JOHNS HOPKINS	Johns Hopkins HealthCare LLC Pharmacy Public Medical Management Drug Policies	Policy Number	MMDP030
		Effective Date	07/17/2019
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	<u>Subject</u>	Revision Date	11/10/2021
JOHNS HOPKINS HEALTHCARE	Evenity	Page	1 of 2

11 : 20

This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Evenity

Tabl	e of Contents	Page Number
I.	POLICY	1
II.	POLICY CRITERIA	1
	A. Evenity	1
III.	AUTHORIZATION PERIOD/LIMITATIONS	1
IV.	EXCLUSIONS	2
V.	RECOMMENDED DOSE	2
VI.	REFERENCES	2
VII.	APPROVALS	2

I. POLICY

Evenity (romosozumab-aqqg) will require prior authorization to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

II. POLICY CRITERIA

- A. Evenity may be approved for patients who have the following condition and meet the following:
 - I. Postmenopausal osteoporosis
 - a. Patient is female and 18 years of age or older
 - b. Documentation has been provided showing a diagnosis of postmenopausal osteoporosis
 - 1. AND **ONE** of the following:
 - i. Bone Mineral Density (BMD) T-score of -2.5 or below in the lumbar spine, femoral neck, total, and/ or 33% (one-third) radius OR
 - ii. Patient is at high risk of fracture defined as:
 - A. A history of previous osteoporotic (fragility) fracture (fracture of the spine, hip, proximal humerus, pelvis, or distal forearm) regardless of T-score OR
 - B. Having a T-score between -1.0 and -2.5 in the spine, femoral neck, total hip, or 33% radius AND ONE of the following:
 - I. Fracture Risk Assessment (FRAX) 10-year probability for major osteoporotic fracture is 20% or greater, or the 10-year probability of hip fracture is 3% or greater OR
 - II. Documented history of repeat falls
 - c. Documentation of treatment failure or contraindication to conventional osteoporosis therapy (two independent bisphosphonate regimens)

III. AUTHORIZATION PERIOD/LIMITATIONS

- 1. Initial authorization period will be limited to 12 months of therapy
- 2. Evenity will not be eligible for coverage renewal beyond the initial 12 months of treatment.

			Version 3.0
DOHNS HOPKINS M E D I C I N E JOHNS HOPKINS HEALTHCARE	Pharmacy Public Medical Management Drug Policies	Policy Number	MMDP030
		Effective Date	07/17/2019
		Review Date	01/15/2020
	<u>Subject</u>	Revision Date	11/10/2021
	Evenity	Page	2 of 2

Varian 20

IV. EXCLUSIONS

- 1. Evenity will <u>NOT</u> be approved for patients with the following:
 - a. Risk for osteosarcoma
 - b. Paget's disease
 - c. Unexplained elevations of alkaline phosphatase
 - d. Prior bone radiation
 - e. Bone metastases or a history of skeletal malignancies
 - f. Metabolic bone diseases other than osteoporosis
 - g. High levels of calcium
 - h. Dual therapy with other human parathyroid hormone related peptide analogs, or monoclonal antibodies
- 2. Evenity is not recommended for more than 1 year of cumulative therapy, and will not be approved for continuation beyond this time.

V. RECOMMENDED DOSE

1. Evenity: 210 mg (two 105mg injections) subcutaneous injection delivered once monthly

VI. <u>REFERENCES</u>

- 1. Evenity: Prescribing information]. Thousand Oaks, CA: Amgen Inc; April 2019.
- American Association of Clinical Endocrinologists and American College of Endocrinology. Clinical Practice 2016 Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis. Endocr. Pract. 2016 Sep;22(9):1111-8. Available at: https://journals.aace.com/doi/pdf/10.4158/EP161435.GL
- 3. WHO Fracture Risk Assessment Tool (FRAX). http://www.shef.ac.uk/FRAX (Accessed July, 2019)

VII. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
07/17/2019	Policy creation
01/15/2020	No policy changes- presented policy for USFHP adoption effective 3/1/2020
11/10/2021	Removed Priority Partners as an applicable LOB

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