Policy and Procedure	
PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCEND073.1025	**ENDOCRINE AND METABOLIC DRUGS OSTEOANABOLIC AGENTS** See Appendix A for medications covered by policy
Effective Date: 10/1/2025	**Review/Revised Date**: 5/22, 03/23, 03/24, 02/25, 08/25 (JEF)
Original Effective Date: 06/22	**P&T Committee Meeting Date**: 04/22, 6/22, 04/23, 04/24, 04/25, 08/25
Approved by: Oregon Region Pharmacy and Therapeutics Committee	

SCOPE:
Providence Health Plan and Providence Health Assurance as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:
Commercial
Medicaid

POLICY CRITERIA:

COVERED USES:
All Food and Drug Administration (FDA)-approved indications not otherwise excluded from the benefit

REQUIRED MEDICAL INFORMATION:
For initial authorization, patient must meet ALL the following criteria:

1. Patient has one of the following (a or b):
    a. High risk of fracture defined as one of the following:
        i. Spine or hip bone mineral density (BMD) T-score of less than -3.0
        ii. Very high fracture probability as indicated by a FRAX (Fracture Risk Assessment) score for hip fracture of greater than 4.5% or other major osteoporotic fracture of greater than 30%
        iii. Fracture History:
            - Fracture within the last 12 months
            - Fracture while on approved osteoporosis therapy
            - Multiple fractures
            - Fracture while on drugs causing skeletal harm (such as long-term glucocorticoids)
        iv. High risk of falls or history of injurious falls
    b. Patient has one of the following:
        i. Trial and failure of anti-resorptive therapy (such as denosumab, bisphosphonates), defined as a new fracture or worsening BMD while adherent to therapy

ii. Contraindication or intolerance to therapy with ALL the following: denosumab, oral bisphosphonate (such as alendronate), and IV bisphosphonate therapy (such as zoledronic acid)

2. For Bonsity®/Forteo®/teriparatide requests, patient must have history of trial and failure or intolerance to Tymlos® (abaloparatide), defined as a new fracture or worsening BMD while adherent to Tymlos®
3. Total duration of therapy does not exceed FDA recommendations

For reauthorization of Bonsity®/Forteo®/teriparatide use exceeding two years in a lifetime, patient must meet both of the following criteria:

1. Clinical improvement from previous treatment with teriparatide, defined as absence/decrease in frequency of new fragility fractures or stable/increased BMD T-score while on teriparatide
2. One of the following:
    a. Patient continues to be at very high risk for fracture, defined as one of the following while on teriparatide:
        i. BMD T-score continues to be less than -3.0
        ii. New vertebral or fragility fracture
    b. Worsening disease upon discontinuation of teriparatide, defined as one of the following:
        i. Decline in BMD
        ii. New onset fragility fracture

EXCLUSION CRITERIA:
Concurrent use with another osteoanabolic agent (such as Bonsity®, Evenity®, Forteo®, and Tymlos®)

For Evenity® only: hypocalcemia

AGE RESTRICTIONS: N/A

PRESCRIBER RESTRICTIONS: N/A

COVERAGE DURATION:
For Bonsity®/Forteo®: Initial authorization may be approved for up to two years. For use beyond two years, may be approved for up to one year provided that cumulative duration of parathyroid analogue therapy (teriparatide, Bonsity®, Forteo®, Tymlos®) does not exceed three years in a lifetime, including both previous and planned future doses.

For Tymlos®: May be approved for up to two years, ensuring the cumulative duration of parathyroid analogue therapy (teriparatide, Bonsity®, Forteo®, Tymlos®) does not exceed two years in a lifetime.

For Evenity®: May be approved for up to one year, ensuring the total duration of Evenity® therapy does not exceed one year of total therapy duration.

Requests for indications that were approved by the FDA within the previous six (6) months may not have been reviewed by the health plan for safety and effectiveness and inclusion on this policy document. These requests will be reviewed using the New Drug and or Indication Awaiting P&T Review; Prior Authorization Request ORPTCOPS047.

Requests for a non-FDA approved (off-label) indication requires the proposed indication be listed in either the American Hospital Formulary System (AHFS), Drugdex, or the National Comprehensive Cancer Network (NCCN) and is considered subject to evaluation of the prescriber's medical rationale, formulary alternatives, the available published evidence-based research and whether the proposed use is determined to be experimental/investigational.

Coverage for Medicaid is limited to a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services.

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

INTRODUCTION:

Tymlos® (abaloparatide) is a parathyroid hormone analog that is self-administered once daily. This unique mechanism of action differs from bisphosphonates, Evista®, Prolia®, HRT, or calcitonin, which decrease bone turnover but do not improve bone structure**.**

Bonsity® (teriparatide) is a biosimilar version of teriparatide. It is a recombinant human parathyroid hormone analog (PTH 1-34). It has an identical sequence to the 34 N-terminal amino acids (the biologically active region) of the 84-amino acid human parathyroid hormone. Teriparatide is manufactured using a strain of Pseudomonas fluorescens modified by recombinant DNA technology.

Forteo® (teriparatide) is a polypeptide hormone that is manufactured by recombinant deoxyribonucleic acid (DNA) technology and contains the same 1 to 34 terminal sequence of the human parathyroid hormone (PTH). The once daily self-administered injection stimulates new bone formation.

Evenity® (romosozumab) is a monoclonal antibody (IgG2) that increases bone formation and, to a lesser extent, decreases bone resorption by binding to and inhibiting sclerostin. Evenity® is an anabolic osteoporosis medication with a unique

mechanism of action compared to current anabolic agents on the market, abaloparatide (Tymlos®) and teriparatide (Bonsity®/Forteo®). Evenity® is administered subcutaneously every month for a total therapy duration of 12 months and should be administered by a health care professional. The bone-building effect of Evenity® is gradually lost with continuous treatment; therefore, therapy is given for only 12 months. It is then necessary to follow that course of Evenity® with an anti-remodeling agent such as a bisphosphonate or denosumab to maintain or improve the gains in bone mineral density and protection from fracture.

FDA APPROVED INDICATIONS AND DURATIONS:

- Evenity®:
  - 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.
  - Duration of therapy should not exceed one year
- Tymlos®:
  - 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.
  - Treatment to increase bone density in men with osteoporosis at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy.
  - Duration of therapy should not exceed two years
- Bonsity®, Forteo®, and teriparatide generic:
  - Treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy (daily dosage equivalent to 5 mg or greater of prednisone) at high risk for fracture or who have failed or are intolerant to other available osteoporosis therapy.
  - Treatment of postmenopausal women with osteoporosis at high risk for fracture or who have failed or are intolerant to other available osteoporosis therapy.
  - Increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture or who have failed or are intolerant to other available osteoporosis therapy.
  - Duration of therapy should be limited to two years. A longer duration may be considered if patient remains at, or has returned to, a high risk for fracture

POSITION STATEMENT:

The 2020 American Association of Clinical Endocrinologists/American College of Endocrinology (AACE/ACE) osteoporosis guidelines recommend that all postmenopausal women over the age of 50 be screened for osteoporosis risk. Treatment is recommended if the individual has osteoporosis or has osteopenia. First line agents that are recommended include alendronate, risedronate, zoledronic acid, and denosumab. The guidelines additionally recommend medications based on fracture risk. For individuals who have low to moderate risk of fracture, alendronate and risendronate are recommended. For individuals with highest risk of fracture and unable to use oral therapy, abaloparatide, denosumab, romosozumab, teriparatide, and zoledronic acid are recommended. The AACE/ACE guidelines further state that ibandronate or raloxifene may be appropriate initial therapy in some cases for patients requiring drugs with spine-specific efficacy. Raloxifene is not recommended for use in the ACP guidelines. Agents such as abaloparatide, romosozumab, and teriparatide may be preferred as initial therapy in patients with a very high risk of fracture. This includes patients with the following:

- Recent fracture (within previous 12 months)
- Fractures while on approved osteoporosis therapy
- Multiple fractures
- Fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids)
- High risk for falls or history of injurious falls
- Very high fracture probability as determined by the FRAX (fracture risk assessment tool) (e.g., major osteoporosis fracture > 30% or hip fracture > 4.5%) or another validated tool.

The FRAX score assessment tool can be found at FRAX WHO Fracture Risk Assessment Tool website. http://www.sheffield.ac.uk/FRAX/tool.jsp?country=9

Drug holiday recommendations from the American Association of Clinical Endocrinologists/American College of Endocrinology and the American Society for Bone and Mineral Research

- Bisphosphonates may retain residual benefit after discontinuation
- May consider a drug holiday from bisphosphonates after five years of therapy in low-risk patients but continue treatment up to an additional five years if fracture risk remains high. For patients with very high risk of fracture, can consider a bisphosphonate holiday after six to 10 years of stability.
- **Drug holidays are NOT recommended for patients on therapies other than bisphosphonates (e.g., denosumab, raloxifene)**
- If a drug holiday is warranted, patients should be re-evaluated at least every 2-3 years, or sooner if clinically appropriate (e.g., new fracture, institution of steroid therapy)

Oral bisphosphonate therapy contraindications:

- Esophageal abnormalities (e.g., stricture or achalasia) that delay esophageal emptying
- Hypersensitivity to bisphosphonates
- Hypocalcemia; correct prior to initiation of therapy
- Inability to stand or sit upright for 60 minutes after administration of oral tablets

Intravenous bisphosphonate therapy contraindications:

- Hypocalcemia
- Creatinine clearance less than 35 mL/min and in those with evidence of acute renal impairment due to an increased risk of renal failure
- Hypersensitivity to bisphosphonates

Forteo and Tymlos:

- Black box warning regarding risk of osteosarcoma has been removed based on post-marketing studies indicating no additional risk versus placebo. Patients at a higher risk of osteosarcoma should avoid these medications

Evenity:

- Black box warning recommends not initiating this medication in patients with a history of myocardial infarction or stroke within the preceding year

REFERENCE/RESOURCES:

1. Tymlos® package insert. Waltham, MA: Radius; 22 Dec.
2. Forteo® package insert. Indianapolis, IN: Eli Lilly and Company; 2015 Feb.
3. Evenity® package insert. Thousand Oaks, CA: Amgen Inc; 2020 Apr.
4. Tymlos® In: DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Reuters (Healthcare) Inc. Updated periodically.
5. Evenity® In: Lexi-Drugs Online [Internet database]. Hudson, OH: Lexi-Comp, Inc. Updated periodically.
6. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists (AACE) and American College Of Endocrinology (ACE). AACE/ACE Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis — 2020 Update. Available at https://pro.aace.com/sites/default/files/2020-05/Vol%2026%20Supplement%201%20(May%202020)%20GL-2019-0524_0.pdf (Accessed March 3, 2024)
7. Gilsenan A, Midkiff K, Harris D, Kellier-Steele N, McSorley D, Andrews EB. Teriparatide Did Not Increase Adult Osteosarcoma Incidence in a 15-Year US Postmarketing Surveillance Study. *J Bone Miner Res*. 2021;36(2):244-251. doi:10.1002/jbmr.4188
8. Bonsity® package insert. Morristown, NJ: Alvogen, Inc; 2025 June.

APPENDIX A.

Brand Name	Generic Name	Benefit
Evenity®	romosozumab-aqqg for subcutaneous injection	Medical
Bonsity®/Forteo®	teriparatide for subcutaneous injection • Forteo® 600 mcg/2.4 mL • Bonsity® 560 mcg/2.24 mL • Teriparatide generic 620 mcg/2.48 mL	Pharmacy for Self-Administration
Tymlos®	abaloparatide for subcutaneous injection	Pharmacy for Self-Administration

BILLING GUIDELINES AND CODING:

DRUG CODE*		
	J3111	Injection, romosozumab-aqqg, 1 mg
RELATED ADMINISTRATION CODES*		
	96372	Ther/proph/diag inj sc/im
	96401	Chemo anti-neopl sq/im

*Coding Notes:
• The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
• HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as “medically unlikely edits” (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.