Corporate Medical Policy: Romosozumab-aqqg (Evenity™)

Restricted Product(s):

- romosozumab-aqqg (Evenity™) subcutaneous injection for administration by a healthcare professional

FDA Approved Use:

- Romosozumab-aqqg (Evenity™)
    - Treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy

Criteria for Medical Necessity:

The restricted product(s) may be considered medically necessary when the following criteria are met:

1. The patient has a confirmed diagnosis of osteoporosis; **AND**
2. The patient is at high risk for fracture as defined by one of the following:
    a. A history of previous osteoporosis related fracture; **OR**
    b. A pre-treatment bone mineral density (BMD) T-score of ≤ -3 at the total hip or femoral neck; **OR**
    c. A pre-treatment bone mineral density (BMD) T-score of ≤ -2.5 at the total hip or femoral neck, **AND one of the following**:
        i. The patient has tried and failed or has an intolerance or contraindication to bisphosphonates; **OR**
        ii. The patient has tried and failed other injectable osteoporosis therapies (i.e., denosumab, abaloparatide, teriparatide) as defined by fracture with loss of BMD despite compliance with osteoporosis therapy; **AND**
3. The requested agent will not be used in combination with other pharmacological agents used to treat osteoporosis; **AND**
4. The patient does not have hypocalcemia or hypocalcemia has been corrected prior to initiating therapy with the requested agent; **AND**
5. The patient has not had a myocardial infarction or stroke within the preceding year; **AND**
6. The total duration of romosozumab (Evenity) therapy will not exceed 12 months; **AND**
7. The requested quantity does NOT exceed the maximum units allowed for the duration of approval (see table below).

Duration of Approval: 12 months total duration

FDA Label Reference				
Medication	**Indication**	**Dosing**	**HCPCS**	**Maximum Units***
Romosozumab-aqqg (Evenity™)	Treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy.	210 mg subcutaneously once every month for 12 doses in the abdomen, thigh, or upper arm	J3111	**2520**

***Maximum units allowed for duration of approval**

References: all information referenced is from FDA package insert unless otherwise noted below.

1. Barrionuevo P, Kapoor E, Asi N, et al. Efficacy of pharmacological therapies for the prevention of fractures in postmenopausal women: a network meta-analysis. *J Clin Endocrinol Metab*. 2019;104(5):1623-30.
2. Cosman F, Crittenden DB, Adachi JD, et al. Romosozumab treatment in postmenopausal women with osteoporosis. *N Engl J Med*. 2016;375(16):1532-43.
3. Cosman F, de Beur SJ, LeBoff MS, et al. National Osteoporosis Foundation (NOF). Clinician's guide to prevention and treatment of osteoporosis. *Osteoporos Int*. 2014;25(10):2359-81.
4. Saag KG, Petersen J, Brandi ML, et al. Romosozumab or alendronate for fracture prevention in women with osteoporosis. *N Engl J Med*. 2017;377(15):1417-27.

Policy Implementation/Update Information:

June 2021: Criteria change: Added maximum units; medical policy formatting change. **Policy notification given 4/16/2021 for effective date 6/16/2021**.
*Further historical criteria changes and updates available upon request from Medical Policy and/or Corporate Pharmacy.

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- You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at *https://ocrportal.hhs.gov/ocr/portal/lobby.jsf,* or by mail or phone at: U.S. Department of Health and Human Services 200 Independence Avenue, SW Room 509F, HHH Building Washington, D.C. 20201 **1-800-368-1019, 800-537-7697** (TDD). Complaint forms are available at *http://www.hhs.gov/ocr/office/file/index.html.*

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1-888-206-4697. المبرقة الكاتبة: 1-800-442-7028.

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau
1-888-206-4697 (TTY: 1-800-442-7028).

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1-888-206-4697 (телетайп: 1-800-442-7028).

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સુચના: જો તમે ગુજરાતી બોલતા હો, તો નિ:સુલ્કુ ભાષા સહાય સેવાઓ તમારા માટે ઉપલબ્ધ છે. ફોન કરો
1-888-206-4697 (TTY: 1-800-442-7028).

ចំណាំ៖ ប្រសិនបើលោកអ្នកនិយាយជាភាសាខ្មែរ សេវាកម្មជំនួយផ្នែកភាសាមានផ្តល់ជូនសម្រាប់លោកអ្នកដោយមិនគិតថ្លៃ។ សូមទំនាក់ទំនងតាមរយៈលេខ៖ 1-888-206-4697 (TTY: 1-800-442-7028)។

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