



Guidelines for Medication Use:

Zoledronic Acid Injection (Reclast®)

Background:

Zoledronic acid injection is a bisphosphonate approved for the following indications:

- Treatment of osteoporosis in postmenopausal women;
- Treatment to increase bone mass in men with osteoporosis;
- Treatment and prevention of glucocorticoid-induced osteoporosis in patients expected to be on glucocorticoids for at least 12 months
- Treatment of Paget's disease of the bone.

Administration:

The dose of Reclast is 5mg, administered as an intravenous infusion over at least 15 minutes. The product is supplied in a 100ml ready-to-infuse bottle.

For the treatment of postmenopausal osteoporosis in women, to increase bone mass in men with osteoporosis, and for the treatment or prevention of osteoporosis in patients on extended glucocorticoid therapy, Reclast should be administered once every 12 months.

For the treatment of Paget's disease of the bone, Reclast should be administered as a single dose. Retreatment may be necessary based on serum alkaline phosphatase levels or continued symptoms.

Note: Criteria for coverage differ for Commercial and Medicare enrollees.

Criteria for Coverage – Commercial Enrollees:

Coverage: Reclast is administered by intravenous infusion, and therefore must be administered by qualified healthcare professionals. Reclast is covered under the medical benefit

1. **Diagnosis – Postmenopausal Osteoporosis in Women and Osteoporosis in**

Men: Candidates for Reclast should have a definitive diagnosis of osteoporosis based on either

- a) A documented previous osteoporotic fracture

OR

- b) A bone mass density (T-score) of -2.5 or lower (which demonstrates a bone mass density greater than 2.5 standard deviations below the premenopausal mean);

AND

- c) The candidate shall meet at least **one** of the following criteria:
- I. Intolerance of oral bisphosphonate therapy or physiological inability to take oral therapy as documented in the enrollee's medical record
 - II. Documented failure to achieve an adequate response to a twelve month trial of oral bisphosphonate therapy as demonstrated by a repeat osteoporotic fracture or lack of stabilization of osteoporosis as shown by repeat T-scores of -2.5 or worse
 - III. Documented severe osteoporosis (T-score worse than -3.0) that would contraindicate an oral bisphosphonate trial.

2. Diagnosis - Treatment and prevention of glucocorticoid-induced osteoporosis in patients expected to treated with systemic glucocorticoid therapy for at least 12 months

- a) Candidates for Reclast should have a history of ongoing systemic glucocorticoid therapy of 2.5mg of prednisone or equivalent daily for at least 12 months duration as documented by their prescription claims.

OR

- b) Candidates for Reclast should be currently receiving systemic glucocorticoid therapy and have a diagnosis for which therapy of at least 12 months in duration could reasonably be expected. These diagnoses include:
- Chronic immunosuppressive therapy post organ transplant surgery
 - Crohn's disease
 - Ulcerative colitis
 - Rheumatic disorders
 - Hematologic disorders

AND

- c) The candidate shall meet at least **one** of the following criteria:
- I. Intolerance of oral bisphosphonate therapy or physiological inability to take oral therapy as documented in the enrollee's medical record
 - II. Documented failure to achieve an adequate response to a twelve month trial of oral bisphosphonate therapy as demonstrated by a repeat osteoporotic fracture or lack of stabilization of osteoporosis as shown by repeat T-scores of -2.5 or worse
 - III. Documented severe osteoporosis (T-score worse than -3.0) that would contraindicate an oral bisphosphonate trial.

3. Diagnosis- Paget's disease: Candidates for Reclast should have a diagnosis of Paget's disease of the bone and:

- a) Have elevations in serum alkaline phosphatase two times or higher the normal limit, **OR**
- b) Experience symptoms associated with their Paget's disease, **OR**
- c) Are at risk from complications associated with their disease;

AND

- d) Reclast is prescribed as a single treatment only. Retreatment may be considered in patients who have relapsed, based on increases in serum alkaline phosphatase, failure to achieve a normal alkaline phosphatase, or appearance of symptoms. Each course of Reclast is subject to authorization.

Criteria for Coverage – Medicare Enrollees:

Coverage: Reclast is administered by intravenous infusion, and therefore must be administered by qualified healthcare professionals. Reclast is covered under the Medicare Part B benefit if provided by and infused in the prescribing provider's office.

1. **Diagnosis – Postmenopausal Osteoporosis in Women and Osteoporosis in Men:** Candidates for Reclast should have a definitive diagnosis of osteoporosis based on either
 - a) A documented previous osteoporotic fracture **OR**
 - b) A bone mass density (T-score) of -2.5 or lower (which demonstrates a bone mass density greater than 2.5 standard deviations below the premenopausal mean);
AND
 - c) Reclast is to be infused once every 12 months.

2. **Diagnosis - Treatment and prevention of glucocorticoid-induced osteoporosis in patients expected to treated with systemic glucocorticoid therapy for at least 12 months:**
 - a) Candidates for Reclast should have a history of ongoing systemic glucocorticoid therapy of 2.5mg of prednisone or equivalent daily for at least 12 months duration as documented by their prescription claims.
OR
 - b) Candidates for Reclast should be currently receiving systemic glucocorticoid therapy and have a diagnosis for which therapy of at least 12 months in duration could reasonably be expected. These diagnoses include:
 - Chronic immunosuppressive therapy post organ transplant surgery
 - Crohn's disease
 - Ulcerative colitis
 - Rheumatic disorders
 - Hematologic disorders

3. **Diagnosis- Paget's Disease:** Candidates for Reclast should have a definitive diagnosis of Paget's disease, **AND** Reclast is prescribed as a single treatment only. Retreatment may be considered in patients who have relapsed, based on increases in serum alkaline phosphatase, failure to achieve a normal alkaline phosphatase, or appearance of symptoms. Each course of Reclast is subject to authorization.

Authorization Procedure:

- 1) All courses of Reclast require prior authorization.
- 2) The prescriber should contact the Pharmacy Authorization Unit at (330) 996-8805 for authorization or further information.
- 3) The Authorization Specialist shall follow the appropriate criteria based on member type (commercial vs. Medicare) and diagnosis.
- 4) The prescriber and member will be notified of authorization or denial as delineated in the SummaCare Pharmacy Benefit Management policies and procedures. The Authorization Specialist will perform any necessary entry into the claims system.

Approved: SummaCare Pharmacy & Therapeutics Committee. March 6, 2008

Revised: May 7, 2009

Medical Director

Pharmacy Director

References:

Product Information for Reclast. Novartis Pharmaceuticals Corporation. December 2008.

Black DM, Delmas PD, Eastell R, et al. Once-Yearly Zoledronic Acid for Treatment of Postmenopausal Osteoporosis. The New England Journal of Medicine 2007; 356: 1809-1822.

Once-Yearly Osteoporosis Treatment and Other Bisphosphonate Developments. Pharmacist's Letter/ Prescriber's Letter 2007; 23(9): 230902

A Once-yearly IV Bisphosphonate for Osteoporosis. Med Letter. 2007; 49 (1273): 89 – 90.

Qaseem A, Snow V, Shekelle P, et al. Screening for Osteoporosis in Men: A Clinical practice Guideline from the American College of Physicians. Ann Intern Med. 2008; 148: 680-684.