Pharmacy Management Drug Policy

SUBJECT: Osteoporosis - Evenity® (romosozumab-aqqg), Forteo® (teriparatide), Teriparatide, Bonsity, Prolia® (denosumab), Jubbonti (denosumab-bbdz), Stoboclo (denosumab-bmwo), Conexxence (denosumab-bnht), Tymlos® (abaloparatide), Miacalcin injection®, calcitonin salmon injection
POLICY NUMBER: PHARMACY-35
EFFECTIVE DATE: 09/2007
LAST REVIEW DATE: 07/25/2025

If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. This drug policy applies to the following line/s of business:

Policy Application

Category:	☒ Commercial Group (e.g., EPO, HMO, POS, PPO)	☒ Medicare Advantage
	☒ On Exchange Qualified Health Plans (QHP)	☐ Medicare Part D
	☒ Off Exchange Direct Pay	☒ Essential Plan (EP)
	☒ Medicaid & Health and Recovery Plans (MMC/HARP)	☒ Child Health Plus (CHP)
	☐ Federal Employee Program (FEP)	☐ Ancillary Services
	☒ Dual Eligible Special Needs Plan (D-SNP)	

DESCRIPTION:

Osteoporosis is a skeletal disorder characterized by decreased bone mass. The most common diagnostic test is the DEXA scan (dual energy X-ray absorptiometry) to measure BMD (bone mineral density). Results are typically reported as a T-score, which compares the BMD of the subject to a standard BMD of a healthy young adult. T-Scores are reported as standard deviations (SD) World Health Organization criteria:

Normal - T-Score within 1 SD of normal

Osteopenia - T-Score of -1 to -2.5 SD below normal

Osteoporosis - T-Score of -2.5 or less SD below normal

Severe Osteoporosis - T-Score of -2.5 or less SD below normal with fragility fractures

FRAX tool - The World Health Organization developed this risk assessment tool to assist clinicians in evaluating osteopenic patients. The algorithms take clinically proven risk factors to determine a 10-year probability of hip fracture and a 10-year probability for a major osteoporotic fracture. The US National Osteoporosis Foundation recommends treatment of osteopenic patients whose FRAX score for hip fracture is 3% or greater, or whose risk for other bone fracture is greater than 20%.

1. **PROLIA:**

Based upon our assessment and review of peer-reviewed literature, **Prolia, Jubbonti, Stoboclo** and **Conexxence** have been medically proven to be effective and therefore **medically necessary** if the request meets all the following criteria:

****Criteria only applies to Safety Net (Medicaid and Essential Plan) and Dual Eligible Special Needs Plans (D-SNP)****

<table>
<tr><th>Diagnosis</th><th>Criteria</th></tr>
<tr><td>Osteoporosis (at high risk for fracture)</td><td>1. The patient must fall into one of the following categories (A, B, or C):
<table>
<tr><td>A. Postmenopausal woman AND

I. History of previous osteoporosis related fracture OR

II.T-score -2.5 SD or less OR

III.T-score between -1.0 and -2.5 SD below normal AND a FRAX score for hip fracture of 3% or greater, or the risk for other bone fracture is greater than 20%</td><td>B. Male at high risk for fracture AND

I. History of previous osteoporosis related fracture OR

II.T-score -2.5 SD or less OR

III.T-score between -1.0 and -2.5 SD below normal AND a FRAX score for hip fracture of 3% or greater, or the risk for other bone fracture is greater than 20%</td><td>C. Patient at risk for steroid induced osteoporosis

I. Chronic steroid use (Greater than 3 month) AND a T-score of -1 SD or less</td></tr>
</table>
AND

2. Step therapy applies: Patient must have had a previous trial and failure (defined as a decrease in BMD or a fracture while on bisphosphonate therapy) or contraindication to an oral bisphosphonate or injectable bisphosphonate

3. For individuals who have severe GI intolerance to an oral bisphosphonate, an injectable bisphosphonate (zoledronic acid or IV ibandronate) will be required prior to approval.</td></tr>
<tr><td>Osteoporosis (at high risk for fracture) follow gastric bypass surgery</td><td>Patients who have had a gastric bypass AND a T-score of -1 SD or less</td></tr>
<tr><td>For treatment of bone loss in men receiving androgen deprivation therapy for prostate cancer</td><td>Treatment is indicated as first-line in patients who have been diagnosed with non-metastatic prostate cancer and who are undergoing treatment with androgen deprivation therapy (bilateral orchiectomy or GnRH-agonist therapy). The expected duration of androgen deprivation therapy must be at least 12 months. The patient must be at high risk for fracture across multiple skeletal sites, having a T-score at the lumbar spine, total hip, or femoral neck of less than -1.0 OR a history of osteoporotic fracture. Approved dosing is per policy guidelines.</td></tr>
</table>

For treatment of bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer	Treatment is indicated as first-line in patients who have been diagnosed with hormone receptor positive breast cancer and who are undergoing treatment with an aromatase inhibitor (such as anastrazole/Arimidex, exemastane/Aromasin, and letrozole/Femara). The patient must be at high risk for fracture across multiple skeletal sites, having a T-score at the lumbar spine, total hip, or femoral neck of less than -1.0 **OR** a history of osteoporotic fracture. Approved dosing is per policy guidelines.
Prolia, Jubbonti, Stoboclo and Conexxence could be considered as initial therapy in those individuals with renal insufficiency (creatinine clearance < 35ml/min)	
Prolia, Jubbonti, Stoboclo and Conexxence may be considered upon special consideration as a first line agent in patients at very high risk for fracture (such as patients with a recent fracture (e.g., within the past 12 months), fractures while on approved osteoporosis therapy, multiple fractures, fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids), very low T-score (e.g., less than −3.0), high risk for falls or history of injurious falls, and very high fracture probability by FRAX® (fracture risk assessment tool) (e.g., major osteoporosis fracture >30%, hip fracture >4.5%). These requests will be limited to endocrinologists, rheumatologists, medical orthopedics, and nephrologists. Jubbonti, Stoboclo and Conexxence are covered as medical benefit only	

2. **FORTEO and TERIPARATIDE**:

Based upon our assessment and review of peer-reviewed literature, **Forteo, Bonsity and teriparatide (manufactured by Alvogen)** have been medically proven to be effective and therefore **medically necessary** if the request meets all the following criteria:

<table>
<tr><th>Diagnosis</th><th>Criteria</th></tr>
<tr><td>Osteoporosis (at high risk for fracture):</td><td>1. The patient must fall into one of the following categories (A, B, or C):
<table>
<tr>
<td>A. Postmenopausal woman AND

I. History of previous osteoporosis related fracture OR

II. T-score -2.5 SD or less OR

III. T-score between -1.0 and -2.5 SD below normal AND a FRAX score for hip fracture of 3% or greater, or the risk for other bone fracture is greater than 20%</td>
<td>B. Male at high risk for fracture AND

I. History of previous Osteoporosis related fracture OR

II. T-score -2.5 SD or less OR

III. T-score between -1.0 and -2.5 SD below normal AND a FRAX score for hip fracture of 3% or greater, or the risk for other bone fracture is greater than 20%</td>
<td>C. Patient at risk for steroid induced osteoporosis

I. Chronic steroid use (greater than 3 month) AND a T-score of -1 SD or less</td>
</tr>
</table>
AND

2. Step therapy applies: Patient must have had a previous trial and failure (defined as a decrease in BMD or a fracture while on bisphosphonate therapy) or contraindication to an oral bisphosphonate or injectable bisphosphonate

3. For individuals who have severe GI intolerance to an oral bisphosphonate, an injectable bisphosphonate (zoledronic acid or IV ibandronate) will be required prior to approval.

4. Step therapy applies: Forteo, Bonsity and teriparatide (manufactured by Alvogen) will not be authorized for new starts unless there is documentation of severe intolerance or a contraindication to Tymlos (only applies to the postmenopausal osteoporosis indication and male at high risk for fracture indication. Note: True ANDA generic teriparatide will not require step through Tymlos but still requires criterion #1,2 and 3 in the PA criteria).</td></tr>
</table>

Parathyroid hormone analogs may be considered upon special consideration as a first line agent in patients at very high risk for fracture (such as patients with a recent fracture (e.g., within the past 12 months), fractures while on approved osteoporosis therapy, multiple fractures, fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids), very low T-score (e.g., less than −3.0), high risk for falls or history of injurious falls, and very high fracture probability by FRAX® (fracture risk assessment tool) (e.g., major osteoporosis fracture >30%, hip fracture >4.5%) or those who need more immediate bone remodeling. These requests will be limited to endocrinologists, rheumatologists, medical orthopedics, and nephrologists. In the event that parathyroid hormone analog is medically appropriate as initial therapy, Tymlos will be the approved therapy. Forteo and Teriparatide 620mcg/2.48mL will not be authorized unless there is documentation of severe intolerance or a contraindication to Tymlos (only applies to the postmenopausal osteoporosis indication and male at high risk for fracture indication).

3. **TYMLOS**:

Based upon our assessment and review of peer-reviewed literature, **TYMLOS** has been medically proven to be effective and therefore medically necessary if the request meets all the following criteria:

<table>
<tr><th>Diagnosis</th><th>Criteria</th></tr>
<tr><td>Osteoporosis (at high risk for fracture):</td><td>1. The patient must fall into one of the following categories (A or B):
<table>
<tr><td>A. Postmenopausal woman AND
I. History of previous osteoporosis related fracture OR
II.T-score -2.5 SD or less OR
III.T-score between -1.0 and -2.5 SD below normal AND a FRAX score for hip fracture of 3% or greater, or the risk for other bone fracture is greater than 20%</td><td>B. Male at high risk for fracture AND
I. History of previous osteoporosis related fracture OR
II.T-score -2.5 SD or less OR
III.T-score between -1.0 and -2.5 SD below normal AND a FRAX score for hip fracture of 3% or greater, or the risk for other bone fracture is greater than 20%</td></tr>
</table>
AND
2. Step therapy applies: Patient must have had a previous trial and failure (defined as a decrease in BMD or a fracture while on bisphosphonate therapy) or contraindication to an oral bisphosphonate or injectable bisphosphonate
3. For individuals who have severe GI intolerance to an oral bisphosphonate, an injectable bisphosphonate (zoledronic acid or IV ibandronate) will be required prior to approval.</td></tr>
<tr><td colspan="2">Parathyroid hormone analogs may be considered upon special consideration as a first line agent in patients at very high risk for fracture (such as patients with a recent fracture (e.g., within the past 12 months), fractures while on approved osteoporosis therapy, multiple fractures, fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids), very low T-score (e.g., less than −3.0), high risk for falls or history of injurious falls, and very high fracture probability by FRAX® (fracture risk assessment tool) (e.g., major osteoporosis fracture >30%, hip fracture >4.5%) or those who need more immediate bone remodeling. These requests will be limited to endocrinologists, rheumatologists, medical orthopedics, and nephrologists. In the event that parathyroid hormone analog is medically appropriate as initial therapy, Tymlos will be the approved therapy.</td></tr>
</table>

4. **EVENITY**:

Based upon our assessment and review of peer-reviewed literature, **Evenity** has been medically proven to be effective and therefore medically necessary if the request meets all the following criteria:

Diagnosis	Criteria
Postmenopausal woman with osteoporosis at high risk for fracture:	1. Postmenopausal woman **AND** 2. The patient must fall into one of the following categories **(A, B, or C):** a. History of previous osteoporosis related fracture **OR** b. T-score -2.5 SD or less **OR** c. T-score between -1.0 and -2.5 SD below normal **AND** a FRAX score for hip fracture of 3% or greater, or the risk for other bone fracture is greater than 20% **AND** 3. For new starts only: a. Step therapy applies for Commercial, Exchange and SafetyNet (Medicaid Managed Care, HARP, CHP, Essential Plan) lines of business: Evenity will not be authorized for new starts unless there is documentation of severe intolerance or a contraindication to Tymlos or Forteo/Teriparatide. b. Medicare Part B: Evenity will not be authorized for new starts unless there is documentation of severe intolerance or a contraindication to Teriparatide. 4. Coverage of Evenity will be limited to 12 monthly doses based on package labeling which states that the anabolic effect of Evenity wanes after 12 monthly doses of therapy. Approvals will be for 13 months for a maximum of 12 monthly doses.

5. **MIACALCIN INJECTION AND GENERIC CALCITONIN SALMON INJECTION:**

Based upon our assessment and review of peer-reviewed literature, **Miacalcin injection and generic calcitonin salmon injection** have been medically proven to be effective and therefore medically necessary if the request meets all the following criteria:

A. Patient must have a diagnosis of symptomatic Paget's disease (i.e., bone pain, bone deformity, fracture, hearing loss, tinnitus) **AND**
   a. Must have had a previous trial or contraindication to an oral bisphosphonate or an injectable bisphosphonate.
      i. For individuals who have severe GI intolerance to an oral bisphosphonate an injectable bisphosphonate (zoledronic acid or pamidronate) will be required prior to approval **OR**
B. Patient must have a diagnosis of postmenopausal osteoporosis **AND**
   a. Patient must be postmenopausal for greater than or equal to 5 years **AND**
   b. Must have a history of previous osteoporosis related fracture **OR**
   c. T-score -2.5 SD or less **OR**

d. T-score between -1.0 and -2.5 SD below normal **AND** a FRAX score for hip fracture of 3% or greater, or the risk for other bone fracture is greater than 20% **AND**
e. Step therapy applies: Must have had a previous trial and failure (defined as a decrease in BMD or a fracture while on bisphosphonate therapy) or contraindication to an oral bisphosphonate or an injectable bisphosphonate **AND** intranasal calcitonin
    i. For individuals who have severe GI intolerance to an oral bisphosphonate an injectable bisphosphonate (zoledronic acid or IV ibandronate) will be required prior to approval **OR**

C. Patient must have diagnosis of hypercalcemia
D. Dosing:
    a. The recommended dose for symptomatic Paget's disease and postmenopausal osteoporosis is 100 USP Units (0.5 mL) per day administered SQ or IM.
    b. The recommended dose for early treatment of hypercalcemia is 4 USP Units/kg every 12 hours by SQ or IM injection. If the response to this dose is not satisfactory after one or two days, the dose may be increased to 8 USP Units/kg every 12 hours. If the response remains unsatisfactory after two more days, the dose may be further increased to a maximum of 8 USP Units/kg every 6 hours.
E. Quantity limit: 8 vials per 30 days. An exception may be granted for a diagnosis of hypercalcemia and will be reviewed in accordance with the FDA-approved weight-based dosing and, as such, will be limited to the minimum number of vials required to obtain the maximum dose of 8 USP units/kg every 6 hours.
F. Authorization for treatment of hypercalcemia will be for 1 month

POLICY GUIDELINES:

1. This policy is applicable to drugs that are included on a specific drug formulary. If a drug referenced in this policy is non-formulary, please reference the Non-Formulary Medication Exception Review Policy for All Lines of Business policy for review guidelines.
2. Utilization Management are contract dependent and coverage criteria may be dependent on the contract renewal date. Additionally, coverage of drugs listed in this policy are contract dependent. Refer to specific contract/benefit language for exclusions
3. This policy does not apply to Medicare Part D and D-SNP pharmacy benefits. The drugs in this policy may apply to all other lines of business including Medicare Advantage.
4. For members with Medicare Advantage, medications with a National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) will be covered pursuant to the criteria outlined by the NCD and/or LCD. NCDs/LCDs for applicable medications can be found on the CMS website at https://www.cms.gov/medicare-coverage-database/search.aspx. Indications that have not been addressed by the applicable medication's LCD/NCD will be covered in accordance with criteria determined by the Health Plan (which may include review per the Health Plan's Off-Label Use of FDA Approved Drugs policy). Step therapy requirements may be imposed in addition to LCD/NCD requirements.
5. Not all contracts cover all Medical Infusible drugs. Refer to specific contract/benefit plan language for exclusions of Injectable Medications.
6. For contracts where Insurance Law § 4903(c-1), and Public Health Law § 4903(3-a) are applicable, if trial of preferred drug(s) is the only criterion that is not met for a given condition, and one of the following circumstances can be substantiated by the requesting provider, then trial of the preferred drug(s) will not be required.
    - The required prescription drug(s) is (are) contraindicated or will likely cause an adverse reaction or physical or mental harm to the member;

- The required prescription drug is expected to be ineffective based on the known clinical history and conditions and concurrent drug regimen;
- The required prescription drug(s) was (were) previously tried while under the current or a previous health plan, or another prescription drug or drugs in the same pharmacologic class or with the same mechanism of action was (were) previously tried and such prescription drug(s) was (were) discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;
- The required prescription drug(s) is (are) not in the patient's best interest because it will likely cause a significant barrier to adherence to or compliance with the plan of care, will likely worsen a comorbid condition, or will likely decrease the ability to achieve or maintain reasonable functional ability in performing daily activities;
- The individual is stable on the requested prescription drug. The medical profile of the individual (age, disease state, comorbidities), along with the rational for deeming stability as it relates to standard medical practice and evidence-based practice protocols for the disease state will be taken into consideration.
- The above criteria are not applicable to requests for brand name medications that have an AB rated generic. We can require a trial of an AB-rated generic equivalent prior to providing coverage for the equivalent brand name prescription drug.

7. Coverage for Forteo and Teriparatide are provided under the prescription drug benefit.
8. Coverage for Tymlos is provided under the prescription drug benefit.
9. Coverage for Prolia is provided under the medical benefit.
10. Coverage for Evenity is provided under the medical benefit.
11. Coverage for Miacalcin injection and generic calcitonin salmon injection are provided under the prescription drug benefit.
12. Prolia is limited to one 60mg subcutaneous injection every 6 months
13. Forteo and Teriparatide are limited to a dose of 20 mcg daily (one pre-filled pen per 28 days).
14. Tymlos will be limited to a dose of 80 mcg subcutaneously once daily (one pre-filled pen= 1.56 mL per 30 days).
15. The recommended dosing for Evenity is 210mg administered subcutaneously in the abdomen, thigh, or upper arm once every month, administered as two separate subcutaneous injections (105mg/1.17mL prefilled syringes), one after the other.
16. The safety and effectiveness of Prolia, Forteo, Teriparatide, Tymlos, Evenity, Miacalcin injection and generic calcitonin salmon injection have not been established in pediatric patients.
17. Consistent with the information found in the products' current package labeling, approval durations for the parathyroid hormone analogs (Forteo, Teriparatide and Tymlos) will be as follows:
    a. Initial approval of Forteo or teriparatide will be for 2 years. Use of Forteo or 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. Requests for continued therapy beyond 2 years will require Provider attestation that the patient has remained at or has returned to having a high risk for fracture.
    b. Coverage of Tymlos will be limited to 2 years, based on package labeling which states that the use of the drug for more than 2 years during a patient's lifetime is not recommended.
18. Unless otherwise stated above within the individual drug criteria, approval time periods are listed in the table below.
    a. Continued approval at time of recertification will require documentation that the drug is providing ongoing benefit to the patient in terms of improvement or stability in disease state or condition. Such documentation may include progress notes, imaging or laboratory findings, and other objective or subjective measures of benefit which support that continued use of the requested product is medically necessary. Also, ongoing use of the requested product must

continue to reflect the current policy's preferred formulary. Recertification reviews may result in the requirement to try more cost-effective treatment alternatives as they become available (i.e., generics, biosimilars, or other guideline-supported treatment options). Requested dosing must continue to be consistent with FDA-approved or off-label/guideline-supported dosing recommendations.

19. All requests will be reviewed to ensure they are being used for an appropriate indication and may be subject to an off-label review in accordance with our Off-Label Use of FDA Approved Drugs Policy (Pharmacy-32).
20. All utilization management requirements outlined in this policy are compliant with applicable New York State insurance laws and regulations. Policies will be reviewed and updated as necessary to ensure ongoing compliance with all state and federally mandated coverage requirements.

Line of Business	Medical Initial approval	Medical Recert
Medicaid Managed Care (MMC) / Child Health Plus (CHP) / Essential Plan (EP)	All sites of service – 3 years	All sites of service – 3 years
Commercial / Exchange	All sites of service – 3 years	All sites of service – 3 years
Medicare	All sites of service – 3 years	All sites of service – 3 years

CODES:

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

Codes may not be covered under all circumstances. Please read the policy and guidelines statements carefully.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

HCPCS:
J0897 Prolia
J3111 Evenity
Q5136 Jubbonti

UPDATES:

Date:	Revision:
07/25/2025	Revised
06/27/2025	Revised
03/06/2025	Revised
02/17/2025	Revised
02/06/2025	P&T Committee Review & Approval
01/01/2025	Revised
06/20/2024	Revised
04/11/2024	Revised
02/08/2024	Reviewed / P&T Committee Approval
01/16/2024	Reviewed
01/01/2024	Revised
12/01/2023	Revised

08/24/2023	Revised
3/20/2023	Revised
03/15/2023	Revised
02/09/2023	P&T Committee Approval
01/31/2023	Revised
2/10/2022	P&T Committee Approval
01/20/2022	Reviewed
01/01/2022	Revised
05/28/2021	Revised
05/10/2021	Revised
04/2021	Revised
03/2021	Revised
02/11/2021	P&T Committee Approval
12/2020	Revised
11/2020	Reviewed
6/20	Revised
04/20	Revised
11/19	P & T Approval
11/19	Reviewed
10/19	Revised
08/19	Revised
05/19	Revised
05/19	P&T Approval
04/19	Reviewed
10/18	Revised
08/18	Revised
9/17	P&T Approval
6/17	Revised
2/17	Revised
3/16	Reviewed
3/15	P&T Approval
12/14	P&T Approval
8/13	Revised
2/12	Revised
10/11	Revised
5/11	Review
9/10	Revised
6/10	Revised
4/10	Revised
9/09	Reviewed
6/09	Revised
9/08	Revised
7/08	Revised
6/08	Revised
4/08	Reviewed
3/08	Reviewed
9/07	Created

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