Clinical Policy: Osteoporosis- Bone Ossification Enhancers

Reference Number: OH.PHAR.PPA.54
Effective Date: 01/01/2020 Revision Log
Last Review Date:
Line of Business: Medicaid

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

Description

BISPHOSPHONATES

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ALENDRONATE tablets (generic of Fosamax®) IBANDRONATE (generic of Boniva®)	ALENDRONATE ORAL SOLN 70mg/75ml (generic of Fosamax®) ATELVIA® (risedronate) BINOSTO® (alendronate sodium effervescent tablet) ETIDRONATE (generic of Didronel®) FOSAMAX PLUS D™ (alendronate/cholecalciferol) RISEDRONATE (generic of Actonel®)

ENDOCRINE AGENTS: OSTEOPOROSIS - BONE OSSIFICATION ENHANCERS - CALCITONIN-SALMON

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
CALCITONIN-SALMON (generic of Miacalcin®)	

ENDOCRINE AGENTS: OSTEOPOROSIS – PARATHYROID HORMONE RELATED PEPTIDE ANALOG*

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	TYMLOS™ (abaloparatide)

FDA approved indication(s)

Alendronate tablets is indicated for:

- Treatment of osteoporosis
- Osteoporosis prophylaxis
- Treatment of Paget's disease (PD)

Alendronate oral solution is indicated for:

- Once-weekly regimen in adults for postmenopausal osteoporosis or osteoporosis in men

Atelvia is indicated for:

- Treatment of osteoporosis in postmenopausal women
- Prevention of postmenopausal osteoporosis

Binosto is indicated for:

- Once-weekly regimen in adults for postmenopausal osteoporosis or osteoporosis in men

Calcitonin-Salmon is indicated for:

- Treatment of osteoporosis in postmenopausal women who are more than 5 years past menopause

Etidronate is indicated for:

- Treatment of symptomatic Paget's disease (PD) of bone
- Prevention and treatment of heterotopic ossification following total hip replacement or due to spinal cord injury

Fosamax Plus D is indicated for:

- Treatment of osteoporosis

Ibandronate is indicated for:

- Treatment of osteoporosis
- Osteoporosis prophylaxis

Risedronate (Actonel) is indicated for:

- Treatment and prevention of osteoporosis in postmenopausal women
- Treatment and prevention of glucocorticoid-induced osteoporosis (GIO)
- Treatment of Paget's disease (PD)

Tymlos is indicated for:

- Treatment of postmenopausal women with osteoporosis at high risk for fracture defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy

Limitations 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.
- Etidronate is not approved for the treatment of osteoporosis
- Because of the unknown relevance of rodent osteosarcoma findings to humans, cumulative use of Tymlos and PTH analogs (e.g., teriparatide) for more than 2 years during a patient's lifetime is not recommended

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 Buckeye Health Plan, an affiliate of Centene Corporation® that Bone Ossification Enhancers are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

1. Prescribed indication is FDA-approved or supported by standard pharmacopeias;
2. Age ≥ 18 years;
3. Failure of ≥ 90 days of one preferred medication, unless member meets one of the following (a, b, or c):
   a. Allergy to medications not requiring prior approval;
   b. Contraindication to or drug interaction with medications not requiring prior approval;
   c. History of unacceptable/toxic side effects to medications not requiring prior approval;
4. Bisphosphonates are not prescribed concurrently with calcitonin-salmon;
5. If request is for Tymlos®, member must meet all of the following (a, b, c, and d):
   a. Member is a postmenopausal female;
   b. Diagnosis of osteoporosis;
   c. Failure of a 12-month trial of bisphosphonates, or if contraindicated, failure of a 2 year trial of calcitonin-salmon;
   d. Total lifetime therapy of parathyroid hormone (PTH) analogs does not exceed 2 years.

   Approval Duration: 12 months

II. 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.

III. Appendices/General Information

Appendix A: Abbreviation Key

DR: delayed-release
FDA: Food and Drug Administration
GIO: glucocorticoid-induced osteoporosis
MO: male osteoporosis
PD: Paget's disease
PMO: postmenopausal osteoporosis
PTH: parathyroid hormone

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 and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
alendronate (Fosamax®)	Osteoporosis: 10 mg PO QD or 70 mg PO q week	Osteoporosis: 10 mg/day or 70 mg/week

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	GIO: 5 mg PO QD or 10 mg PO QD (in postmenopausal women not receiving estrogen) Osteoporosis prophylaxis:5 mg PO QD or 35 mg PO q week PD: 40 mg PO QD for 6 months	GIO: 5 mg/day or 10 mg/day (in postmenopausal women not receiving estrogen) Osteoporosis prophylaxis: 5 mg/day or 35 mg/week PD: 40mg/day for 6 months
ibandronate (Boniva®)	GIO: 150 mg PO q month PMO: 150 mg PO q month PMO prophylaxis: 150 mg PO q month	150 mg/month
Calcitonin-salmon	PMO: 200 IU (1 spray) intranasally QD. Alternate the nostril used daily.	200 IU/day

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 emptying such as stricture or achalasia; inability to stand/sit upright for at least 60 minutes; hypocalcemia; hypersensitivity
  - osteomalacia (etidronate)
  - fish hypersensitivity (calcitonin-salmon)
- Boxed warning(s): risk of osteosarcoma, new primary malignancy (Tymlos)

Appendix D: General Information

The World Health Organization uses the following classifications for osteoporosis and osteopenia:

Category	T-score
Normal	-1.0 or above
Low bone mass (osteopenia)	Between -1.0 and -2.5
Osteoporosis	-2.5 or below

IV. Dosage and Administration

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Fosamax® Plus D (alendronate/ cholecalciferol)	Osteoporosis: 70 mg alendronate/2,800 units cholecalciferol or 70 mg alendronate/5,600 units cholecalciferol PO q week	70 mg alendronate/5,600 units cholecalciferol/week
risedronate (Actonel®, Atelvia®)	Osteoporosis (including prophylaxis): 5 mg PO QD or 35 mg PO q week or 75 mg PO QD for 2 consecutive days for 2 doses/month or 150 mg PO q month GIO: 5 mg PO QD	Osteoporosis (including prophylaxis): 5 mg/day or 35 mg/week or 75 mg/day for 2 days per month or 150 mg/month GIO: 5 mg/day
Alendronate solution	PMO: 70 mg PO q week	70 mg/week
Binosto® (alendronate effervescent)	PMO: 70 mg PO q week	70 mg/week
Etidronate disodium	PD: 5 to 10 mg/kg/day PO for no longer than 6 months or 11 to 20 mg/kg/day PO for no longer than 3 months. Heterotopic ossification: Spinal cord injury: 20mg/kg PO QD for 2 weeks, followed by 10mg/kg PO QD for 10 weeks Hip arthroplasty: 20mg/kg PO QD preoperatively for 1 month, followed by 20 mg/kg PO QD post-op for 3 months.	20 mg/kg/day
Tymlos® (abaloparatide)	80 mcg SQ QD	80 mcg/day for up to 2 years cumulative use of PTH analogs per lifetime

For preferred agents please see Appendix B.

V. Product Availability

Drug	Availability
Alendronate (Fosamax, Binosto)	Tablet: 5 mg, 10 mg, 35 mg, 70 mg Effervescent tablet: 70 mg Oral solution: 70mg/75 mL
Alendronate/cholecalciferol (Fosamax Plus D)	Tablet: 70 mg/2800 IU, 70 mg/5600 IU
Calcitonin-Salmon	Nasal spray: 200 U/actuation
Etidronate	Tablet: 200 mg, 400 mg
Ibandronate (Boniva)	Tablet: 150 mg
Risedronate (Actonel, Atelvia)	Tablet: 5 mg, 30 mg, 35 mg, 75 mg, 150 mg DR tablet: 35 mg
Tymlos	Single-patient-use prefilled pen: 3120 mcg/1.56 mL (30 daily doses of 80 mcg)

VI. References

Refer to package inserts

Reviews, Revisions, and Approvals	Date	Approval Date
Policy created	10/19	

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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.