

Market Applicability/Effective Date														
Market	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	N/A	N/A	X	N/A	X	X	X	X	X	X	N/A	N/A	X

*FHK- Florida Healthy Kids

abaloparotide

DRUG.00103

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
abaloparotide

APPROVAL CRITERIA

Abaloparotide may be approved for the treatment of osteoporosis to increase bone mass when the following criteria are met:

- I. Individual is a postmenopausal female with a confirmed diagnosis of osteoporosis (defined as a bone mineral density [BMD] T-score of less than or equal to -2.5 as compared to a young-adult reference population), or a clinical diagnosis based on history of a low trauma fracture (fragility fracture)) considered at high risk for additional fractures; **AND**
 - II. Has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of a preferred oral bisphosphonate; **OR**
Preferred agents: Alendronate tablet (generic Fosamax), alendronate oral solution (generic Fosamax oral solution)
 - III. Is intolerant to or has a contraindication to an oral bisphosphonate as defined by one of the following (1 through 5):
 1. Hypersensitivity to TWO oral bisphosphonates (one of which must be generic alendronate); **OR**
 2. Inability to stand or sit upright for at least 30 minutes; **OR**
 3. A pre-existing gastrointestinal disorder (for example, Barrett's esophagus, hypersecretory disorders, delayed esophageal emptying, etc.); **OR**
 4. Uncorrected hypocalcemia; **OR**
 5. Severe renal insufficiency as defined by creatinine clearance less than 35 mL/min for alendronate agents or creatinine clearance less than 30 mL/min for risedronate and ibandronate;
- AND**
- IV. The individual is not using abaloparotide in combination with **any** of the following (1through 5):
 1. Prolia (denosumab); **OR**
 2. Bisphosphonates; **OR**
 3. Evista (raloxifene); **OR**
 4. Miacalcin/Fortical (calcitonin nasal spray); **OR**

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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5. Reclast (zoledronic acid).

Requests for abaloparotide may not be approved for the following:

- I. Individual is male.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

1. Agency for Healthcare Research and Quality. Treatment to prevent fractures in men and women with low bone density or osteoporosis: update of a 2007 Report. Comparative effectiveness review. 2012 March. Publication No 12-EHC023-EF. Available at: <http://www.ncbi.nlm.nih.gov/books/NBK92566/pdf/TOC.pdf>. Accessed on December 12, 2016.
2. American Association of Clinical Endocrinologists and American College of Endocrinology. Clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis. Endocr Pract. 2016; 22(Suppl 4):1-42. Available at: <https://www.aace.com/files/final-appendix-sept-7.pdf>. Accessed December 9, 2016.
3. Cosman F, de Beur SJ, LeBoff MS, et al. Clinician's guide to prevention and treatment of osteoporosis. Osteoporosis Int. 2014. Available at: <http://nof.org/files/nof/public/content/file/3593/upload/995.pdf>. Accessed on January 9, 2017.
4. Grossman JM, Gordon R, Ranganath VK, et al. American College of Rheumatology 2010 Recommendations for the prevention and treatment of glucocorticoid-induced osteoporosis. Revised 2010. Available at: http://www.rheumatology.org/Practice/Clinical/Guidelines/Clinical_Practice_Guidelines/. Accessed on December 12, 2016.
5. National Institute of Health (NIH). Osteoporosis and related bone diseases. National resource center. June 2015. Available at: https://www.niams.nih.gov/health_info/bone/bone_health/bone_mass_measure.asp. Accessed on January 4, 2017.
6. National Institute of Health (NIH). Osteoporosis prevention, diagnosis, and therapy. NIH Consensus Statement. 2000; 17(1):1-45. Available at: <http://consensus.nih.gov/2000/2000Osteoporosis111html.htm>. Accessed on January 4, 2017.
7. National Osteoporosis Foundation. Clinician's guide to prevention and treatment of osteoporosis. Revised 2013. Available at: <https://my.nof.org/bone-soruce/education/clinicians-guide-to-the-prevention-and-treatment-of-osteoporosis>. Accessed on January 4, 2017.
8. North American Menopause Society. Management of osteoporosis in postmenopausal women: 2010 position statement of the North American Menopause Society. Menopause. 2010; 17(1):25-54.
9. Watts NB, Bilezikian JP, Camacho PM, et al. American Association of Clinical Endocrinologists (AACE). Medical guidelines for clinical practice for the diagnosis and treatment of postmenopausal osteoporosis. Endocr Pract. 2010; 16(Suppl 3):1-37.

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