Health Net®

Prior Authorization Protocol

RECLAST® (zoledronic acid)

NATL

Coverage of drugs is first determined by the member's pharmacy or medical benefit. Please consult with or refer to the Evidence of Coverage document.

I. FDA Approved Indications:

- Treatment and prevention of postmenopausal osteoporosis
- Treatment to increase bone mass in men with osteoporosis
- Treatment and prevention of glucocorticoid-induced osteoporosis
- Treatment of Paget's disease of bone in men and women
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II. Health Net Approved Indications and Usage Guidelines:

- Confirmed diagnosis of Paget's disease

  OR
- Postmenopausal osteoporosis (PMO) or high risk of PMO

  OR
- Male osteoporosis or high risk of osteoporosis

  OR
- Glucocorticoid-induced Osteoporosis (GIO) or high risk of GIO

III. Coverage is Not Authorized For:

- Non-FDA approved indications, which are not listed in the Health Net Approved Indications and Usage Guidelines section, unless there is sufficient documentation of efficacy and safety in the published literature

IV. General Information:

- The safety and efficacy of Reclast for the treatment of osteoporosis is based on clinical data of three years duration. The optimal duration of use has not been determined. All patients on bisphosphonate therapy should have the need for continued therapy re-evaluated on a periodic basis. Patients at low-risk for fracture should be considered for drug discontinuation after 3 to 5 years of use. Patients who discontinue therapy should have their risk for fracture re-evaluated periodically.
- Reclast is contraindicated in patients with hypocalcemia. Pre-existing hypocalcemia and disturbances of mineral metabolism must be effectively treated before initiating therapy with Reclast. Hypocalcemia following Reclast administration is a significant risk in Paget's disease. All patients with Paget's should take 1500 mg of elemental calcium daily in divided doses of two to three times per day and 800 IU of vitamin D daily, particularly in the two weeks following administration. Patients being treated for osteoporosis should take supplemental calcium and vitamin D if their dietary intake is inadequate. An average of at least 1200 mg calcium and 800-1000 IU vitamin D is recommended.

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- According to the National Osteoporosis Foundation, sequential treatment with anabolic therapy followed by an antiresorptive is generally preferred to concomitant combination therapy. However, combination therapy with teriparatide and an antiresorptive can be considered in a few clinical settings in patients with very severe osteoporosis. There are few indications for combining two antiresorptive treatments, but such options could be considered in the short-term in women who are experiencing active bone loss while on low dose hormone therapy for menopausal symptoms or raloxifene for breast cancer prevention.

V. Therapeutic Alternatives:

Drug	Dosing Regimen	Dose Limit/Maximum Dose
alendronate (Fosamax®)	Postmenopausal Osteoporosis (PMO) prevention: 5 mg PO QD or 35 mg PO once weekly PMO treatment: 10 mg PO QD or 70 mg once weekly Male osteoporosis treatment: 10 mg PO QD or 70 mg PO once weekly GIO treatment: 5 mg PO QD or 10mg PO QD (in postmenopausal women not receiving estrogen) Paget's disease: 40 mg PO QD for 6 months	Osteoporosis: 10 mg/day or 70 mg/week Paget's disease: 40 mg/day for 6 months.
Fosamax Plus D® (alendronate/ cholecalciferol) *	PMO treatment and Male osteoporosis treatment: 70 mg alendronate/ 2,800 units cholecalciferol or 70 mg alendronate /5,600 units cholecalciferol PO once weekly	70 mg alendronate/5,600 units cholecalciferol/week
risedronate (Actonel®)*	PMO prevention & treatment: 5 mg PO QD or 35 mg PO once weekly or 150 mg PO once monthly Male osteoporosis treatment: 35 mg PO once weekly GIO prevention & treatment: 5 mg PO QD	Osteoporosis: 5 mg/day 35 mg/week 150 mg/month Paget's disease: 30 mg/day for 2 months

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Drug	Dosing Regimen	Dose Limit/Maximum Dose
	Paget's disease: 30 mg PO QD for 2 months	
ibandronate (Boniva®)*	PMO prevention & treatment (tablets): 150 mg PO once monthly PMO treatment (injection): 3 mg IV every 3 months over 15 to 30 seconds	PO: 150 mg/month IV: 3 mg per dose once every 3 months
raloxifene (Evista®)	PMO prevention & treatment: 60 mg PO QD	60 mg/day
calcitonin-salmon nasal spray (Miacalcin®, Fortical® Nasal Spray)	PMO treatment: 200 IU spray in one nostril QD	Nasal Spray: 200 IU/day
Forteo® (teriparatide) *	PMO treatment, GIO treatment, Male osteoporosis treatment: 20 mcg SC QD	20 mcg/day for a maximum of 2 years
Prolia™ (denosumab) *	PMO treatment, Male osteoporosis treatment: 60 mg SC every 6 months Prolia should be administered by a healthcare professional.	60 mg per dose once every 6 months
Miacalcin® Injection (calcitonin - salmon) *	PMO treatment: 100 IU SC/IM QOD Treatment of Paget's Disease: 100 IU SC/IM QD	Injection: 100 IU/day
etidronate disodium (Didronel®)	Treatment of Paget's Disease: Initial treatment: 5-10 mg/kg/day PO not to exceed 6 months or11-20 mg/kg/day PO not to exceed 3 months	20 mg/kg/day Re-treatment should occur only after a drug-free period of at least 3 months, and then only in the presence of biochemical, symptomatic, or other evidence of active disease. Although some patients may have extended drug-free periods, it is recommended that monitoring be performed every 3 to 6 months. Re-treatment regimens are the same as initial treatment regimens

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Drug	Dosing Regimen	Dose Limit/Maximum Dose
pamidronate disodium (Aredia®)	Treatment of Paget's Disease: 30 mg daily as a 4-hour IV infusion on 3 consecutive days for a total dose of 90 mg	30 mg/day If clinically indicated patients may be retreated with the same dose

* Requires Prior Authorization

VI. Recommended Dosing Regimen and Authorization Limit:

Drug	Dosing Regimen	Authorization Limit
Reclast	Treatment of Paget's Disease: 5 mg IV infusion over at least 15 minutes for one dose PMO treatment, Male osteoporosis treatment and GIO prevention and treatment: 5 mg IV infusion over at least 15 minutes once a year PMO prevention: 5 mg IV infusion over at least 15 minutes once every two years	Length of benefit

VII. Product Availability:

Injection: 5 mg/100 ml bottle

VIII. References:

1. Reclast [Prescribing Information] East Hanover, NJ: Novartis Pharmaceuticals Corp.; April 2015.
2. National Osteoporosis Foundation. Clinician's Guide to Prevention and Treatment of Osteoporosis. Available at: http://nof.org/files/nof/public/content/file/2791/upload/919.pdf. Accessed February 25, 2016.
3. The North American Menopause Society. Management of osteoporosis in postmenopausal women: 2010 position statement of the North American Menopause Society. Menopause2010;17(1):22-54.
4. Watts NB, Bilezikian JP, Camacho PM, et al. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the diagnosis and treatment of postmenopausal osteoporosis. Endocr Pract 2010;16(Suppl 3):1-37.
5. Grossman JM, Gordon R, Ranganath VK, et al. American College of Rheumatology 2010 recommendations for the prevention and treatment of glucocorticoid-induced osteoporosis. Arthritis Care Res 2010;62(11):1515-1526.

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6. Zoledronic acid. American Hospital Formulary Service Drug Information. Available at: http://www.medicinescomplete.com/mc/ahfs.current/. Accessed February 25, 2016.
7. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed February 25, 2016.
8. Clinical Pharmacology Web site. Available at http://cpip.gsm.com/. Accessed February 25, 2016.

The materials provided to you are guidelines used by this health plan to authorize, modify, or determine coverage for persons with similar illnesses or conditions. Specific care and treatment may vary depending on individual needs and the benefits covered under your contract.

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