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

Last Review Date: December 4, 2020

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 indication: 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** for osteoporosis, prevention of osteoporosis, or Paget's disease who have had an inadequate response, intolerance, or contraindication to the generic.

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

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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 4, 2020 and is effective on January 1, 2021.