

Utilization Management and Clinical Medical Policy

Policy Name: Human Parathyroid Hormone Agents: abaloparatide (Tymlos®), teriparatide (Forteo®), Bonsity®)	Policy Number: MP-RX-FP-37-23	Scope: ☒ MMM MA ☒ MMM MultiHealth	Origination Date: 11/30/2023 Last Review Date: 7/22/2026	Effective Date: 7/22/2026 Frequently Revision: Annual
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Service Category:

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| ☐ Anesthesia | ☐ Medicine Services and Procedures |
| ☐ Surgery | ☐ Evaluation and Management Services |
| ☐ Radiology Procedures | ☐ DME/Prosthetics or Supplies |
| ☐ Pathology and Laboratory Procedures | ☒ Other: 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 (AAACE/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.

The safety and efficacy of Tymlos have not been evaluated beyond 2 years of treatment. Use of the drug for more than 2 years during a patient's lifetime is not recommended. 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

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.

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- 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. None.

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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.

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 *(Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

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

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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 (denosumab), Xgeva (denosumab) Conexence/Bomyntra (denosumab-bnht), Jubbonti, Wyost (denosumab-bbdz), Ospomyv/ Xbry (denosumab-dssb), or Stoboclo/Osenvelt (denosumab-bmwo);
 - B. Bisphosphonates;
 - C. Evista (raloxifene);
 - D. Miacalcin (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**

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- 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), Xgeva (denosumab) Conexence/Bomyntra (denosumab-bnht), Jubbonti, Wyost (denosumab-bbdz), Ospomyv/ Xbry (denosumab-dssb), or Stoboclo/Osenvelt (denosumab-bmwo);
 - B. Bisphosphonates;
 - C. Evista (raloxifene);
 - D. Miacalcin (calcitonin nasal spray);
 - E. Reclast (zoledronic acid);
 - F. Forteo (teriparatide) or Bonsity (teriparatide);
 - G. Evenity (romosozumab-aqqg)

C. Authorization Duration

- i. Initial Approval Duration: Up to 12 months
- ii. Reauthorization Approval Duration: Up to 12 months
- iii. Maximum approval time: 24 months
 - A. The safety and efficacy of Tymlos (abaloparatide) have not been evaluated beyond 2 years of treatment. Use of the drug for more than 2 years during a patient's lifetime is not recommended.

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

Teriparatide (Forteo®, Bonsity®)

- A. Criteria For Initial Approval** *(Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

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

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- 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)
 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;

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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) or Bonsity (teriparatide) in combination with any of the following:

- A. Prolia (denosumab), Xgeva (denosumab) Conexence/Bomyntra (denosumab-bnht), Jubbonti, Wyost (denosumab-bbdz), Ospomyv/ Xbry (denosumab-dssb), or Stoboclo/Osenvelt (denosumab-bmwo);
- B. Bisphosphonates;
- C. Evista (raloxifene);
- D. Miacalcin(calcitonin nasal spray);
- E. Reclast (zoledronic acid);
- F. Forteo (teriparatide) or Bonsity (teriparatide);
- G. Evenity (romosozumab-aqqg)
- H. Another teriparatide agent.

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:

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- A. Prolia (denosumab), Xgeva (denosumab) Conexxence/Bomyntra (denosumab-bnht), Jubbonti, Wyost (denosumab-bbdz), Ospomyv/ Xbry (denosumab-dssb), or Stoboclo/Osenvelt (denosumab-bmwo);
- B. Bisphosphonates;
- C. Evista (raloxifene);
- D. Miacalcin (calcitonin nasal spray);
- E. Reclast (zolendronic acid);
- F. Forteo (teriparatide) or Bonsity (teriparatide);
- G. Evenity (romosozumab-aqqg)
- H. Another teriparatide agent.

C. Authorization Duration

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

D. 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), Bonsity (teriparatide), or Teriparatide may not be approved when the above criteria are not met and for all other indications.

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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 560 mcg/2.24 mL	1 pen per 28 days
Bonsity (teriparatide) Injection 560 MCG/2.24ML	1 pen per 28 days
Teriparatide 560 mg/2.24 mL	1 pen per 28 days
Exceptions	
N/A	

Codes Information:

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.

ICD-10 Diagnostic Codes:

Codes	Description
Z78.0	Asymptomatic menopausal state
M80.00XA-M80.8B9S	Osteoporosis with current pathological fracture
M81.0-M81.8	Osteoporosis without current pathological fracture

HCPCS Codes:

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

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Reference Information:

1. Alvogen, Inc. Bonsity® (teriparatide injection), for subcutaneous use: Prescribing Information. Revised January 2025. Available at: <https://www.bonsity.com/static/documents/prescribing-information.pdf>. Accessed May 19, 2026.
2. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists and American College of Endocrinology Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis – 2020 Update. Endocrine Practice. 2020;26(1):1-46.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2026. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
4. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>.
5. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
6. Drug Facts and Comparisons. Facts and Comparisons [database online]. St. Louis, MO: Wolters Kluwer Health, Inc; 2024. Updated periodically.
7. 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>.
8. 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 June 29, 2023.
9. 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 June 29, 2023.
10. Lilly USA, LLC. Forteo® (teriparatide injection), for subcutaneous use: Prescribing Information. Revised June 2025. Available at: <http://uspl.lilly.com/forteo/forteo.html#pi>. Accessed May 19, 2026.
11. Radius Health, Inc. Tymlos® (abaloparatide) injection, for subcutaneous use: Prescribing Information. Revised March 2025. Available at: <https://radiuspharm.com/wp-content/uploads/tymlos/tymlos-prescribing-information.pdf>. Accessed May 19, 2026.
12. 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.
13. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2026; Updated periodically.

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

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Policy History:

Type of Review	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Annual Review	Added treatment duration up to 2 years to the Background Information per prescribing information. Added denosumab biosimilars Conexxence/Bomyntra, Ospomyv/Xbry and Stoboclo/Osenvelt to criteria; remove Fortical as obsolete. Updated wording and formatting of teriparatide agents; include Bonsity and Teriparatide. Coding Reviewed: Removed Bonsity from HCPCS J3110 and added to HCPCS NOC J3490 and C9399. Added ICD-10-CM M80.8AXA-M80.8B9S to range M80.00XA-M80.88XS. Wording and formatting changes. Updated reference information and incorporated new policy template.	7/13/2026	7/22/2026
Annual Review	Added to authorization duration of Tymlos: Maximum approval time: 24 months. The safety and efficacy of Tymlos (abaloparatide) have not been evaluated beyond 2 years of treatment. Use of the drug for more than 2 years during a patient's lifetime is not recommended. Added authorization duration for Forteo and Bonsity for 12 months. Included in clinical criteria for all drugs in combination therapy: denosumab biosimilars. Updated syringe presentations for Forteo and Bonsity.	8/25/2025	9/8/2025
Annual Review	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	8/18/23: Elevance Health's Medical Policy adoption.	N/A	11/30/2023