0 Modifier	Investigational clinical service provided in a qualifying clinical research study
Q1 Modifier	Routine clinical service provided in a qualifying clinical research study

BENEFIT APPLICATION

This Reimbursement Policy does not constitute a description of benefits. Rather, it assists in the administration of the members' benefits which may vary by line of business. Applicable benefit documents govern which services/items are eligible for coverage, subject to benefit limits, or excluded completely from coverage.

DESCRIPTION OF SERVICES

Clinical trials are research studies involving human participants designed to evaluate the safety, effectiveness, or appropriate use of drugs, biologics, devices, procedures, diagnostics, or other healthcare interventions. Medicare provides coverage for routine costs associated with participation in qualifying clinical trials under Medicare National Coverage Determination (NCD) 310.1 and other applicable Medicare requirements. Covered routine costs include medically necessary services that would otherwise be covered by Medicare and are furnished for the direct clinical management of a member participating in a qualifying clinical trial.

DEFINITIONS

Clinical Trial: A research study involving human participants designed to evaluate medical, surgical, diagnostic, preventive, or behavioral interventions.

Qualifying Clinical Trial: A clinical trial that meets the requirements for Medicare coverage of routine costs under Medicare National Coverage Determination (NCD) 310.1.

Investigational Item or Service: A drug, biologic, device, procedure, or service that is the subject of the clinical trial and is being evaluated for safety, efficacy, or clinical utility.

DISCLAIMER

Approval or denial of payment does not constitute medical advice and is not intended to guide nor influence medical decision making. Policy Bulletins are developed to assist in administering plan benefits and constitute neither offers of coverage nor medical advice. This Policy Bulletin may be updated and therefore is subject to change.

POLICY HISTORY

This section provides a high-level summary of changes to the policy since the previous version.

Summary	Version	Version Date
New Policy	A	09/16/2026

REFERENCES

1. Novitas Solutions: Clinical Trials Background
2. Centers for Medicare & Medicaid Services (CMS): Medicare Clinical Trial Policies | CMS
3. Centers for Medicare & Medicaid Services (CMS): NCD - Routine Costs in Clinical Trials (310.1)
4. Centers for Medicare & Medicaid Services (CMS): Medicare Claims Processing Manual

5. Code of Federal Regulations: eCFR :: 42 CFR 422.109 -- Effect of national coverage determinations (NCDs) and legislative changes in benefits; coverage of clinical trials and A and B device trials.