Pharmacy Management Drug Policy

SUBJECT: Osteoporosis - Evenity® (romosozumab-aqqg), Forteo® (teriparatide), Prolia® (denosumab), Tymlos® (abaloparatide), Boniva injection® (Ibandronate)
POLICY NUMBER: Pharmacy-35
EFFECTIVE DATE: 9/07
LAST REVIEW DATE: 11/21/2019

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. Medical or drug policies apply to commercial, and Health Care Reform products only when a contract benefit for the specific service exists.

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** has been medically proven to be effective and therefore **medically necessary** if the request meets all of 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. 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 could be considered as initial therapy in those individuals with renal insufficiency (creatinine clearance < 35ml/min)	

2. **FORTEO**: Based upon our assessment and review of peer-reviewed literature, **FORTEO** has been medically proven to be effective and therefore **medically necessary** if the request meets all of 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. 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. Forteo will not be authorized for new starts unless there is documentation of severe intolerance or a contraindication to Tymlos.</td></tr>
</table>

Parathyroid hormone analogs may be considered upon special consideration as a first line agent in patients at high risk for fracture or those who need more immediate bone remodeling. These requests will be limited to endocrinologists, rheumatologists and medical orthopedics. In the event that parathyroid hormone analog is medically appropriate as initial therapy, Tymlos will be the approved therapy. Forteo will not be authorized unless there is documentation of severe intolerance or a contraindication to Tymlos.

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 of 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. 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 4. 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.
Parathyroid hormone analogs may be considered upon special consideration as a first line agent in patients at high risk for fracture or those who need more immediate bone remodeling. These requests will be limited to endocrinologists, rheumatologists and medical orthopedics. In the event that parathyroid hormone analog is medically appropriate as initial therapy, Tymlos will be the approved therapy.	

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. Evenity will not be authorized for new starts unless there is documentation of severe intolerance or a contraindication to Tymlos or Forteo.

5. **IBANDRONATE INJECTION (BONIVA):** Based upon our assessment and review of peer-reviewed literature, **IBANDRONATE INJECTION** has been medically proven to be effective and therefore medically necessary if the request meets all the following criteria:

****Criteria only applies to Medicaid Managed Care (MMC) / Child Health Plus (CHP)****

Diagnosis	Criteria
Postmenopausal woman with osteoporosis:	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. 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

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. Prior-authorization is contract dependent.
3. 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.

4. Coverage for Forteo is provided under the prescription drug benefit.
5. Coverage for Tymlos is provided under the prescription drug benefit.
6. Coverage for Prolia is provided under the medical benefit.
7. Coverage for Evenity is provided under the medical benefit.
8. Coverage for Ibandronate injection is provided under the medical benefit.
9. Prolia is limited to one 60mg subcutaneous injection every 6 months
10. Forteo is limited to a dose of 20 mcg daily (one pre-filled pen per 28 days).
11. Tymlos will be limited to a dose of 80 mcg subcutaneously once daily (one pre-filled pen= 1.56 mL per 30 days).
12. 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.
13. The recommended dosing for Ibandronate injection is 3 mg IV every 3 months according to the prescribing information.
14. The safety and effectiveness of Prolia, Forteo, Tymlos, Evenity and Ibandronate injection have not been established in pediatric patients.
15. Coverage of Forteo and Tymlos will be limited to a maximum of 2 years of cumulative use (a total of 2 years of therapy taking into consideration use of both of agents) based on package labeling which states that cumulative use of parathyroid hormone analogs for more than 2 years during a patient's lifetime is not recommended.
16. 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 and that if osteoporosis therapy remains warranted, continued therapy with an anti-resorptive agent should be considered.
17. 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.

Line of Business	Medical Initial approval	Medical Recert
Medicaid Managed Care (MMC) / Child Health Plus (CHP)	6 months	12 months
Commercial / Exchange	Outpatient Hospital – 2 years	Outpatient Hospital – 2 years
	Home Care or Office Based – 3 years	Home Care or Office Based – 3 years
Medicare	Outpatient Hospital – 2 years	Outpatient Hospital – 2 years
	Home Care or Office Based – 3 years	Home Care or Office Based – 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 (effective 10/1/19)

UPDATES:

Date:	Revision:
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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