Medical Drug Clinical Criteria

Subject:	Human Parathyroid Hormone		
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Overview

This document addresses the use of human parathyroid hormone agents for the treatment of osteoporosis. Agents included in this clinical guideline include:

- Tymlos (abaloparatide)
- Forteo (teriparatide)
- Bonsity (teriparatide)

Tymlos (abaloparatide), Forteo (teriparatide), and Bonsity (teriparatide) are approved for the treatment of postmenopausal osteoporosis in a select population of women considered at high risk for fracture. Forteo and Bonsity are also approved for glucocorticoid-induced osteoporosis and men with hypogonadal osteoporosis at high risk for fracture. Bonsity is a follow-on to Forteo and carries the same indications. Its approval, in part, was based on safety and efficacy data from Forteo.

The American College of Endocrinology (AACE/ACE) (2020) osteoporosis treatment guidelines stratify initial treatment based on risk status. For those at high risk/no prior fractures, initial therapy options include bisphosphonates (alendronate, risedronate, or zoledronic acid) or denosumab. For those at very high risk, initial therapy options are denosumab, abaloparatide, teriparatide, romosozumab, or zoledronic acid. The Endocrine Society osteoporosis guideline update (2020) recommends initial therapy with bisphosphonates (alendronate, risedronate, zoledronic acid, or ibandronate) or alternatively denosumab for those at high risk. Teriparatide and abaloparatide are recommended for very high risk of fracture such as those with severe or multiple vertebral fractures.

Osteoporosis may be diagnosed by bone mineral density (BMD) testing indicating a T-score in the spine, femoral neck, total hip or distal 1/3 of the radius of less than or equal to -2.5 as compared to a young-adult reference population. It also may be clinically diagnosed based on a history of a fragility fracture (low trauma fracture). High risk for fracture is defined in the FDA label as history of osteoporotic fracture; or multiple risk factors for fractures; or a failure or intolerance to other osteoporosis therapies.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Tymlos (abaloparatide)

Initial requests for Tymlos (abaloparatide) may be approved for the following:

I. Individual has one of the following:
   A. Individual is a postmenopausal female with the following a diagnosis of osteoporosis (defined as a bone mineral density (BMD) T-score in the spine, femoral neck, total hip or distal 1/3 of the radius of less than or equal to -2.5 as compared to a young-adult reference population OR a clinical diagnosis based on history of a low trauma fracture (fragility fracture)) at high risk for fracture; **OR**
   B. Individual is a male diagnosed with osteoporosis (defined as BMD T-score in the spine, femoral neck, total hip or distal 1/3 of the radius of less than or equal to -2.5 as compared to young-adult reference population OR a clinical diagnosis based on history of a low trauma fracture (fragility fracture)) at high risk for fracture using to increase bone mass;

AND

II. The individual meets one of the following:
   A. Individual is at very high risk for fracture as defined by one or more of the following (AACE/ACE 2020):

1. Recent fracture (within the past 12 months)
2. Fractures while on approved osteoporosis therapy
3. Multiple fractures
4. Fractures while on drugs causing skeletal harm (e.g. long-term glucocorticoids)
5. Very low T-score (less than -3.0)
6. High risk for falls or history of injurious falls
7. Very high fracture probability by FRAX (fracture risk assessment tool) (e.g. major osteoporosis fracture >30%, hip fracture >4.5%) or other validated fracture risk algorithm;

OR

B. Individual has been refractory to a prior trial of a bisphosphonate; **OR**
C. Individual is intolerant to or has a contraindication to a bisphosphonate as defined by:
   1. Hypersensitivity to TWO bisphosphonates (one of which must be alendronate); **OR**
   2. Inability to stand or sit upright for at least 30 minutes; **OR**
   3. Pre-existing gastrointestinal disorders (Barrett's esophagus, hypersecretory disorders, delayed esophageal emptying, atrophic gastritis, etc.); **OR**
   4. Uncorrected hypocalcemia; **OR**
   5. Severe renal insufficiency as defined by creatinine clearance less than 35 mL/min for alendronate agents and zoledronic acid or creatinine clearance less than 30 mL/min for risedronate and ibandronate;

AND

III. Individual is not using Tymlos (abaloparatide) in combination with any of the following:
   A. Prolia, Xgeva (denosumab) or Jubbonti, Wyost (denosumab-bbdz);
   B. Bisphosphonates;
   C. Evista (raloxifene);
   D. Miacalcin/Fortical (calcitonin nasal spray);
   E. Reclast (zoledronic acid);
   F. Forteo (teriparatide) or Bonsity (teriparatide);
   G. Evenity (romosozumab-aqqg).

Continuation of therapy with Tymlos (abaloparatide) may be approved if the following criteria are met:

I. There is clinically significant response to therapy (including but not limited to no new fractures or reduction of fractures, or no worsening vertebral fractures, or no clinically significant adverse reaction); AND
II. If individual has been on therapy ≥ 24 months of treatment, a repeat BMD demonstrates a stable or increase in BMD.

AND

III. Individual is not using Tymlos (abaloparatide) in combination with any of the following:
   A. Prolia, Xgeva (denosumab) or Jubbonti, Wyost (denosumab-bbdz);
   B. Bisphosphonates;
   C. Evista (raloxifene);
   D. Miacalcin/Fortical (calcitonin nasal spray);
   E. Reclast (zoledronic acid);
   F. Forteo (teriparatide) or Bonsity (teriparatide);
   G. Evenity (romosozumab-aqqg).

Forteo (teriparatide); Bonsity (teriparatide)

Initial requests for Forteo (teriparatide) or Bonsity (teriparatide) may be approved for the following:

I. Individual has one of the following:
   A. Individual is a postmenopausal female with diagnosis of osteoporosis (defined as bone mineral density (BMD) T-score in the spine, femoral neck, total hip or distal 1/3 of the radius of less than or equal to -2.5 as compared to young-adult reference population OR a clinical diagnosis based on history of a low trauma fracture (fragility fracture)) at high risk for fracture; **OR**
   B. Individual is a male diagnosed with primary or hypogonadal osteoporosis (defined as BMD T-score in the spine, femoral neck, total hip or distal 1/3 of the radius of less than or equal to -2.5 as compared to young-adult reference population OR a clinical diagnosis based on history of a low trauma fracture (fragility fracture)) at high risk for fracture using to increase bone mass; **OR**
   C. Individual has a diagnosis of osteoporosis (defined as BMD T-score in the spine, femoral neck, total hip or distal 1/3 of the radius of less than or equal to -2.5 as compared to young-adult reference population OR a clinical diagnosis based on history of a low trauma fracture (fragility fracture)) associated with sustained systemic glucocorticoid therapy (daily dosage equivalent to 5 mg or greater of prednisone for at least 3 months) at high risk for fracture;

AND

II. Individual meets one of the following:
   A. Individual is a postmenopausal female at very high risk for fracture as defined by one or more of the following (AACE/ACE 2020):
      1. Recent fracture (within the past 12 months)
      2. Fractures while on approved osteoporosis therapy
      3. Multiple fractures
      4. Fractures while on drugs causing skeletal harm (e.g. long-term glucocorticoids)
      5. Very low T-score (less than -3.0)
      6. High risk for falls or history of injurious falls
      7. Very high fracture probability by FRAX (fracture risk assessment tool) (e.g. major osteoporosis fracture >30%, hip fracture >4.5%) or other validated fracture risk algorithm;

      OR
   B. Individual has been refractory to a prior trial of a bisphosphonate; **OR**
   C. Individual is intolerant to or has a contraindication to a bisphosphonate as defined by:
      1. Hypersensitivity to TWO bisphosphonates (one of which must be alendronate); **OR**
      2. Inability to stand or sit upright for at least 30 minutes; **OR**
      3. Pre-existing gastrointestinal disorders (Barrett's esophagus, hypersecretory disorders, delayed esophageal emptying, atrophic gastritis, etc.); **OR**
      4. Uncorrected hypocalcemia; **OR**
      5. Severe renal insufficiency as defined by creatinine clearance less than 35 mL/min for alendronate agents and zoledronic acid or creatinine clearance less than 30 mL/min for risedronate and ibandronate;

AND

III. Individual is not using Forteo (teriparatide) in combination with any of the following:
   A. Prolia, Xgeva (denosumab) or Jubbonti, Wyost (denosumab-bbdz);
   B. Bisphosphonates
   C. Evista (raloxifene)
   D. Miacalcin/Fortical (calcitonin nasal spray)
   E. Reclast (zoledronic acid)
   F. Tymlos (abaloparatide);
   G. Evenity (romosozumab-aqqg);
   H. Another teriparatide agent.

Continuation of therapy with Forteo (teriparatide) or Bonsity (teriparatide) may be approved if the following criteria are met:

I. There is clinically significant response to therapy (including but not limited to no new fractures reduction of fractures, or no worsening vertebral fractures, or no clinically significant adverse reaction); **AND**
II. If individual has been on therapy ≥ 24 months of treatment, a repeat BMD demonstrates a stable or increase in BMD;

AND

III. Individual is not using Forteo (teriparatide) or Bonsity (teriparatide) in combination with any of the following:
   A. Prolia, Xgeva (denosumab) or Jubbonti, Wyost (denosumab-bbdz)
   B. Bisphosphonates
   C. Evista (raloxifene)
   D. Miacalcin/Fortical (calcitonin nasal spray)
   E. Reclast (zoledronic acid)
   F. Tymlos (abaloparatide);
   G. Evenity (romosozumab-aqqg);
   H. Another teriparatide agent.

Requests for Forteo (teriparatide), Bonsity (teriparatide), and Tymlos (abaloparatide) may not be approved when the above criteria are not met and for all other indications.

Quantity Limits

Miscellaneous Osteoporosis Agents Quantity Limit

Drug	Limit
Tymlos (abaloparatide) Injection 3120 mcg/1.56 mL	1 pen per 30 days
Forteo (teriparatide) Injection 600 mcg/2.4 mL	1 pen per 28 days
Bonsity (teriparatide) Injection 620 mcg/ 2.48 mL	1 pen per 28 days

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

C9399	Unclassified drugs or biologicals [when specified as abaloparatide (Tymlos)]
J3490	Unclassified drugs [when specified as abaloparatide (Tymlos)]
J3110	Injection, teriparatide, 10 mcg [Bonsity] [Forteo]

ICD-10 Diagnosis

Z78.0	Asymptomatic menopausal state
M80.00XA-M80.88XS	Osteoporosis with current pathological fracture
M81.0-M81.8	Osteoporosis without current pathological fracture

Document History

Revised: 08/16/2024
Document History:

- 08/16/2024: add Xgeva and denosumab biosimilars Wyatt and Jubbonti in combination therapy. Coding Reviewed. No changes.
- 08/18/2023: Annual Review: Change document name, Wording and formatting. Coding Reviewed: No changes.
- 03/13/2023: Select Review: Add FDA indication Tymlos for men. Coding Reviewed: No changes.
- 08/19/2022: Annual Review: No change. Coding Reviewed: Added ICD-10-CM Z78.0.
- 02/25/2022: Select Review: modify Tymlos continuation criteria and remove 24 month restriction on Tymlos. Coding Reviewed: No changes.
- 08/20/2021- Annual Review: Wording and formatting changes, addition of continuation criteria, remove 24 month restriction on Forteo/Bonsity. Coding reviewed: No changes.
- 08/21/2020 – Annual Review: Update criteria to include factors for very high fracture risk in individuals who have not had a trial of a bisphosphonate. Administrative update to add drug specific quantity limit. Coding Reviewed: Added drug Forteo to J3110
- 02/21/2020 – Select Review: Add PA and QL for Bonsity (teriparatide); add Bonsity as potential preferred in step therapy; Update Tymlos and Forteo criteria to include references to Bonsity where applicable. Coding Reviewed: Added HCPCS C9399 for Tymlos, Added HCPCS J3110 for Bonsity
- 08/16/2019 – Annual Review: Update bisphosphonate trial requirement wording to account for intravenous options; add Evenity to list of agents that may not be used in combination. Coding Reviewed: Removed HCPCS J3110 Forteo.
- 11/02/2018 – Added HCPCS for Forteo: J3110.
- 08/17/2018 – Annual Review: Initial review of DRUG.00103. Add new ST for Non-Preferred Human Parathyroid Hormone Agents for Osteoporosis. Update Tymlos PA to delete embedded ST through Prolia or zoledronic acid and Forteo. Update Tymlos PA to add atrophic gastritis as an example of a pre-existing gastrointestinal disorder for consistency.

References

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Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.