



Guidelines for Medication Use:

Ibandronate Injection (Boniva I.V.®)

Background:

Ibandronate injection is a bisphosphonate approved for the treatment of osteoporosis.

Administration:

Boniva I.V. is administered as an intravenous injection. A 3 mg dose is administered as an intravenous push over 15 to 30 seconds. Boniva I.V. is distributed in a 3mg/3ml prefilled syringe.

The most widely reported side effects of ibandronate administration include an acute phase reaction consisting of musculoskeletal pain, flu-like symptoms, and fever. Transient reductions in serum calcium may occur after administration. Of note, the incidence of gastrointestinal symptoms following administration of Boniva I.V. were not significantly lower than those reported after the administration of a dose of oral Boniva.

Special Instructions:

The use of concurrent Forteo in combination with a bisphosphonate has not been shown to result in additive reduction in fracture risk; therefore, combination therapy is not recommended at this time.

Criteria for approval:

- Coverage:** Boniva I.V. is administered by intravenous bolus, and therefore must be administered by qualified healthcare professionals.
Commercial: Boniva I.V. is covered under the medical benefit
Medicare: Palmetto GBA has determined that Boniva I.V. will be covered under the Medical Part B benefit when used for the treatment of osteoporosis in women who are medically unable to be treated with an oral bisphosphonate.
- Candidates for Boniva I.V. should have a definitive diagnosis of osteoporosis based on either
 - A documented previous osteoporotic fracture **OR**
 - 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**
- The candidate shall meet at least **one** of the following criteria:

- a) Intolerance of oral bisphosphonate therapy or physiological inability to take oral therapy as documented in the enrollee's medical record
- b) 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.
- c) Documented severe osteoporosis (T-score worse than -3.0) that would contraindicate an oral bisphosphonate trial.

Authorization Procedure:

- 1) All courses of Boniva I.V. require prior authorization.
- 2) Walgreen Specialty shall be the preferred provider of Boniva I.V. for SummaCare enrollees.
- 3) Duration of authorization: 12 months.
- 4) The prescriber should contact the Pharmacy Authorization Unit at (330) 996-8781 for authorization or further information.
- 5) The prescriber and member will be notified of authorization or denial as delineated in the SummaCare Pharmacy Benefit Management policies and procedures. The Pharmacy Authorization Specialist will perform any necessary entry into the pharmacy claims system.

Approved: SummaCare Pharmacy & Therapeutics Committee. July 6, 2006

Medical Director

Pharmacy Director

References:

Product Information for Boniva I.V. Roche Pharmaceuticals. January 2006

New Formulation: Ibandronate (Boniva) injection. Pharmacist's Letter/Prescriber's Letter 2006; 22(3): 220304.