Clinical Policy: Oral Bisphosphonates

Reference Number: PA.CP.PMN.43
Effective Date: 01/18
Last Review Date: 02/17
Line of Business: Medicaid

Coding Implications
Revision Log

Description
Risedronate (Actonel®, Atelvia®), ibandronate (Boniva®), and etidronate (Didronel®) are oral bisphosphonates requiring prior authorization.

FDA approved indication
Actonel is indicated for:
- 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
  Limitation of use: Optimal duration of use has not been determined. For patients at low-risk for fracture, consider during discontinuation after 3 to 5 years of use.

Boniva is indicated for:
- Treatment and prevention of postmenopausal osteoporosis

Didronel is indicated for:
- Treatment of Paget's Disease
- Prevention and treatment of heterotopic ossification following total hip replacement or due to spinal cord injury

Atelvia is indicated for:
- Treatment of postmenopausal osteoporosis
  Limitation of use: Optimal duration of use has not been determined. For patients at low-risk for fracture, consider during discontinuation after 3 to 5 years of use.

Policy/Criteria
** Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria **

It is the policy of Pennsylvania Health and Wellness that non-preferred oral bisphosphonates are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Osteoporosis/Osteoporosis Prophylaxis (must meet all)**:**

1. Request is for treatment or prophylaxis of osteoporosis;
2. Member meets one of the following (a or b):
   a. Failure of alendronate as evidenced by a documented history of fracture while on therapy;
   b. Failure of ≥ 12 month trial of alendronate at maximum indicated doses as evidenced by a lack of improvement in baseline bone mineral density, unless member experiences clinically significant adverse effects or has contraindication(s) to alendronate;
3. Request is for Actonel, Atelvia, or Boniva.

Approval duration: 12 months

B. Paget's Disease (must meet all)**:**
1. Diagnosis of Paget's disease;
2. Failure of ≥ 6 month trial of alendronate at maximum indicated doses as evidenced by inability to achieve normal serum alkaline phosphate levels, unless member experiences clinically significant adverse effects or has contraindication(s) to alendronate;
3. Request is for Didronelor Actonel.

Approval duration: Didronel - 3 months; Actonel: 2 months

C. Heterotopic Ossification (must meet all):
1. Diagnosis of heterotopic ossification resulting from spinal cord injury or following total hip arthroplasty;
2. Request is for Didronel.

Approval duration: Total hip arthroplasty- 4 months; Spinal cord injury - 3 months

D. Hypercalcemia Associated with Malignant Neoplasms (must meet all):
1. Diagnosis of hypercalcemia associated with malignancy;
2. Request is for Didronel.

Approval duration: 30 days

E. Other diagnoses/indications – Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

II. Continued Therapy

A. Osteoporosis/Osteoporosis Prophylaxis (must meet all)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or Continuity of Care policy applies;
2. Responding positively to therapy.

Approval duration: 12 months

B. Paget's Disease
1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or Continuity of Care policy applies;
2. Member has had a medication-free period of 90 days if on Didronel and 60 days for Actonel.

Approval duration: Didronel and Skelid - 3 months; Actonel: 2 months

C. Heterotopic Ossification
1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or Continuity of Care policy applies;

2. Member has NOT received ≥ 3 months of treatment for heterotopic ossification from spinal cord injury or ≥ 4 months treatment following total hip arthroplasty;
3. Responding positively to therapy.

Approval duration:
Allow for no more than 4 months of treatment TOTAL for total hip arthroplasty
Allow for no more than 3 months of treatment TOTAL for spinal cord injury

D. Hypercalcemia Associated with Malignant Neoplasms

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or Continuity of Care policy applies.
2. Responding positively to therapy;

Approval duration: Up to an additional 60 days (maximum total therapy of 90 days)

E. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or
2. Refer to PA.CP.PMN.53 if requested indication is NOT listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

Approval duration: 6 months

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation Key
Not applicable

V. Dosage and Administration

Drug	Recommended Dose	Maximum Dose
Actonel (risedronate)	Treatment of postmenopausal osteoporosis: 5 mg daily, 35 mg once-a-week, 75 mg two consecutive days each month, 150 mg once-a-month Prevention of postmenopausal osteoporosis: 5 mg daily, 35 mg once-a-week Men with osteoporosis: 35 mg once-a-week Glucocorticoid-induced osteoporosis: 5 mg daily Paget's Disease: 30 mg daily for 2 months	Osteoporosis: 5 mg/day, 35 mg/week (either immediate-release or delayed-release tablets), or 150 mg/month Paget's disease: 30 mg/day

Fosamax (alendronate)	Treatment of osteoporosis in postmenopausal women and in men: 10 mg daily or 70 mg (tablet or oral solution) once weekly. Prevention of osteoporosis in postmenopausal women: 5 mg daily or 35 mg once weekly. Glucocorticoid-induced osteoporosis: 5 mg daily; or 10 mg daily in postmenopausal women not receiving estrogen. Paget's disease: 40 mg daily for six months	Osteoporosis: 10 mg/day PO or 70 mg/week Paget's disease: 40 mg/day
Boniva (ibandronate)	Take one 150 mg tablet once monthly on the same day each month	2.5 mg/day or 150 mg/month
Didronel (etidronate)	Paget's disease: 5 to 10 mg/kg/day, not to exceed 6 months or 11 to 20 mg/kg/day, not to exceed 3 months Heterotopic ossification: Total Hip Replacement Patients: 20 mg/kg/day for 1 month before and 3 months after surgery (4 months total) Spinal Cord Injured Patients: 20 mg/kg/day for 2 weeks followed by 10 mg/kg/day for 10 weeks (12 weeks total)	20 mg/kg/day
Atelvia (risedronate)	35 mg once a week	35 mg/week

VI. Product Availability

Drug	**Availability**
Actonel (risedronate)	5 mg, 30 mg, 35 mg, 75 mg, and 150 mg tablets
Fosamax (alendronate)	70 mg tablet
Boniva (ibandronate)	150 mg tablet
Didronel (etidronate)	200 mg, 400mg tablet
Atelvia (risedronate)	35 mg delayed-release tablet

VII. References

1. Actonel Prescribing Information. Rockaway, NJ: Warner Chilcot, LLC. April 2015. Available at http://www.allergan.com/. Accessed December 2016.
2. Fosamax Prescribing Information. Whitehouse Station, NJ: Merck & Co., Inc., August 2015. Available at https://dailymed.nlm.nih.gov. Accessed December 2016.

3. Boniva Prescribing Information. South San Francisco, CA: Genetech USA, Inc. October 2015. Available at https://www.gene.com/. Accessed December 2016.
4. Didronel Prescribing Information. Morgantown, WV: Mylan Pharmaceuticals Inc. April 2015. Available at https://dailymed.nlm.nih.gov/. Accessed December 2016.
5. Skelid Prescribing Information. Bridgewater, NJ: Sanofi-Aventis US, LLC. March 2010. Available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/020707s006lbl.pdf. Accessed December 2016.
6. Atelvia Prescribing Information. North Norwich, NY: Norwich Pharmaceuticals, Inc. March 2015.Available at http://www.allergan.com. Accessed December 2016.
7. Camacho PM, Petak SM, Brinkley N et al. AACE/ACE Guidelines- American Association of Clinical Endocrinologists and American College of Endocrinology Clinical Practice Guidelines for Diagnosis and Treatment of Postmenopausal Osteoporosis. Endocrine Practice Vol 22 (suppl 4) September 2016.

Reviews, Revisions, and Approvals	Date	Approval Date