BlueCross BlueShield Minnesota

COMMERCIAL REIMBURSEMENT POLICY

Clinical Trial

Active

Section: General Coding
Policy Number: 073
Effective Date: 07/01/24

Description

Blue Cross and Blue Shield of MN (Blue Cross) complies with the legislation below by allowing reimbursement for routine costs related to certain clinical trials. This policy applies to professional (837P) and facility (837I) claims.

Federal Patient Protection and Affordable Care Act (PPACA or ACA) legislation requires certain fully insured group and individual plans and self-insured group plans to provide coverage for routine patient costs related to certain clinical trials[1]. In May of 2013, the state of Minnesota enacted comparable legislation[2].

[1] *Affordable Care Act of 2010, section 1201 enacting Public Health Service Act section 2709*

[2] *Minn.Stat.§62Q.526*

This policy does not apply to FEP.

Definitions

Clinical trials: Scientific studies conducted to find better ways to prevent, screen for, diagnose, or treat disease. Clinical trials may also show which medical approaches work best for certain illnesses or groups of people. Clinical trials produce high-quality data for healthcare decision making.

Routine costs: Includes all items and services covered by the health plan when the items or services are typically covered for an enrollee who is not a qualified individual enrolled in an approved clinical trial.
Routine patient costs do not include:

- an investigational item, device, or service that is part of the trial
- an item or service provided solely to satisfy data collection and analysis needs for the trial if the item or service is not used in the direct clinical management of the patient;
- a service that is clearly inconsistent with widely accepted and established standards of care for the individual's diagnosis; or
- an item or service customarily provided and paid for by the sponsor of a trial

Policy Statement

All services provided as part of a clinical trial must be billed with the appropriate clinical research modifier:

Q0: Investigational clinical service provided in a clinical research study that is an An approved clinical research study: these services are not reimbursable

Q1: Routine clinical service provided in a clinical research study that is an approved clinical research study

Additionally, the service must be billed with ICD-10 diagnosis code Z00.6 in either the primary or secondary position of the diagnosis codes on the claim; and
837I Value Code D4 along with the 8-digit clinical trial as the value.

For inpatient claims, revenue code 0624 (FDA Investigational Device) must be present, along with the IDE number in the line-level detail information in Loop 2300.

837I claims must contain condition code 30 (Non research services provided to patients enrolled in a qualified clinical trial).

It is mandatory to report a clinical trial number on claims for items/services provided in clinical trials/studies/registries, or under Coverage with Evidenced Development (CED) in the 837I or 837P 2300 loop.

Documentation Submission

Documentation must clearly identify and support procedures performed. If a denial is appealed, complete documentation must be submitted with the appeal.

Coverage

Eligible services will be subject to the subscriber benefits, the applicable fee schedule amount, and any coding edits.

The following applies to all claim submissions.

All coding and reimbursement is subject to all terms of the Provider Service Agreement and subject to changes, updates, or other requirements of coding rules and guidelines. All codes are subject to federal HIPAA rules, and in the case of medical code sets (HCPCS, CPT, ICD), only codes valid for the date of service may be submitted or accepted. Reimbursement for all Health Services is subject to current Blue Cross Medical Policy criteria, policies found in the Provider Policy and Procedure Manual sections, Reimbursement Policies and all other provisions of the Provider Service Agreement (Agreement).

In the event that any new codes are developed during the course of Provider's Agreement, such new codes will be paid according to the standard or applicable Blue Cross fee schedule until such time as a new agreement is reached and supersedes the Provider's current Agreement.

All payment for codes based on Relative Value Units (RVU) will include a site of service differential and will be calculated using the appropriate facility or non-facility components, based on the site of service identified, as submitted by Provider.

Coding

The following codes are included below for informational purposes only and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply subscriber coverage or provider reimbursement.

CPT/HCPCS Modifier: Q0 Q1

ICD-10 Diagnosis: Z00.6
ICD-10 Procedure: N/A
CPT/HCPCS: N/A
Revenue Codes: 0624

Resources

Current Procedural Terminology (CPT®)
Healthcare Common Procedure Coding System (HCPCS)
Medicare Claims Processing Manual Chapter 32 – Billing Requirements for Special Services

Policy History

07/14/2020	Initial Committee Approval
05/23/2023	Annual Policy Review
05/28/2024	Annual Policy Review
06/25/2024	Revised