Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Human Parathyroid Hormone Agents: abaloparatide (Tymlos®), teriparatide (Forteo®, Bonsity®)	MP-RX-FP-37-23	☒ MMM MA ☒ MMM Multihealth

Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B Drugs

Service Description

This document addresses the use of Human Parathyroid Hormone Agents: abaloparatide (Tymlos®), teriparatide (Forteo, Bonsity) , a parathyroid hormone analog, (PTH 1-34), approved by the Food and Drug Administration (FDA) for the treatment of osteoporosis.

Background Information

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.

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Approved Indications

A. Approved for the treatment of postmenopausal women with osteoporosis at high risk for fractures or patients who have failed or are intolerant to other available osteoporosis therapy.

B. Approved for the treatment of men with osteoporosis at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy

C. Treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture or patients who have failed or are intolerant to other available osteoporosis therapy (Forteo and Bonsity only).

Other Uses

A. N/A

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Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

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

Medical Necessity Guidelines

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.

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Clinical Criteria:

B vs D Criteria: All drugs included in this PA are subject to B vs D evaluation. Medication must be furnished "incident to" physician service provided and usually not self-administered to be covered by Medicare and to be eligible to be evaluated through part B. If not, medication must be evaluated through part D.

Abaloparatide (Tymlos)

A. Criteria For Initial Approval

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

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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)

B. Criteria For Continuation of Therapy

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

i. There is confirmation of clinically significant response to therapy (including but not limited to confirmation of 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 (denosumab);
   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)

C. Conditions not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

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

D. Approval Duration

i. Initial Approval Duration: Up to 12 months
ii. Reauthorization Approval Duration: Up to12 months

Teriparatide (Forteo), Teriparatide (Bonsity)

A. Criteria For Initial Approval

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. The 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)

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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 (denosumab);
   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)

B. Criteria For Continuation of Therapy

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

i. There is confirmation of clinically significant response to therapy (including but not limited to confirmation of 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 Forteo (teriparatide) or Bonsity (teriparatide) in combination with any of the following:
   A. Prolia , Xgeva (denosumab) or Jubbonti, Wyost (denosumab-bbdz);

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B. Bisphosphonates;
C. Evista (raloxifene);
D. Miacalcin/Fortical (calcitonin nasal spray);
E. Reclast (zolendronic acid);
F. Forteo (teriparatide) or Bonsity (teriparatide);
G. Evenity (romosozumab-aqqg)
H. Another teriparatide agent.

C. Conditions not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

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

D. Authorization Duration

i. Teriparatide treatment should not exceed a total of 24 months in lifetime. Use of teriparatide for more than 2 years during a patient's lifetime should only be considered if a patient remains at or has returned to having a high risk for fracture.

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Limits or Restrictions

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

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
Exceptions	
N/A	

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Reference Information

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2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: http://www.clinicalpharmacology.com. Updated periodically.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: January 10, 2022.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Drug Facts and Comparisons. Facts and Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health, Inc; 2022. Updated periodically.
6. Eastell R, Rosen CJ, Black DM, et al. Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Clinical Practice Guideline, The Journal of Clinical Endocrinology & Metabolism, Volume 104, Issue 5, May 2019, Pages 1595–1622, https://doi.org/10.1210/jc.2019-00221.
7. Gilsenan A, Midkiff K, Harris D, et al. Assessing the incidence of osteosarcoma among teriparatide users based on Medicare Part D and US State Cancer Registry Data. Pharmacoepidemiol Drug Saf. 2020 Dec;29(12):1616-1626. Available at: https://onlinelibrary.wiley.com/doi/10.1002/pds.5103 Accessed July 8, 2021.
8. Gilsenan A, Midkiff K, Harris D, et al. Teriparatide Did Not Increase Adult Osteosarcoma Incidence in a 15-Year US Postmarketing Surveillance Study. J Bone Miner Res. 2021 Feb;36(2):244-251. Available at: https://asbmr.onlinelibrary.wiley.com/doi/10.1002/jbmr.4188 Accessed July 8, 2021.
9. Shoback D, Rosen CJ, Black DM, et al. Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Guideline Update, The Journal of Clinical Endocrinology & Metabolism, Volume 105, Issue 3, March 2020, Pages 587-594.
10. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.

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.

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Policy History

Revision Type	Summary of Changes	P&T Approval Date	MPCC Approval Date
Choose an item.			
Annual Review. 08/18/2024	Update service description, approved indications (for Forteo and Bonsity). Added sections: Conditions not Covered, Approval duration, Therapeutic alternatives. Add Xgeva and denosumab biosimilars Wyatt and Jubbonti in combination therapy. Coding Reviewed. No changes.	2/18/2025	3/6/2025
Policy Inception 8/18/2023	Elevance Health's Medical Policy adoption.	N/A	11/30/2023