Priority Health	BILLING POLICY No. 038
CLINICAL TRIALS	
Date of origin: Oct. 7, 2024	**Review dates: 2/2025**

APPLIES TO

- Commercial
- Medicare follows CMS NCD/LCD policies unless otherwise noted
- Medicaid follows MDHHS/CHAMPS unless otherwise noted

MEDICAL POLICY

- Clinical Trials - 91606
- Clinical Trials for Self-Funded Groups Opting Out of PPACA – 91448

POLICY SPECIFIC INFORMATION

Clinical trial services are reimbursed for approved studies. Related services are payable when considered reasonable and necessary in providing services or items for approved clinical trial outcomes. This may include administration of experimental drugs or procedures, treatment of complications from clinical trial services, routine supplies associated with qualified clinical trial (not an all-inclusive list). Bundling/unbundling may apply.

We won't reimburse the following:

- Experimental, investigational and/or unproven services, drugs or devices associated with trial testing
- Data collection associated with the clinical trial
- Services that aren't consistent with standards of care or within scope of practice
- Exclusions defined in member benefits or plan documents
- Services that wouldn't be payable outside of the clinical trial
- Services or devices supplied at no charge from clinical trial sponsor or other entity
- Items or service unrelated to health care (meals, personal care services, etc.) associated with clinical trials

Payment is based on the physician fee schedule, lab fee schedule, DME, fee schedule, etc.

Billing information

Providers should enter clinical trial and non-clinical trial services on separate lines when both types of services are submitted on the same claim form.

Items and services provided free of charge by research sponsors shouldn't be billed to Priority Health. If these items are required for payment of another payable service, providers should submit the items as non-covered (use modifiers FB and GX or GY).

Routine costs of an approved clinical trial should be submitted as follows:

- Report modifier "Q1" with each service.
- ICD-10-CM code Z00.6 (examination of participant in clinical trial) should be reported as the secondary diagnosis.

- It’s mandatory to report a clinical trial number on claims for items and services provided in clinical trials that are qualified for coverage.

Don’t append modifiers to service lines that are unrelated to the clinical trial protocol. Services unrelated to the clinical trials should be reported on separate claim lines.

Report the appropriate modifier for services reported as part of a clinical trial and include the 8-digit national clinical trial number (NCT.)

Documentation requirements

Documentation must include trial name, sponsor and sponsor-assigned protocol number.

CPT / HCPCS / Revenue codes

Reportable, no charge, no payment:

- 0624 FDA investigational devices
- 0256 Experimental drugs

Explanatory notes must accompany claims billed with unlisted codes. Failure to provide a description or documentation will result in a denial.

Resources

- Clinical Trials – Community Plan Medical Policy (United Healthcare Community Plan)
- Clinical Trials – Medical Policy Article (CMS)

DISCLAIMER

Priority Health’s billing policies outline our guidelines to assist providers in accurate claim submissions and define reimbursement or coding requirements if the service is covered by a Priority Health member’s benefit plan. The determination of visits, procedures, DME, supplies and other services or items for coverage under a member’s benefit plan or authorization isn’t being determined for reimbursement. Authorization requirements and medical necessity requirements appropriate to procedure, diagnosis and frequency are still required. We use Current Procedural Terminology (CPT), Centers for Medicare and Medicaid Services (CMS), Michigan Department of Health and Human Services (MDHHS) and other defined medical coding guidelines for coding accuracy.

An authorization isn’t a guarantee of payment when proper billing and coding requirements or adherence to our policies aren’t followed. Proper billing and submission guidelines must be followed. We require industry standard, compliant codes defined by CPT, HCPCS and revenue codes for all claim submissions. CPT, HCPCPS, revenue codes, etc., can be reported only when the service has been performed and fully documented in the medical record to the highest level of specificity. Failure to document for services rendered or items supplied will result in a denial. To validate billing and coding accuracy, payment integrity pre- or post-claim reviews may be performed to prevent fraud, waste and abuse. Unless otherwise detailed in the policy, our billing policies apply to both participating and non-participating providers and facilities.

If guidelines detailed in government program regulations, defined in policies and contractual requirements aren’t followed, Priority Health may:

- Reject or deny the claim
- Recover or recoup claim payment

An authorization on file for an item or services doesn’t supersede coding, billing or reimbursement requirements.

These policies may be superseded by mandates defined in provider contracts or state, federal or CMS contracts or requirements. We make every effort to update our policies in a timely manner to align to

these requirements or contracts. If there's a delay in implementation of a policy or requirement defined by state or federal law, as well as contract language, we reserve the right to recoup and/or recover claim payments to the effective dates per our policy. We reserve the right to update policies when necessary. Our most current policy will be made available in our Provider Manual.

CHANGE / REVIEW HISTORY

Date	Revisions made
Feb. 13, 2025	Added "Disclaimer" section