Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: **Actonel (risedronate) and Atelvia (risedronate delayed release) Step**
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***January 2009 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Actonel (risedronate) and Atelvia (risedronate delayed release).

Risedronate sodium (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, and treatment of
Paget's disease.

Risedronate sodium delayed-release (Atelvia®) is indicated for treatment of postmenopausal osteoporosis. Optimal duration of use has not been determined. For patients at low-risk for fracture, consider drug discontinuation after 3 to 5 years of use.

DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drugs, Actonel (risedronate) and Atelvia (risedronate delayed release), are subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

1. The criterion for automatic coverage of Actonel (risedronate) and Atelvia (risedronate delayed release) is as follows:
   - The member must have a documented pharmacy claim history of prior therapy with alendronate sodium (Fosamax®) oral tablet or ibandronate sodium (Boniva®) oral tablet.

2. For members without a prior claim history of a alendronate or ibandronate oral tablet, a medical necessity review is completed, and the following criterion must be met:
   - Must have documentation indicating that the member has tried and failed or has an intolerance or contraindication to alendronate and ibandronate oral tablet

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to duration of member's membership with plan
Reauthorization	N/A

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Actonel® [prescribing information]. Cincinnati, OH: Procter & Gamble Pharmaceuticals, Inc.; July 2009.
2. Atelvia® [prescribing information]. North Norwich, NY: Norwich Pharmaceuticals, Inc.; April 2013.
3. Boniva [prescribing information]. Nutley, NJ: Roche Pharmaceuticals, Inc.; January 2010.
4. Fosamax [prescribing information]. Whitehouse Station, NJ: Merck & Co., Inc.; May 2014

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual Review	*02/17, 02/18*