Clinical Policy: Etidronate (Didronel)

Reference Number: CP.PMN.94
Effective Date:03.01.18
Last Review Date: 02.18
Line of Business: Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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 (including such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® 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 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. Previously received medication via Centene benefit or member has previously met initial approval criteria;
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 Centene benefit or member has previously met initial approval criteria;
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 Centene benefit or member has previously met initial approval criteria.
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 Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to 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 - 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
-New policy created -Split from CP.PMN.43 – oral bisphosphonates. -No significant changes from previous corporate approved policy. -References reviewed and updated.	12.01.17	02.18

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.