Pharmacy Management Drug Policy

SUBJECT: Osteoporosis - Bildyos® (denosumab-nxxp), Bonsity®, Bosaya (denosumab-kyqq), calcitonin salmon injection, Conexxence (denosumab-bnht), Enoby® (denosumab-qbde), Evenity® (romosozumab-aqqg), Forteo® (teriparatide), Jubbonti® (denosumab-bbdz), Ospomyv® (denosumab-dssb), Osvyrti® (denosumab-desu), Prolia® (denosumab), Stoboclo® (denosumab-bmwo), Teriparatide, Tymlos® (abaloparatide)
POLICY NUMBER: PHARMACY-35
EFFECTIVE DATE: 09/2007
LAST REVIEW DATE: 08/06/2026

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. **Denosumab:**

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

****Criteria apply to All Lines of Business****

Enoby and Bildyos are the preferred denosumab products and will be covered under pharmacy or medical benefit without prior authorization for all lines of business.

IMPORTANT: Requests for non-preferred denosumab products will require a previous trial and failure (defined as a decrease in BMD or a fracture while on osteoporosis therapy) of **BOTH** Bildyos and Enoby unless there is medical reason why Bildyos and Enoby cannot be used due to formulation differences in the inactive ingredient(s) (e.g., differences in stabilizing agent, buffering agent, and/or surfactant) which, according to the prescriber, would result in a significant allergy or serious adverse reaction (documentation required)

- Applies to New Starts for all lines of business (including Medicare Advantage)
- Applies to Existing Users for Commercial and SafetyNet lines of business

A. Must have a diagnosis of one of the following:
   a. Osteoporosis (at high risk for fracture)

A. Postmenopausal woman **AND**	B. Male at high risk for fracture **AND**	C. Patient at risk for steroid induced osteoporosis
I. History of previous osteoporosis related fracture **OR**	I. History of previous osteoporosis related fracture **OR**	I. Chronic steroid use (Greater than 3 month) **AND** a T-score of -1 SD or less
II.T-score -2.5 SD or less **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%	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%	

   b. Osteoporosis (at high risk for fracture) followed gastric bypass surgery
   c. For the treatment of bone loss in men receiving androgen deprivation therapy for prostate cancer
   d. For the treatment of bone loss in women receiving adjuvant aromatase inhibitor therapy for breast cancer

B. Jubbonti, Stoboclo, Conexxence, Osvyrti, Bosaya and Ospomyv 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 Medicaid Managed Care (MMC/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. Utilization Management is contract dependent. Refer to specific contract/benefit language for exclusions.
   - Coverage criteria may be dependent on the contract renewal date.
   - Coverage of drugs listed in this policy are contract dependent.
   - Not all contracts/benefits allow coverage of healthcare professional administered drugs as part of their pharmacy benefit.
   - Not all contracts/benefits cover all medical infusible drugs.
2. Clinical documentation must be submitted for each request (initial and recertification [if applicable]) unless otherwise specified (e.g., provider attestation required). Supporting documentation includes, but is not limited to, progress notes documenting previous treatments and treatment history, diagnostic testing, laboratory test results, genetic testing or biomarker results, imaging and other objective or subjective measures of benefit. For recertification, continued approval requires documentation demonstrating that the requested product is providing ongoing benefit to the patient, evidenced by improvement or stability in disease state or condition, and that continued use remains medically necessary. Ongoing use of the requested product must continue align with the current policy's preferred formulary. Recertification reviews may result in a requirement to trial more cost-effective treatment alternatives as they become available (i.e., generics, biosimilars, or other guideline-supported treatment options). Requested dosing must remain consistent with FDA-approved or off-label/guideline-supported dosing recommendations.
3. 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.
4. 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.
5. 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).

6. Dose and frequency should be in accordance with the FDA label or recognized compendia (for off-label uses). When services are performed in excess of established parameters, they may be subject to review for medical necessity.
7. 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. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS permits a Medicare Advantage Organization (MAO) to establish its own coverage determinations in accordance with 42 CFR § 422.101(b)(6). 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.
8. Not all contracts cover all Medical Infusible drugs. Refer to specific contract/benefit plan language for exclusions of Injectable Medications.
9. Coverage for Forteo and Teriparatide are provided under the prescription drug benefit.
10. Coverage for Tymlos is provided under the prescription drug benefit.
11. Coverage for Prolia, Bildyos, and Enoby may be provided under the pharmacy or medical benefit depending on the contract of line of business.
12. Coverage for Jubbonti, Stoboclo, Conexxence, Bosaya, and Ospomyv are covered as medical benefit only.
13. Coverage for Evenity is provided under the medical benefit.
14. Coverage for Miacalcin injection and generic calcitonin salmon injection are provided under the prescription drug benefit.
15. Denosumab is limited to 1-60 mg subcutaneous injection every 6 months
16. Forteo and Teriparatide are limited to a dose of 20 mcg daily (one pre-filled pen per 28 days).
17. Tymlos will be limited to a dose of 80 mcg subcutaneously once daily (one pre-filled pen= 1.56 mL per 30 days).
18. 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.
19. The safety and effectiveness of Prolia, denosumab biosimilars, Forteo, Teriparatide, Tymlos, Evenity, Miacalcin injection and generic calcitonin salmon injection have not been established in pediatric patients.
20. 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.
21. Unless otherwise stated above within the individual drug criteria, approval time periods are listed in the table below.
22. For commercial contracts, medical necessity determinations align with the Certificate of Coverage issued by the Health Plan, which states that covered services must be clinically appropriate and not primarily for the convenience of the member, the member's family, or the provider.

23. This policy is based on available evidence as of the last review date. Coverage determinations are subject to applicable plan documents, state and federal regulations, and individual patient circumstances. This policy does not constitute medical advice.
24. This policy is subject to ongoing revision. Newly marketed drugs and existing drugs with new indications may be subject to prior authorization until formal coverage criteria are established. Inclusion of a drug in this policy does not guarantee its current availability on the market, as some agents may be discontinued, withdrawn, or otherwise unavailable. As product status changes, drugs may be removed from the policy.
25. 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.
26. Manufacturers may either discontinue participation in, or may not participate in, the Medicaid Drug Rebate Program (MDRP). Under New York State Medicaid requirements, physician-administered drugs must be produced by manufacturers that participate in the MDRP. Products made by manufacturers that do not participate in the MDRP will not be covered under Medicaid Managed Care/HARP lines of business. Drug coverage will not be available for any product from a non-participating manufacturer. For a complete list of New/Reinstated & Terminated Labelers please visit: https://www.medicaid.gov/medicaid/prescriptiondrugs/medicaid-drug-rebate-program/newreinstated-terminated-labeler-information/index.html
27. The requested site of care may impact approval timeframe and is subject to review.

Line of Business	Medical Initial approval	Medical Recert
Medicaid Managed Care (MMC) / Child Health Plus (CHP) / Essential Plan (EP) / HARP	2 years	2 years
Commercial / Exchange	2 years	2 years
Medicare	2 years	2 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).
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HCPCS:
Q5161 Bosaya
Q5158 Conexxence
Q5136 Jubbonti
Q5159 Ospomyv
Q5166 Osvyrti
Q5157 Stoboclo

UPDATES:

Date:	Revision:
08/06/2026	Revised
08/04/2026	Revised
08/01/2026	Revised
03/19/2026	Revised
02/12/2026	P&T Committee Review & Approval
01/23/2026	Revised
11/19/2025	Revised
10/03/2025	Revised
07/25/2025	Revised
06/27/2025	Revised
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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
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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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