Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date**:
Policy Number:	**Effective Date:** **Revision Date:**
Policy Name:	**HC Approval Date:**

Type of Submission – Check all that apply:

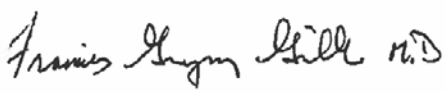
- ☐ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review – No Revisions**
- ☐ **Attestation of HC PARP Policy** – *This option should only be used during Readiness Review for Community HealthChoices. The policy must be identical to the PARP approved policy for the HealthChoices Program, with the exception of revisions/clarifications adding the term "Community HealthChoices" to the policy.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

This policy is being retired and replaced by the following policy:

Retire drug is no longer on the market

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Tiludronate (Skelid)

Reference Number: PA.CP.PMN.106
Effective Date: 03.01.18
Last Review Date: 07.18

Revision Log

Description
Tiludronate (Skelid®) is an oral bisphosphonate.

FDA Approved indication(s)
Skelid is indicated for the treatment of Paget's disease.

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 Skelid 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. Age ≥ 18 years;
3. Failure of ≥ 6 month trial of alendronate at maximum indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
4. Current (within the last 30 days) lab shows elevated (outside the upper limit of normal) serum alkaline phosphatase;
5. Dose does not exceed 400 mg/day (2 tablets/day).

Approval duration: 3 months

B. 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 Skelid;
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 400 mg/day (2 tablets/day).

Approval duration: 3 months

B. 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 3 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/Acronym 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
Tiludronate (Skelid)	400 mg daily for 3 months	400 mg/day

VI. Product Availability

Tablet: 200 mg

VII. References

1. Skelid Prescribing Information. Bridgewater, NJ: Sanofi-Aventis US, LLC. February 2011. Available at http://products.sanofi.com.au/aus_pi_skelid.pdf. Accessed December 1, 2017.

2. 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	P & T Approval Date
Retire drug is no longer on the market	01/19	