Clinical Policy: Risedronate (Actonel, Atelvia)
Reference Number: CP.PMN.100
Effective Date: 03.01.18
Last Review Date: 02.20
Line of Business: Commercial, HIM, Medicaid

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

Description
Risedronate IR (Actonel®) and risedronate DR (Atelvia®) are oral bisphosphonates.

FDA Approved Indication(s)
Actonel is indicated for:
- Postmenopausal osteoporosis (PMO): Treatment and prevention of osteoporosis in postmenopausal women.
- Glucocorticoid-induced osteoporosis (GIO): Treatment and prevention of GIO.
- Male osteoporosis: Treatment to increase bone mass in men with osteoporosis.
- Paget disease: Treatment of Paget’s disease of bone.
Atelvia is indicated for:
- PMO: Treatment of osteoporosis in postmenopausal women.

Limitation of use: The optimal duration of use for bisphosphonates has not been determined. The safety and effectiveness of bisphosphonates for the treatment of osteoporosis are based on clinical data of one to four years duration. All patients on bisphosphonate therapy should have the need for continued therapy re-evaluated on a periodic basis. Patients at low-risk for fracture should be considered for drug discontinuation after 3 to 5 years of use. Patients who discontinue therapy should have their risk for fracture re-evaluated periodically.

Policy/Criteria
Provider must submit documentation (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 Actonel and Atelvia are medically necessary when the following criteria are met:

I. Initial Approval Criteria
A. Osteoporosis (must meet all):
   1. Prescribed for one of the following (a or b):
      a. Treatment or prevention of PMO or GIO;
      b. Treatment of male osteoporosis;
   2. Age ≥ 18 years or documentation of closed epiphyses on x-ray;
   3. Failure of a 12-month trial of alendronate at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
   4. Request meets one of the following (a or b):
      a. Actonel: Dose does not exceed 5 mg (1 tablet) per day;
b. Atelvia (PMO treatment only): Dose does not exceed 35 mg (1 tablet) per week.

Approval duration:
Medicaid/HIM – 12 months
Commercial – Length of Benefit

B. Paget’s Disease (must meet all):
1. Request is for Actonel;
2. Diagnosis of Paget’s disease of the bone;
3. Age ≥ 18 years or documentation of closed epiphyses on x-ray;
4. Failure of ≥ 6-month trial of alendronate at maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 30 mg (1 tablet) per day.

Approval duration: 2 months

C. Other diagnoses/indications
1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy
A. Osteoporosis (must meet all):
1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed (a or b):
   a. Actonel: 5 mg (1 tablet) per day;
   b. Atelvia (PMO treatment only): 35 mg (1 tablet) per week.

Approval duration:
Medicaid/HIM – 12 months
Commercial – Length of Benefit

B. Paget’s Disease (must meet all):
1. Currently receiving Actonel via Centene benefit or member has previously met initial approval criteria;
2. Two months have elapsed since the completion of previous therapy with Actonel;
3. Member is responding positively to therapy;
4. If request is for a dose increase, new dose does not exceed 30 mg (1 tablet) per day.

Approval duration: 2 months

C. 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 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is
CLINICAL POLICY
Risedronate

NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

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 policies – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information
   Appendix A: Abbreviation/Acronym Key
   BMD: bone mineral density  
   FDA: Food and Drug Administration  
   GIO: glucocorticoid-induced osteoporosis  
   PMO: postmenopausal osteoporosis

   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.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
</table>
| alendronate (Fosamax®) | • Treatment: PMO, male osteoporosis 10 mg PO QD or 70 mg PO once weekly  
• Treatment: GIO 5 mg PO QD or 10 mg PO QD in postmenopausal women not receiving estrogen  
• Prevention: PMO 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.

Appendix C: Contraindications/Boxed Warnings
   • Contraindication(s): abnormalities of the esophagus which delay esophageal emtyping such as stricture or achalasia; inability to stand/sit upright for at least 30 minutes; hypocalcemia; hypersensitivity
   • Boxed warning(s): none reported

V. Dosage and Administration

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
</table>
| Risedronate (Actonel) | PMO treatment and prevention | 5 mg PO QD or 35 mg PO once weekly or 75 mg PO QD taken on two consecutive days each month or 150 mg PO once monthly | 5 mg/day  
35 mg/week  
150 mg/month |
### II. Dosing Regimen

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Male osteoporosis treatment</td>
<td>35 mg PO once weekly</td>
<td>35 mg/week</td>
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<tr>
<td></td>
<td>GIO treatment and prevention</td>
<td>5 mg PO QD</td>
<td>5 mg/day</td>
</tr>
<tr>
<td></td>
<td>Paget disease</td>
<td>30 mg PO QD for 2 months</td>
<td>30 mg QD not to exceed 2 months</td>
</tr>
<tr>
<td>Risedronate (Atelvia)</td>
<td>PMO treatment</td>
<td>35 mg PO once weekly</td>
<td>35 mg/week</td>
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### VI. Product Availability

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Availability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risedronate (Actonel)</td>
<td>Tablets: 5mg, 30 mg, 35 mg, 75 mg, 150 mg</td>
</tr>
<tr>
<td>Risedronate (Atelvia)</td>
<td>Delayed-release tablet: 35 mg</td>
</tr>
</tbody>
</table>

### VII. References


**Osteoporosis Diagnosis, Fracture Risk, and Treatment**


**Male Osteoporosis**


**Glucocorticoid-Induced Osteoporosis**

**Paget Disease**


<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>New policy created</td>
<td></td>
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<tr>
<td>Policy split from existing oral bisphosphonate policy for all lines for business - no significant change from previous corporate approved policy. Combined policy for Medicaid, market place and commercial lines of business. References reviewed and updated.</td>
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</tr>
<tr>
<td>1Q 2019 annual review: Paget’s disease – removed alkaline phosphate requirement, to align with other oral bisphosphonates, modified continuation of therapy requirement to state “Disease has relapsed or progressed (e.g., increases in or failure to achieve normalization of serum ALP, radiographic progression of disease)”; references reviewed and updated.</td>
<td>11.05.18</td>
<td>02.19</td>
</tr>
<tr>
<td>1Q 2020 annual review: removed HIM disclaimer for HIM NF drugs; osteoporosis: closed epiphyses added if less than 18 yo; alendronate trial changed to 12-month trial; Paget disease: age added, continuation of therapy requirements removed for individualization of therapy; references reviewed and updated.</td>
<td>11.19.19</td>
<td>02.20</td>
</tr>
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</table>

**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.

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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.

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