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**Effective Date: 04/11/2024**

**Evenity® (romosozumab-aqqg)**

**HCPCS: J3111**

**Policy:**

*Requests must be supported by submission of chart notes and patient specific documentation.*

- A. Coverage of the requested drug is provided when all the following are met:
  - a. The patient meets one of the following (i. or ii.)
    - i. History of fragility fracture  
OR
    - ii. FDA approved diagnosis  
AND  
Treatment with a bisphosphonate has been ineffective after at least a 12 month treatment period based on objective documentation (such as reduction in T score or fracture) UNLESS the patient meets one of the following:
      - 1. Treatment with bisphosphonates (both oral and intravenous) are not tolerated or contraindicated
      - 2. History of fracture(s)
      - 3. T-score less than -3.0
  - b. Will not be used in combination with bisphosphonates, another anabolic bone-modifying agent or denosumab
  - c. Trial and failure, contraindication, or intolerance to the preferred drugs as listed in BCBSM/BCN's prior authorization and step therapy documents
- B. Quantity Limitations, Authorization Period and Renewal Criteria
  - a. Quantity Limits: Align with FDA recommended dosing
  - b. Authorization Period: 12 months
  - c. Renewal Criteria: Not applicable as no further authorization will be provided

\*\*\*Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at <http://www.cms.hhs.gov/>. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

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## Background Information:

- Evenity is indicated for the treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy.
- The American Association for Clinical Endocrinology (AACE)/American College of Endocrinology (ACE) Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis (2020) consider a diagnosis of osteoporosis and recommend pharmacologic therapy for the following clinical scenarios:
  - Presence or history of fragility fractures in the absence of other metabolic bone disorders, even in those with normal bone mineral density (BMD) as measured by axial dual-energy X-ray absorptiometry (DXA) scan
  - T-score of -2.5 or lower in the lumbar spine, femoral neck, total hip, or 1/3 radius; measured by DXA scan
  - T-score between -1.0 and -2.5 and if the FRAX<sup>®</sup> (fracture risk assessment tool) 10-year probability for major osteoporotic fracture is  $\geq 20\%$  or the 10-year probability of hip fracture is  $\geq 3\%$  in the United States or above the country-specific threshold in other countries or regions
- Guidelines recommend bisphosphonates as the initial treatment option for most patients with osteoporosis. Bisphosphonates decrease the breakdown of the bone (antiresorptive) and have been shown to increase bone mineral density and reduce the incidence of fractures in patients with osteoporosis. Contraindications to bisphosphonates include hypocalcemia and severe renal impairment. In addition, oral bisphosphonates are contraindicated in patients with the inability to stand or sit upright for at least 30 minutes and may not be an appropriate option in patients with underlying gastrointestinal issues. However, use of an IV bisphosphonate is still appropriate in these situations.
- Prolia<sup>®</sup> (denosumab) is another antiresorptive therapy that is often reserved for use in patients who are unable to use oral bisphosphonate therapy, those that prefer to avoid IV bisphosphonates due to side effects, or those that have impaired renal function. In 2024, the FDA revised the Prolia prescribing information to include a new Boxed Warning for increased risk of severe hypocalcemia in patients with advanced chronic kidney disease, particularly those on dialysis or those with a condition known as mineral and bone disorder (CK-MBD), who are taking Prolia.
- Guidelines include evidence supporting superiority of certain antiresorptive agents (Prolia and IV zoledronate) and anabolic agents (Evenity, Tymlos<sup>®</sup>, and Forteo<sup>®</sup>) over oral bisphosphonates for individuals who are unable to use oral bisphosphonates and as initial therapy or for individuals with osteoporosis who are at very high risk for fracture, such as those with a T-score less than -3.0 or those with a history of fracture.
- Guidelines recommend sequential treatment with antiresorptive osteoporosis therapies to maintain bone mineral density gains and reduce fracture risk after completing a course of treatment with anabolic drugs.
- Until the effect of combination therapy on fracture risk is better understood, the AACE does not recommend concomitant use of FDA approved osteoporosis agents for the prevention or treatment of postmenopausal osteoporosis.
- Guidelines do not recommend use of one anabolic agent over another as there is insufficient evidence to establish one as safer or more effective than another.
- The goal of monitoring osteoporosis is to identify those who have significant bone loss. AACE recommends repeat DXA scan every 1 to 2 years after initiation of therapy until BMD is stable. Bone turnover markers (BTMs) are also useful for assessing patient compliance and efficacy of therapy. Reductions in BTMs are conferred by antiresorptive

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therapy and are associated with fracture reduction. Significant increases in BTMs indicate good response to anabolic therapy.

- Evenity is limited to a 12 month duration of treatment. After 12 monthly doses, the anabolic effect of Evenity wanes, which is the reason for the duration limit. If osteoporosis therapy is still necessary, continued treatment with an antiresorptive agent should be considered (e.g., a bisphosphonate).

## References:

1. Forteo [prescribing information]. Indianapolis, IN: Eli Lilly; September 2021.
2. Teriparatide [prescribing information]. Morristown, NJ: Alvogen; October 2019.
3. Tymlos [prescribing information]. Waltham, MA: Radius Health; December 2023.
4. Evenity [package insert]. Thousand Oaks, CA: Amgen; April 2020.
5. Bisphosphonates. Facts and Comparisons. 2020. Available from Wolters Kluwer Health, Inc.
6. Buckley L, Guyatt G, Fink H, et al. 2017 American College of Rheumatology Guideline for the Prevention and Treatment of Glucocorticoid-Induced Osteoporosis. *Arthritis and Rheumatology*. 2017;69:1521-37.
7. Shoback D, Rosen C, Black D 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, dgaa048, <https://doi.org/10.1210/clinem/dgaa048>.
8. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists/American College of Endocrinology Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis-2020 Update. *Endocrine practice : official journal of the American College of Endocrinology and the American Association of Clinical Endocrinologists*. 2020;26:1-46.
9. Saag KG, Shane E, Boonen S, et al. Teriparatide or alendronate in glucocorticoid-induced osteoporosis. *N Engl J Med*. 2007;357:2028-2039.
10. Hadji P, Zanchetta JR, Russo L, et al. The effect of teriparatide compared with risedronate on reduction of back pain in postmenopausal women with osteoporotic vertebral fractures. *Osteoporos Int*. 2012;23:2141-2150.
11. Kendler DL, Marin F, Zerbini CA, et al. Effects of teriparatide and risedronate on new fractures in post-menopausal women with severe osteoporosis (VERO): a multicentre, double-blind, doubledummy, randomised controlled trial. *Lancet*. 2017;391:230-240.
12. Saag KG, Petersen J, Brandi ML, et al. Romosozumab or alendronate for fracture prevention in women with osteoporosis. *New Engl J Med*. 2017;377:1417-1427.
13. Prolia [prescribing information]. Thousand Oaks, CA: Amgen; January 2024.

Policy History												
#	Date	Change Description										
1.8	Effective Date: 04/11/2024	Annual review - no changes made to existing criteria										
1.7	Effective Date: 04/06/2023	Annual review – No changes made to existing criteria										
1.6	Effective Date: 04/14/2022	Updated to allow for clinical situations where patients are not required to use bisphosphonates as first line treatment										
1.5	Effective Date: 10/07/2021	Annual review of criteria was performed, no changes were made.										
1.4	Effective Date: 10/08/2020	Annual review of criteria was performed, no changes were made.										
1.3	Effective Date: 11/7/2019	Policy update: trial and failure of oral and IV bisphosphonate, not to be used with other anabolic agents or denosumab										
1.2	11/01/2019	UM medical management system update for MAPPO and BCNA <table border="1" data-bbox="483 751 1365 961"> <thead> <tr> <th>Line of Business</th> <th>PA Required in Medical Management System (Yes/No)</th> </tr> </thead> <tbody> <tr> <td>BCBS</td> <td>Yes</td> </tr> <tr> <td>BCN</td> <td>Yes</td> </tr> <tr> <td>MAPPO</td> <td>Yes</td> </tr> <tr> <td>BCNA</td> <td>Yes</td> </tr> </tbody> </table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	Yes	BCNA	Yes
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1.1	Effective Date: 08/01/2019	UM medical management system update for BCBSM <table border="1" data-bbox="483 1052 1365 1262"> <thead> <tr> <th>Line of Business</th> <th>PA Required in Medical Management System (Yes/No)</th> </tr> </thead> <tbody> <tr> <td>BCBS</td> <td>Yes</td> </tr> <tr> <td>BCN</td> <td>Yes</td> </tr> <tr> <td>MAPPO</td> <td>No</td> </tr> <tr> <td>BCNA</td> <td>No</td> </tr> </tbody> </table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	No	BCNA	No
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1.0	Effective Date: 06/01/2019	UM medical management system update for BCN New full drug review <table border="1" data-bbox="483 1381 1365 1591"> <thead> <tr> <th>Line of Business</th> <th>PA Required in Medical Management System (Yes/No)</th> </tr> </thead> <tbody> <tr> <td>BCBS</td> <td>No</td> </tr> <tr> <td>BCN</td> <td>Yes</td> </tr> <tr> <td>MAPPO</td> <td>No</td> </tr> <tr> <td>BCNA</td> <td>No</td> </tr> </tbody> </table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	No	BCN	Yes	MAPPO	No	BCNA	No
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\* The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or <http://dailyed.nlm.nih.gov/dailymed/index.cfm>.

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