



### Medical Necessity Criteria for Osteoporosis Agents

**Drug Class** - Osteoporosis Agents. This drug class includes multiple agents primarily used in the treatment of osteoporosis. Currently four subclasses of agents are used in the treatment of osteoporosis: bisphosphonates, selective estrogen receptor modulators (SERMs), parathyroid hormone 1-34 amino acids (PTH), and calcitonins.

*Bisphosphonates:*

- Alendronate (Fosamax) & Alendronate plus D (Fosamax plus D)
- Ibandronate (Boniva)
- Risedronate (Actonel) & risedronate plus calcium (Actonel with Calcium)

*SERMs:*

- Raloxifene (Evista)

*PTH:*

- Teriparatide (Forteo)

*Calcitonins:*

- Calcitonin-salmon (Miacalcin)
- Recombinant calcitonin (Fortical)

**Background** - After evaluating the relative clinical and cost effectiveness of the osteoporosis agents, the DoD P&T Committee recommended that the following medications be designated as non-formulary. This recommendation has been approved by the Director, TMA.

- Calcitonin-salmon (Miacalcin)

**Effective date:** 26 Nov 2008

Patients or parents of patients currently using Miacalcin, a nonformulary osteoporosis agent may wish to ask their doctor to consider a formulary alternative.

### Uniform Formulary Status, Cost Shares, and Therapeutic Alternatives for Osteoporosis Agents\*, \*\*

Uniform Formulary Status	Medication	Military Treatment Facilities (MTFs) (up to a 90 day supply)	TMOP (up to a 90 day supply)	Retail Network (up to a 30-day supply)
Non-Formulary (Tier 3)	Miacalcin	Not available**	Non-Formulary cost share applies	Non-Formulary cost share applies
Formulary: Brand Name (Tier 2)	Fosamax, Fosamax plus D, Boniva, Actonel, Actonel plus calcium, Evista, Forteo, Fortical	\$0	Formulary (Brand) cost share applies	Formulary (Brand) cost share applies
Formulary: Generic (Tier 1)	Alendronate	\$0	Generic cost share applies	Generic cost share applies

\* Active duty cost share always \$0 in all points of service for all three tiers; active duty service members may not fill prescriptions for a non-formulary medication unless it is determined to be medically necessary.

\*\* MTFs will be able to fill non-formulary requests for non-formulary medications only if both of the following conditions are met: 1) a MTF provider writes the prescription, and 2) medical necessity is established for the non-formulary medication. MTFs may (but are not required to) fill a prescription for a non-formulary medication written by a non-MTF provider to whom the patient was referred, as long as medical necessity has been established.

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The non-formulary copay for calcitonin-salmon (Miacalcin) may be reduced to the formulary copay if the patient meets any of the following criteria.

1. Use of Fortical, the formulary alternative is contraindicated (e.g., due to hypersensitivity).
2. The patient has experienced or is likely to experience significant adverse effects from Fortical, the formulary alternative.
3. Use of Fortical, the formulary alternative has resulted in therapeutic failure.
4. The patient previously responded to Miacalcin and changing to a uniform formulary agent would incur unacceptable risk.

Medical necessity criteria for Miacalcin are recommended by the DoD Pharmacy & Therapeutics Committee at the Jun 2008 meeting & approved by the Director, TMA on 27 Aug 2008. For more information, please see the DoD P&T Committee minutes for these meetings.

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