Wellmark Advantage Health Plan

Wellmark Advantage Health Plan, Inc. is an independent licensee of the Blue Cross and Blue Shield Association.

Medical benefit drug policies are a source for Wellmark Advantage Health Plan medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

Effective Date: 04/16/2022

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. History of fragility fracture
      OR
      FDA approved indication
      AND
   b. 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:
      i. Treatment with bisphosphonates (both oral and intravenous) are not tolerated or contraindicated
      ii. History of fracture(s)
      iii. T-score less than -3.0
   c. Will not be used in combination with bisphosphonates, another anabolic bone-modifying agent, or denosumab
   d. Trial and failure of the preferred products as specified in the Wellmark Advantage Health Plan medical utilization management drug list

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 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.

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 guidelines (2020) define osteoporosis as a bone mineral density (BMD) T-score at or lower than -2.5. However, a non- or low-traumatic fracture (fragility fracture) is considered osteoporosis regardless of T-score.

- Guidelines recommend bisphosphonates as the initial treatment option. Bisphosphonates decrease the breakdown of the bone 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.

- Guidelines state there is evidence supporting superiority of anabolic agents, such as parathyroid hormone analogs and romosozumab, over anti-resorptive therapies such as bisphosphonates in reducing vertebral fracture risk in patients with a very high risk of fracture, such as those with T-score less than -3.0, because of its anabolic (i.e., bone building) properties. 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.

- Guidelines do not recommend combination use of anabolic osteoporosis drugs with other anti-resorptive drugs.

- 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.

- 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; April 2021.
2. Teriparatide [prescribing information]. Morristown, NJ: Alvogen; November 2019.
3. Tymlos [prescribing information]. Waltham, MA: Radius Health; September 2021.
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 Preventionand 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 PostmenopausalWomen: 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 PostmenopausalOsteoporosis-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. NEngl J Med. 2007;357:2028-2039.
10. Hadji P, Zanchetta JR, Russo L, et al. The effect of teriparatide compared with risedronate on reduction ofback 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 sever 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 withosteoporosis. New Engl J Med. 2017;377:1417-1427.

Policy History		
#	Date	Change Description
1.1	Effective Date: 04/14/2022	Updated to allow for clinical situations where patients are not required to use bisphosphonates as first line treatment
1.0	Effective Date: 01/01/2022	Effective as of date on policy.

** 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://dailymed.nlm.nih.gov/dailymed/index.cfm.*