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Section:	Prescription Drugs	**Effective Date:**	October 1, 2023
Subsection:	Endocrine and Metabolic Drugs	**Original Policy Date:**	January 1, 2021
Subject:	Reclast	**Page:**	1 of 3

Last Review Date: September 8, 2023

Reclast

Description

Reclast (zoledronic acid)

Background
Reclast (zoledronic acid) is a bisphosphonate and acts primarily on bone. It is an inhibitor of osteoclast-mediated bone resorption. The selective action of bisphosphonates on bone is based on their high affinity for mineralized bone. Intravenously administered zoledronic acid rapidly partitions to bone and localizes preferentially at sites of high bone turnover (1).

Regulatory Status
FDA-approved indications: Reclast is indicated for: (1)

- Osteoporosis
- Prevention of osteoporosis
- Paget's disease

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Reclast may be considered **medically necessary** if the conditions indicated below are met.

Reclast may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Osteoporosis
2. Prevention of osteoporosis
3. Paget's disease

AND the following for **ALL** diagnoses:

a. Patient **MUST** have tried the preferred product (generic Reclast: zoledronic acid) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Reclast (zoledronic acid) is a bisphosphonate and acts primarily on bone. It is an inhibitor of osteoclast-mediated bone resorption. The selective action of bisphosphonates on bone is based on their high affinity for mineralized bone. Intravenously administered zoledronic acid rapidly partitions to bone and localizes preferentially at sites of high bone turnover (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Reclast while maintaining optimal therapeutic outcomes.

References

1. Reclast [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2020.

Policy History

Date	Action
December 2020	Addition to PA. Annual review
September 2021	Annual review
September 2022	Annual review
December 2022	Annual review
September 2023	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 8, 2023 and is effective on October 1, 2023.