Investigational-Experimental Procedures

Reimbursement Policy ID: RPC.0111.0100

Recent review date: 02/2025

Next review date: 09/2026

Keystone First reimbursement policies and their resulting edits are based on guidelines from established industry sources, such as the Centers for Medicare and Medicaid Services (CMS), the American Medical Association (AMA), state and federal regulatory agencies, and medical specialty professional societies. Reimbursement policies are intended as a general reference and do not constitute a contract or other guarantee of payment. Keystone First may use reasonable discretion in interpreting and applying its policies to services provided in a particular case and may modify its policies at any time.

In making claim payment determinations, the health plan also uses coding terminology and methodologies based on accepted industry standards, including Current Procedural Terminology (CPT®); the Healthcare Common Procedure Coding System (HCPCS); and the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM), and other relevant sources. Other factors that may affect payment include medical record documentation, legislative or regulatory mandates, a provider's contract, a member's eligibility in receiving covered services, submission of clean claims, other health plan policies, and other relevant factors. These factors may supplement, modify, or in some cases supersede reimbursement policies.

This reimbursement policy applies to all health care services billed on a CMS-1500 form or its electronic equivalent, or when billed on a UB-04 form or its electronic equivalent.

Policy Overview

The purpose of this policy is to establish parameters for reimbursement of supplies, devices, procedures, or services that are considered Investigational or Experimental.

Exceptions

An investigational or experimental supply, device, service, or procedure may be reimbursable if it has been determined to be medically necessary through prior authorization.

Reimbursement Guidelines

Investigation or Experimental supplies, devices, services, and procedures, including drugs and equipment, are not considered to be covered services and are therefore not reimbursable.
A supply, device, service, or procedure is considered experimental or investigational if it includes any of the following (not an exhaustive list):

- It is in the testing stage or in early field trials on animals or humans.

- It is under clinical investigation by health professionals or is undergoing clinical trial by any governmental agency.

Definitions

Investigational/Experimental
A medical device, supply, drug, procedure or service that has been tested in a laboratory and has been approved by the U.S. Food and Drug Administration (FDA) for testing in human beings. Clinical trials then test how well an investigational medical device, supply, drug, procedure or service performs and whether it is safe to use in human beings.

Edit Sources

I. Current Procedural Terminology (CPT) and associated publications and services.
II. International Classification of Diseases,10th Revision, Clinical Modification (ICD-10).
III. Healthcare Common Procedure Coding System (HCPCS).
IV. Centers for Medicare and Medicaid Services (CMS).
V. The National Correct Coding Initiative (NCCI).
VI. Pennsylvania Medicaid Fee Schedule(s).

Attachments

N/A

Associated Policies

N/A

Policy History

02/2025	Reimbursement Policy Committee Approval
04/2024	Revised preamble
08/2023	Removal of policy implemented by Keystone First from Policy History section
01/2023	Template Revised • Revised preamble • Removal of Applicable Claim Types table • Coding section renamed to Reimbursement Guidelines • Added Associated Policies section