

Clinical Policy: Etidronate (Didronel)

Reference Number: PA.CP.PMN.94

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[Revision Log](#)

Description

Etidronate (Didronel®) is an oral bisphosphonate.

FDA Approved Indication(s)

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.

Policy/Criteria

Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health & Wellness that Didronel is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Paget's Disease (must meet all):

1. Diagnosis of Paget's disease;
2. Failure of ≥ 6 month trial of alendronate at maximum indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
3. Current (within the last 30 days) lab shows elevated (outside the upper limit of normal) serum alkaline phosphatase;
4. Dose does not exceed 10 mg/kg/day.

Approval duration: 6 months

B. Heterotopic Ossification or Hypercalcemia of Malignancy (must meet all):

1. Diagnosis of one of the following:
 - a. Hypercalcemia associated with malignancy;
 - b. Heterotopic ossification resulting from spinal cord injury or following total hip arthroplasty;
2. Dose does not exceed 20 mg/kg/day.

Approval duration:

Hypercalcemia - 1 month

Spinal cord injury - 3 months

Total hip arthroplasty - 4 months

C. 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. Paget's Disease

1. Currently receiving medication via PA Health & Wellness benefit or member has met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
 2. Three months have elapsed since the completion of previous therapy with Didronel;
 3. Current (within the last 30 days) lab shows elevated (outside the upper limit of normal) serum alkaline phosphatase;
 4. If request is for a dose increase, new dose does not exceed 20 mg/kg/day.
- Approval duration: 6 months** (*3 months if dose is > 10 mg/kg/day*).

B. Heterotopic Ossification

1. Currently receiving medication via PA Health & Wellness benefit or member has met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) 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. Member is responding positively to therapy;
4. If request is for a dose increase, dose does not exceed 20 mg/kg/day.

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

C. Hypercalcemia of Malignancy

1. Currently receiving medication via PA Health & Wellness benefit or member has met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Member has not received ≥ 90 days of therapy;
3. Member is responding positively to therapy;
4. If request is for a dose increase, dose does not exceed 20 mg/kg/day.

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

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

1. Currently receiving medication via PA Health & Wellness benefit or member has met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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

FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug	Dosing Regimen	Dose Limit/ Maximum Dose
alendronate (Fosamax [®])	PMO/MO treatment: 10 mg PO QD or 70 mg PO once weekly PMO Prevention: 5 mg PO QD or 35 mg PO once weekly Paget's disease: 40 mg PO QD for 6 months	40 mg/day 70 mg/week

Therapeutic alternatives are listed as Brand name[®] (generic) when the drug is available by brand name only and generic (Brand name[®]) when the drug is available by both brand and generic.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Etidronate (Didronel)	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

VI. Product Availability

Tablets: 200 mg, 400 mg

VII. References

1. Didronel Prescribing Information. Morgantown, WV: Mylan Pharmaceuticals Inc. March 2017. Available at <https://dailymed.nlm.nih.gov/>. Accessed December 1, 2017.
2. 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	P & T Approval Date