Priority Health	BILLING POLICY No. 038
CLINICAL TRIALS	
Date of origin: Oct. 7, 2024	**Review dates: None yet recorded**

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 (if applicable)

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

CHANGE / REVIEW HISTORY

Date	Revisions made