

***Title: Concurrent Osteoporosis Medication***

<b>Origination:</b> 02/24/05	<b>Revised:</b> 11/11/11	<b>Annual Review:</b> 12/15/11
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**Purpose:**

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

**Background Information:**

***Medication Summary***

- Bisphosphonates (Fosamax, Actonel, Boniva, Reclast) are used for the treatment of Paget's disease, prevention and treatment of osteoporosis, and treatment of glucocorticoid-induced osteoporosis. Evista is used for the prevention and treatment of osteoporosis in postmenopausal women. Calcitonin (Miacalcin) is used for the treatment of Paget's disease and osteoporosis. Medical literature does not support the safety and additive benefits of concurrent use.

***Reference Statement***

- Guidelines are compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

***Eligibility Criteria***

- Member must be eligible and have applicable benefits.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

***Exclusions***

- Bisphosphonate concurrently with Evista or Calcitonin.
- Evista concurrently with Bisphosphonate or Calcitonin.
- Calcitonin concurrently with Bisphosphonate or Evista.

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**Procedure:**

- 1.0 Medical literature does not support the safety and additive benefits of concurrent use (i.e., receiving more than one (1) osteoporosis medication therapy including, but not limited to, Actonel, Atelvia, Boniva, Evista, Fosamax, Miacalcin, Prolia, or Reclast):
  - 1.1 AvMed will only provide benefit coverage for one (1) osteoporosis medication therapy.

**References:**

1. Fosamax Package Insert, Merck & Co., Inc., West Point, PA, May 2007.
2. Hodgson, Stephen F., MD, FACE and Johnston Jr., C. Conrad, MD, FACE, AACE Clinical Practice Guidelines for the Prevention and Treatment of Postmenopausal Osteoporosis: 2001 edition with selected updates for 2003 AACE. [Online.]
3. Foundation For Osteoporosis Research And Education, Guidelines of Care on Osteoporosis for the Primary Care Physician. Fourth Edition 2002.
4. Johnston, Jr., C. Conrad, MD, et. al. *Physician's Guide to Prevention and Treatment of Osteoporosis*, 2000, National Osteoporosis Foundation (NOF). [Online.]
5. Recommendations for the prevention and treatment of glucocorticoid-induced osteoporosis: 2001 update. American College of Rheumatology Ad Hoc Committee on Glucocorticoid-Induced Osteoporosis. *Arthritis Rheum* 2001 Jul;44(7):1496-503. [54 references]
6. North American Menopause Society. Management of osteoporosis in postmenopausal women: 2006 position statement of The North American Menopause Society. *Menopause* 2006 May-Jun;13(3):340-67.
7. Boniva Package Insert, Roche Laboratories, Inc., Nutley, NJ August 2006.
8. Reclast Package Insert, Novartis Pharmaceuticals Corp., East Hanover, NJ August 2007.
9. Actonel Package Insert, Procter & Gamble Pharmaceuticals, Inc., Cincinnati, OH May 2007.
10. Evista Package Insert, Eli Lilly and Company, Indianapolis, IN September 2007.
11. Miacalcin Package Insert, Novartis Pharmaceuticals Corp., East Hanover, NJ June 2006.



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**Disclaimer Information:**

Prior Authorization criteria are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions based on the Member's benefit plan contract and these criteria. This guideline sets forth concise clinical coverage criteria which have been developed from a review of current literature, policies of the FDA and other government agencies, and other appropriate references, in consultation and with approval from practicing physicians who are members of AvMed's Pharmacy and Therapeutic committee. Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change. The use of these criteria is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.