Evenity® (Romosozumab-Aqqg)

Policy Number: 2026D0080M
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➲ Instructions for Use

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Community Plan Policy

- Evenity® (Romosozumab-Aqqg)

Application

UnitedHealthcare Commercial

This Medical Benefit Drug Policy applies to UnitedHealthcare Commercial benefit plans.

UnitedHealthcare Individual Exchange

This Medical Benefit Drug Policy applies to Individual Exchange benefit plans.

Coverage Rationale

➲ See Benefit Considerations

Evenity is proven for the treatment of osteoporosis in postmenopausal patients at high risk for fracture when all of the following criteria are met:

- Diagnosis of postmenopausal osteoporosis; **and**
- Patient is at high risk for fracture (e.g., history of osteoporotic fracture, multiple risk factors for fracture, patients who have failed or are intolerant to other available osteoporosis therapy); **and**
- Dosing is in accordance with the U.S. Food and Drug Administration (FDA)–approved labeling; **and**
- Authorization is for no more than 12 months

Reauthorization/Continuation of Care Criteria

The clinical benefit of Evenity has not been demonstrated beyond 12 months in phase 3 clinical trials. The continued use of Evenity beyond 12 months is unproven.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other policies and guidelines may apply.

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HCPCS Code	Description
J3111	Injection, romosozumab-aqqg, 1 mg

Diagnosis Code	Description
M80.00XA	Age-related osteoporosis with current pathological fracture, unspecified site, initial encounter for fracture
M80.00XD	Age-related osteoporosis with current pathological fracture, unspecified site, subsequent encounter for fracture with routine healing
M80.00XG	Age-related osteoporosis with current pathological fracture, unspecified site, subsequent encounter for fracture with delayed healing
M80.00XK	Age-related osteoporosis with current pathological fracture, unspecified site, subsequent encounter for fracture with nonunion
M80.00XP	Age-related osteoporosis with current pathological fracture, unspecified site, subsequent encounter for fracture with malunion
M80.00XS	Age-related osteoporosis with current pathological fracture, unspecified site, sequela
M80.011A	Age-related osteoporosis with current pathological fracture, right shoulder, initial encounter for fracture
M80.011D	Age-related osteoporosis with current pathological fracture, right shoulder, subsequent encounter for fracture with routine healing
M80.011G	Age-related osteoporosis with current pathological fracture, right shoulder, subsequent encounter for fracture with delayed healing
M80.011K	Age-related osteoporosis with current pathological fracture, right shoulder, subsequent encounter for fracture with nonunion
M80.011P	Age-related osteoporosis with current pathological fracture, right shoulder, subsequent encounter for fracture with malunion
M80.011S	Age-related osteoporosis with current pathological fracture, right shoulder, sequela
M80.012A	Age-related osteoporosis with current pathological fracture, left shoulder, initial encounter for fracture
M80.012D	Age-related osteoporosis with current pathological fracture, left shoulder, subsequent encounter for fracture with routine healing
M80.012G	Age-related osteoporosis with current pathological fracture, left shoulder, subsequent encounter for fracture with delayed healing
M80.012K	Age-related osteoporosis with current pathological fracture, left shoulder, subsequent encounter for fracture with nonunion
M80.012P	Age-related osteoporosis with current pathological fracture, left shoulder, subsequent encounter for fracture with malunion
M80.012S	Age-related osteoporosis with current pathological fracture, left shoulder, sequela
M80.019A	Age-related osteoporosis with current pathological fracture, unspecified shoulder, initial encounter for fracture
M80.019D	Age-related osteoporosis with current pathological fracture, unspecified shoulder, subsequent encounter for fracture with routine healing
M80.019G	Age-related osteoporosis with current pathological fracture, unspecified shoulder, subsequent encounter for fracture with delayed healing
M80.019K	Age-related osteoporosis with current pathological fracture, unspecified shoulder, subsequent encounter for fracture with nonunion
M80.019P	Age-related osteoporosis with current pathological fracture, unspecified shoulder, subsequent encounter for fracture with malunion
M80.019S	Age-related osteoporosis with current pathological fracture, unspecified shoulder, sequela
M80.021A	Age-related osteoporosis with current pathological fracture, right humerus, initial encounter for fracture
M80.021D	Age-related osteoporosis with current pathological fracture, right humerus, subsequent encounter for fracture with routine healing

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Diagnosis Code	Description
M80.021G	Age-related osteoporosis with current pathological fracture, right humerus, subsequent encounter for fracture with delayed healing
M80.021K	Age-related osteoporosis with current pathological fracture, right humerus, subsequent encounter for fracture with nonunion
M80.021P	Age-related osteoporosis with current pathological fracture, right humerus, subsequent encounter for fracture with malunion
M80.021S	Age-related osteoporosis with current pathological fracture, right humerus, sequela
M80.022A	Age-related osteoporosis with current pathological fracture, left humerus, initial encounter for fracture
M80.022D	Age-related osteoporosis with current pathological fracture, left humerus, subsequent encounter for fracture with routine healing
M80.022G	Age-related osteoporosis with current pathological fracture, left humerus, subsequent encounter for fracture with delayed healing
M80.022K	Age-related osteoporosis with current pathological fracture, left humerus, subsequent encounter for fracture with nonunion
M80.022P	Age-related osteoporosis with current pathological fracture, left humerus, subsequent encounter for fracture with malunion
M80.022S	Age-related osteoporosis with current pathological fracture, left humerus, sequela
M80.029A	Age-related osteoporosis with current pathological fracture, unspecified humerus, initial encounter for fracture
M80.029D	Age-related osteoporosis with current pathological fracture, unspecified humerus, subsequent encounter for fracture with routine healing
M80.029G	Age-related osteoporosis with current pathological fracture, unspecified humerus, subsequent encounter for fracture with delayed healing
M80.029K	Age-related osteoporosis with current pathological fracture, unspecified humerus, subsequent encounter for fracture with nonunion
M80.029P	Age-related osteoporosis with current pathological fracture, unspecified humerus, subsequent encounter for fracture with malunion
M80.029S	Age-related osteoporosis with current pathological fracture, unspecified humerus, sequela
M80.031A	Age-related osteoporosis with current pathological fracture, right forearm, initial encounter for fracture
M80.031D	Age-related osteoporosis with current pathological fracture, right forearm, subsequent encounter for fracture with routine healing
M80.031G	Age-related osteoporosis with current pathological fracture, right forearm, subsequent encounter for fracture with delayed healing
M80.031K	Age-related osteoporosis with current pathological fracture, right forearm, subsequent encounter for fracture with nonunion
M80.031P	Age-related osteoporosis with current pathological fracture, right forearm, subsequent encounter for fracture with malunion
M80.031S	Age-related osteoporosis with current pathological fracture, right forearm, sequela
M80.032A	Age-related osteoporosis with current pathological fracture, left forearm, initial encounter for fracture
M80.032D	Age-related osteoporosis with current pathological fracture, left forearm, subsequent encounter for fracture with routine healing
M80.032G	Age-related osteoporosis with current pathological fracture, left forearm, subsequent encounter for fracture with delayed healing
M80.032K	Age-related osteoporosis with current pathological fracture, left forearm, subsequent encounter for fracture with nonunion
M80.032P	Age-related osteoporosis with current pathological fracture, left forearm, subsequent encounter for fracture with malunion
M80.032S	Age-related osteoporosis with current pathological fracture, left forearm, sequela

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Diagnosis Code	Description
M80.039A	Age-related osteoporosis with current pathological fracture, unspecified forearm, initial encounter for fracture
M80.039D	Age-related osteoporosis with current pathological fracture, unspecified forearm, subsequent encounter for fracture with routine healing
M80.039G	Age-related osteoporosis with current pathological fracture, unspecified forearm, subsequent encounter for fracture with delayed healing
M80.039K	Age-related osteoporosis with current pathological fracture, unspecified forearm, subsequent encounter for fracture with nonunion
M80.039P	Age-related osteoporosis with current pathological fracture, unspecified forearm, subsequent encounter for fracture with malunion
M80.039S	Age-related osteoporosis with current pathological fracture, unspecified forearm, sequela
M80.041A	Age-related osteoporosis with current pathological fracture, right hand, initial encounter for fracture
M80.041D	Age-related osteoporosis with current pathological fracture, right hand, subsequent encounter for fracture with routine healing
M80.041G	Age-related osteoporosis with current pathological fracture, right hand, subsequent encounter for fracture with delayed healing
M80.041K	Age-related osteoporosis with current pathological fracture, right hand, subsequent encounter for fracture with nonunion
M80.041P	Age-related osteoporosis with current pathological fracture, right hand, subsequent encounter for fracture with malunion
M80.041S	Age-related osteoporosis with current pathological fracture, right hand, sequela
M80.042A	Age-related osteoporosis with current pathological fracture, left hand, initial encounter for fracture
M80.042D	Age-related osteoporosis with current pathological fracture, left hand, subsequent encounter for fracture with routine healing
M80.042G	Age-related osteoporosis with current pathological fracture, left hand, subsequent encounter for fracture with delayed healing
M80.042K	Age-related osteoporosis with current pathological fracture, left hand, subsequent encounter for fracture with nonunion
M80.042P	Age-related osteoporosis with current pathological fracture, left hand, subsequent encounter for fracture with malunion
M80.042S	Age-related osteoporosis with current pathological fracture, left hand, sequela
M80.049A	Age-related osteoporosis with current pathological fracture, unspecified hand, initial encounter for fracture
M80.049D	Age-related osteoporosis with current pathological fracture, unspecified hand, subsequent encounter for fracture with routine healing
M80.049G	Age-related osteoporosis with current pathological fracture, unspecified hand, subsequent encounter for fracture with delayed healing
M80.049K	Age-related osteoporosis with current pathological fracture, unspecified hand, subsequent encounter for fracture with nonunion
M80.049P	Age-related osteoporosis with current pathological fracture, unspecified hand, subsequent encounter for fracture with malunion
M80.049S	Age-related osteoporosis with current pathological fracture, unspecified hand, sequela
M80.051A	Age-related osteoporosis with current pathological fracture, right femur, initial encounter for fracture
M80.051D	Age-related osteoporosis with current pathological fracture, right femur, subsequent encounter for fracture with routine healing
M80.051G	Age-related osteoporosis with current pathological fracture, right femur, subsequent encounter for fracture with delayed healing
M80.051K	Age-related osteoporosis with current pathological fracture, right femur, subsequent encounter for fracture with nonunion

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Diagnosis Code	Description
M80.051P	Age-related osteoporosis with current pathological fracture, right femur, subsequent encounter for fracture with malunion
M80.051S	Age-related osteoporosis with current pathological fracture, right femur, sequela
M80.052A	Age-related osteoporosis with current pathological fracture, left femur, initial encounter for fracture
M80.052D	Age-related osteoporosis with current pathological fracture, left femur, subsequent encounter for fracture with routine healing
M80.052G	Age-related osteoporosis with current pathological fracture, left femur, subsequent encounter for fracture with delayed healing
M80.052K	Age-related osteoporosis with current pathological fracture, left femur, subsequent encounter for fracture with nonunion
M80.052P	Age-related osteoporosis with current pathological fracture, left femur, subsequent encounter for fracture with malunion
M80.052S	Age-related osteoporosis with current pathological fracture, left femur, sequela
M80.059A	Age-related osteoporosis with current pathological fracture, unspecified femur, initial encounter for fracture
M80.059D	Age-related osteoporosis with current pathological fracture, unspecified femur, subsequent encounter for fracture with routine healing
M80.059G	Age-related osteoporosis with current pathological fracture, unspecified femur, subsequent encounter for fracture with delayed healing
M80.059K	Age-related osteoporosis with current pathological fracture, unspecified femur, subsequent encounter for fracture with nonunion
M80.059P	Age-related osteoporosis with current pathological fracture, unspecified femur, subsequent encounter for fracture with malunion
M80.059S	Age-related osteoporosis with current pathological fracture, unspecified femur, sequela
M80.061A	Age-related osteoporosis with current pathological fracture, right lower leg, initial encounter for fracture
M80.061D	Age-related osteoporosis with current pathological fracture, right lower leg, subsequent encounter for fracture with routine healing
M80.061G	Age-related osteoporosis with current pathological fracture, right lower leg, subsequent encounter for fracture with delayed healing
M80.061K	Age-related osteoporosis with current pathological fracture, right lower leg, subsequent encounter for fracture with nonunion
M80.061P	Age-related osteoporosis with current pathological fracture, right lower leg, subsequent encounter for fracture with malunion
M80.061S	Age-related osteoporosis with current pathological fracture, right lower leg, sequela
M80.062A	Age-related osteoporosis with current pathological fracture, left lower leg, initial encounter for fracture
M80.062D	Age-related osteoporosis with current pathological fracture, left lower leg, subsequent encounter for fracture with routine healing
M80.062G	Age-related osteoporosis with current pathological fracture, left lower leg, subsequent encounter for fracture with delayed healing
M80.062K	Age-related osteoporosis with current pathological fracture, left lower leg, subsequent encounter for fracture with nonunion
M80.062P	Age-related osteoporosis with current pathological fracture, left lower leg, subsequent encounter for fracture with malunion
M80.062S	Age-related osteoporosis with current pathological fracture, left lower leg, sequela
M80.069A	Age-related osteoporosis with current pathological fracture, unspecified lower leg, initial encounter for fracture
M80.069D	Age-related osteoporosis with current pathological fracture, unspecified lower leg, subsequent encounter for fracture with routine healing

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Diagnosis Code	Description
M80.069G	Age-related osteoporosis with current pathological fracture, unspecified lower leg, subsequent encounter for fracture with delayed healing
M80.069K	Age-related osteoporosis with current pathological fracture, unspecified lower leg, subsequent encounter for fracture with nonunion
M80.069P	Age-related osteoporosis with current pathological fracture, unspecified lower leg, subsequent encounter for fracture with malunion
M80.069S	Age-related osteoporosis with current pathological fracture, unspecified lower leg, sequela
M80.071A	Age-related osteoporosis with current pathological fracture, right ankle and foot, initial encounter for fracture
M80.071D	Age-related osteoporosis with current pathological fracture, right ankle and foot, subsequent encounter for fracture with routine healing
M80.071G	Age-related osteoporosis with current pathological fracture, right ankle and foot, subsequent encounter for fracture with delayed healing
M80.071K	Age-related osteoporosis with current pathological fracture, right ankle and foot, subsequent encounter for fracture with nonunion
M80.071P	Age-related osteoporosis with current pathological fracture, right ankle and foot, subsequent encounter for fracture with malunion
M80.071S	Age-related osteoporosis with current pathological fracture, right ankle and foot, sequela
M80.072A	Age-related osteoporosis with current pathological fracture, left ankle and foot, initial encounter for fracture
M80.072D	Age-related osteoporosis with current pathological fracture, left ankle and foot, subsequent encounter for fracture with routine healing
M80.072G	Age-related osteoporosis with current pathological fracture, left ankle and foot, subsequent encounter for fracture with delayed healing
M80.072K	Age-related osteoporosis with current pathological fracture, left ankle and foot, subsequent encounter for fracture with nonunion
M80.072P	Age-related osteoporosis with current pathological fracture, left ankle and foot, subsequent encounter for fracture with malunion
M80.072S	Age-related osteoporosis with current pathological fracture, left ankle and foot, sequela
M80.079A	Age-related osteoporosis with current pathological fracture, unspecified ankle and foot, initial encounter for fracture
M80.079D	Age-related osteoporosis with current pathological fracture, unspecified ankle and foot, subsequent encounter for fracture with routine healing
M80.079G	Age-related osteoporosis with current pathological fracture, unspecified ankle and foot, subsequent encounter for fracture with delayed healing
M80.079K	Age-related osteoporosis with current pathological fracture, unspecified ankle and foot, subsequent encounter for fracture with nonunion
M80.079P	Age-related osteoporosis with current pathological fracture, unspecified ankle and foot, subsequent encounter for fracture with malunion
M80.079S	Age-related osteoporosis with current pathological fracture, unspecified ankle and foot, sequela
M80.08XA	Age-related osteoporosis with current pathological fracture, vertebra(e), initial encounter for fracture
M80.08XD	Age-related osteoporosis with current pathological fracture, vertebra(e), subsequent encounter for fracture with routine healing
M80.08XG	Age-related osteoporosis with current pathological fracture, vertebra(e), subsequent encounter for fracture with delayed healing
M80.08XK	Age-related osteoporosis with current pathological fracture, vertebra(e), subsequent encounter for fracture with nonunion
M80.08XP	Age-related osteoporosis with current pathological fracture, vertebra(e), subsequent encounter for fracture with malunion
M80.08XS	Age-related osteoporosis with current pathological fracture, vertebra(e), sequela

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Diagnosis Code	Description
M80.0AXA	Age-related osteoporosis with current pathological fracture, other site, initial encounter for fracture
M80.0AXD	Age-related osteoporosis with current pathological fracture, other site, subsequent encounter for fracture with routine healing
M80.0AXG	Age-related osteoporosis with current pathological fracture, other site, subsequent encounter for fracture with delayed healing
M80.0AXK	Age-related osteoporosis with current pathological fracture, other site, subsequent encounter for fracture with nonunion
M80.0AXP	Age-related osteoporosis with current pathological fracture, other site, subsequent encounter for fracture with malunion
M80.0AXS	Age-related osteoporosis with current pathological fracture, other site, sequela
M80.0B1A	Age-related osteoporosis with current pathological fracture, right pelvis, initial encounter for fracture
M80.0B1D	Age-related osteoporosis with current pathological fracture, right pelvis, subsequent encounter for fracture with routine healing
M80.0B1G	Age-related osteoporosis with current pathological fracture, right pelvis, subsequent encounter for fracture with delayed healing
M80.0B1K	Age-related osteoporosis with current pathological fracture, right pelvis, subsequent encounter for fracture with nonunion
M80.0B1P	Age-related osteoporosis with current pathological fracture, right pelvis, subsequent encounter for fracture with malunion
M80.0B1S	Age-related osteoporosis with current pathological fracture, right pelvis, sequela
M80.0B2A	Age-related osteoporosis with current pathological fracture, left pelvis, initial encounter for fracture
M80.0B2D	Age-related osteoporosis with current pathological fracture, left pelvis, subsequent encounter for fracture with routine healing
M80.0B2G	Age-related osteoporosis with current pathological fracture, left pelvis, subsequent encounter for fracture with delayed healing
M80.0B2K	Age-related osteoporosis with current pathological fracture, left pelvis, subsequent encounter for fracture with nonunion
M80.0B2P	Age-related osteoporosis with current pathological fracture, left pelvis, subsequent encounter for fracture with malunion
M80.0B2S	Age-related osteoporosis with current pathological fracture, left pelvis, sequela
M80.0B9A	Age-related osteoporosis with current pathological fracture, unspecified pelvis, initial encounter for fracture
M80.0B9D	Age-related osteoporosis with current pathological fracture, unspecified pelvis, subsequent encounter for fracture with routine healing
M80.0B9G	Age-related osteoporosis with current pathological fracture, unspecified pelvis, subsequent encounter for fracture with delayed healing
M80.0B9K	Age-related osteoporosis with current pathological fracture, unspecified pelvis, subsequent encounter for fracture with nonunion
M80.0B9P	Age-related osteoporosis with current pathological fracture, unspecified pelvis, subsequent encounter for fracture with malunion
M80.0B9S	Age-related osteoporosis with current pathological fracture, unspecified pelvis, sequela
M80.811A	Other osteoporosis with current pathological fracture, right shoulder, initial encounter for fracture
M80.811D	Other osteoporosis with current pathological fracture, right shoulder, subsequent encounter for fracture with routine healing
M80.811G	Other osteoporosis with current pathological fracture, right shoulder, subsequent encounter for fracture with delayed healing
M80.811K	Other osteoporosis with current pathological fracture, right shoulder, subsequent encounter for fracture with nonunion
M80.811P	Other osteoporosis with current pathological fracture, right shoulder, subsequent encounter for fracture with malunion

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Diagnosis Code	Description
M80.811S	Other osteoporosis with current pathological fracture, right shoulder, sequela
M80.812A	Other osteoporosis with current pathological fracture, left shoulder, initial encounter for fracture
M80.812D	Other osteoporosis with current pathological fracture, left shoulder, subsequent encounter for fracture with routine healing
M80.812G	Other osteoporosis with current pathological fracture, left shoulder, subsequent encounter for fracture with delayed healing
M80.812K	Other osteoporosis with current pathological fracture, left shoulder, subsequent encounter for fracture with nonunion
M80.812P	Other osteoporosis with current pathological fracture, left shoulder, subsequent encounter for fracture with malunion
M80.812S	Other osteoporosis with current pathological fracture, left shoulder, sequela
M80.819A	Other osteoporosis with current pathological fracture, unspecified shoulder, initial encounter for fracture
M80.819D	Other osteoporosis with current pathological fracture, unspecified shoulder, subsequent encounter for fracture with routine healing
M80.819G	Other osteoporosis with current pathological fracture, unspecified shoulder, subsequent encounter for fracture with delayed healing
M80.819K	Other osteoporosis with current pathological fracture, unspecified shoulder, subsequent encounter for fracture with nonunion
M80.819P	Other osteoporosis with current pathological fracture, unspecified shoulder, subsequent encounter for fracture with malunion
M80.819S	Other osteoporosis with current pathological fracture, unspecified shoulder, sequela
M80.821A	Other osteoporosis with current pathological fracture, right humerus, initial encounter for fracture
M80.821D	Other osteoporosis with current pathological fracture, right humerus, subsequent encounter for fracture with routine healing
M80.821G	Other osteoporosis with current pathological fracture, right humerus, subsequent encounter for fracture with delayed healing
M80.821K	Other osteoporosis with current pathological fracture, right humerus, subsequent encounter for fracture with nonunion
M80.821P	Other osteoporosis with current pathological fracture, right humerus, subsequent encounter for fracture with malunion
M80.821S	Other osteoporosis with current pathological fracture, right humerus, sequela
M80.822A	Other osteoporosis with current pathological fracture, left humerus, initial encounter for fracture
M80.822D	Other osteoporosis with current pathological fracture, left humerus, subsequent encounter for fracture with routine healing
M80.822G	Other osteoporosis with current pathological fracture, left humerus, subsequent encounter for fracture with delayed healing
M80.822K	Other osteoporosis with current pathological fracture, left humerus, subsequent encounter for fracture with nonunion
M80.822P	Other osteoporosis with current pathological fracture, left humerus, subsequent encounter for fracture with malunion
M80.822S	Other osteoporosis with current pathological fracture, left humerus, sequela
M80.829A	Other osteoporosis with current pathological fracture, unspecified humerus, initial encounter for fracture
M80.829D	Other osteoporosis with current pathological fracture, unspecified humerus, subsequent encounter for fracture with routine healing
M80.829G	Other osteoporosis with current pathological fracture, unspecified humerus, subsequent encounter for fracture with delayed healing
M80.829K	Other osteoporosis with current pathological fracture, unspecified humerus, subsequent encounter for fracture with nonunion

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Diagnosis Code	Description
M80.829P	Other osteoporosis with current pathological fracture, unspecified humerus, subsequent encounter for fracture with malunion
M80.829S	Other osteoporosis with current pathological fracture, unspecified humerus, sequela
M80.831A	Other osteoporosis with current pathological fracture, right forearm, initial encounter for fracture
M80.831D	Other osteoporosis with current pathological fracture, right forearm, subsequent encounter for fracture with routine healing
M80.831G	Other osteoporosis with current pathological fracture, right forearm, subsequent encounter for fracture with delayed healing
M80.831K	Other osteoporosis with current pathological fracture, right forearm, subsequent encounter for fracture with nonunion
M80.831P	Other osteoporosis with current pathological fracture, right forearm, subsequent encounter for fracture with malunion
M80.831S	Other osteoporosis with current pathological fracture, right forearm, sequela
M80.832A	Other osteoporosis with current pathological fracture, left forearm, initial encounter for fracture
M80.832D	Other osteoporosis with current pathological fracture, left forearm, subsequent encounter for fracture with routine healing
M80.832G	Other osteoporosis with current pathological fracture, left forearm, subsequent encounter for fracture with routine healing
M80.832K	Other osteoporosis with current pathological fracture, left forearm, subsequent encounter for fracture with nonunion
M80.832P	Other osteoporosis with current pathological fracture, left forearm, subsequent encounter for fracture with malunion
M80.832S	Other osteoporosis with current pathological fracture, left forearm, sequela
M80.839A	Other osteoporosis with current pathological fracture, unspecified forearm, initial encounter for fracture
M80.839D	Other osteoporosis with current pathological fracture, unspecified forearm, subsequent encounter for fracture with routine healing
M80.839G	Other osteoporosis with current pathological fracture, unspecified forearm, subsequent encounter for fracture with delayed healing
M80.839K	Other osteoporosis with current pathological fracture, unspecified forearm, subsequent encounter for fracture with nonunion
M80.839P	Other osteoporosis with current pathological fracture, unspecified forearm, subsequent encounter for fracture with malunion
M80.839S	Other osteoporosis with current pathological fracture, unspecified forearm, sequela
M80.841A	Other osteoporosis with current pathological fracture, right hand, initial encounter for fracture
M80.841D	Other osteoporosis with current pathological fracture, right hand, subsequent encounter for fracture with routine healing
M80.841G	Other osteoporosis with current pathological fracture, right hand, subsequent encounter for fracture with delayed healing
M80.841K	Other osteoporosis with current pathological fracture, right hand, subsequent encounter for fracture with nonunion
M80.841P	Other osteoporosis with current pathological fracture, right hand, subsequent encounter for fracture with malunion
M80.841S	Other osteoporosis with current pathological fracture, right hand, sequela
M80.842A	Other osteoporosis with current pathological fracture, left hand, initial encounter for fracture
M80.842D	Other osteoporosis with current pathological fracture, left hand, subsequent encounter for fracture with routine healing
M80.842G	Other osteoporosis with current pathological fracture, left hand, subsequent encounter for fracture with delayed healing

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Diagnosis Code	Description
M80.842K	Other osteoporosis with current pathological fracture, left hand, subsequent encounter for fracture with nonunion
M80.842P	Other osteoporosis with current pathological fracture, left hand, subsequent encounter for fracture with malunion
M80.842S	Other osteoporosis with current pathological fracture, left hand, sequela
M80.849A	Other osteoporosis with current pathological fracture, unspecified hand, initial encounter for fracture
M80.849D	Other osteoporosis with current pathological fracture, unspecified hand, subsequent encounter for fracture with routine healing
M80.849G	Other osteoporosis with current pathological fracture, unspecified hand, subsequent encounter for fracture with delayed healing
M80.849K	Other osteoporosis with current pathological fracture, unspecified hand, subsequent encounter for fracture with nonunion
M80.849P	Other osteoporosis with current pathological fracture, unspecified hand, subsequent encounter for fracture with malunion
M80.849S	Other osteoporosis with current pathological fracture, unspecified hand, sequela
M80.851A	Other osteoporosis with current pathological fracture, right femur, initial encounter for fracture
M80.851D	Other osteoporosis with current pathological fracture, right femur, subsequent encounter for fracture with routine healing
M80.851G	Other osteoporosis with current pathological fracture, right femur, subsequent encounter for fracture with delayed healing
M80.851K	Other osteoporosis with current pathological fracture, right femur, subsequent encounter for fracture with nonunion
M80.851P	Other osteoporosis with current pathological fracture, right femur, subsequent encounter for fracture with malunion
M80.851S	Other osteoporosis with current pathological fracture, right femur, sequela
M80.852A	Other osteoporosis with current pathological fracture, left femur, initial encounter for fracture
M80.852D	Other osteoporosis with current pathological fracture, left femur, subsequent encounter for fracture with routine healing
M80.852G	Other osteoporosis with current pathological fracture, left femur, subsequent encounter for fracture with delayed healing
M80.852K	Other osteoporosis with current pathological fracture, left femur, subsequent encounter for fracture with nonunion
M80.852P	Other osteoporosis with current pathological fracture, left femur, subsequent encounter for fracture with malunion
M80.852S	Other osteoporosis with current pathological fracture, left femur, sequela
M80.859A	Other osteoporosis with current pathological fracture, unspecified femur, initial encounter for fracture
M80.859D	Other osteoporosis with current pathological fracture, unspecified femur, subsequent encounter for fracture with routine healing
M80.859G	Other osteoporosis with current pathological fracture, unspecified femur, subsequent encounter for fracture with delayed healing
M80.859K	Other osteoporosis with current pathological fracture, unspecified femur, subsequent encounter for fracture with nonunion
M80.859P	Other osteoporosis with current pathological fracture, unspecified femur, subsequent encounter for fracture with malunion
M80.859S	Other osteoporosis with current pathological fracture, unspecified femur, sequela
M80.861A	Other osteoporosis with current pathological fracture, right lower leg, initial encounter for fracture
M80.861D	Other osteoporosis with current pathological fracture, right lower leg, subsequent encounter for fracture with routine healing

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Diagnosis Code	Description
M80.861G	Other osteoporosis with current pathological fracture, right lower leg, subsequent encounter for fracture with delayed healing
M80.861K	Other osteoporosis with current pathological fracture, right lower leg, subsequent encounter for fracture with nonunion
M80.861P	Other osteoporosis with current pathological fracture, right lower leg, subsequent encounter for fracture with malunion
M80.861S	Other osteoporosis with current pathological fracture, right lower leg, sequela
M80.862A	Other osteoporosis with current pathological fracture, left lower leg, initial encounter for fracture
M80.862D	Other osteoporosis with current pathological fracture, left lower leg, subsequent encounter for fracture with routine healing
M80.862G	Other osteoporosis with current pathological fracture, left lower leg, subsequent encounter for fracture with delayed healing
M80.862K	Other osteoporosis with current pathological fracture, left lower leg, subsequent encounter for fracture with nonunion
M80.862P	Other osteoporosis with current pathological fracture, left lower leg, subsequent encounter for fracture with malunion
M80.862S	Other osteoporosis with current pathological fracture, left lower leg, sequela
M80.869A	Other osteoporosis with current pathological fracture, unspecified lower leg, initial encounter for fracture
M80.869D	Other osteoporosis with current pathological fracture, unspecified lower leg, subsequent encounter for fracture with routine healing
M80.869G	Other osteoporosis with current pathological fracture, unspecified lower leg, subsequent encounter for fracture with delayed healing
M80.869K	Other osteoporosis with current pathological fracture, unspecified lower leg, subsequent encounter for fracture with nonunion
M80.869P	Other osteoporosis with current pathological fracture, unspecified lower leg, subsequent encounter for fracture with malunion
M80.869S	Other osteoporosis with current pathological fracture, unspecified lower leg, sequela
M80.871A	Other osteoporosis with current pathological fracture, right ankle and foot, initial encounter for fracture
M80.871D	Other osteoporosis with current pathological fracture, right ankle and foot, subsequent encounter for fracture with routine healing
M80.871G	Other osteoporosis with current pathological fracture, right ankle and foot, subsequent encounter for fracture with delayed healing
M80.871K	Other osteoporosis with current pathological fracture, right ankle and foot, subsequent encounter for fracture with nonunion
M80.871P	Other osteoporosis with current pathological fracture, right ankle and foot, subsequent encounter for fracture with malunion
M80.871S	Other osteoporosis with current pathological fracture, right ankle and foot, sequela
M80.872A	Other osteoporosis with current pathological fracture, left ankle and foot, initial encounter for fracture
M80.872D	Other osteoporosis with current pathological fracture, left ankle and foot, subsequent encounter for fracture with routine healing
M80.872G	Other osteoporosis with current pathological fracture, left ankle and foot, subsequent encounter for fracture with delayed healing
M80.872K	Other osteoporosis with current pathological fracture, left ankle and foot, subsequent encounter for fracture with nonunion
M80.872P	Other osteoporosis with current pathological fracture, left ankle and foot, subsequent encounter for fracture with malunion
M80.872S	Other osteoporosis with current pathological fracture, left ankle and foot, sequela

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Diagnosis Code	Description
M80.879A	Other osteoporosis with current pathological fracture, unspecified ankle and foot, initial encounter for fracture
M80.879D	Other osteoporosis with current pathological fracture, unspecified ankle and foot, subsequent encounter for fracture with routine healing
M80.879G	Other osteoporosis with current pathological fracture, unspecified ankle and foot, subsequent encounter for fracture with delayed healing
M80.879K	Other osteoporosis with current pathological fracture, unspecified ankle and foot, subsequent encounter for fracture with nonunion
M80.879P	Other osteoporosis with current pathological fracture, unspecified ankle and foot, subsequent encounter for fracture with malunion
M80.879S	Other osteoporosis with current pathological fracture, unspecified ankle and foot, sequela
M80.88XA	Other osteoporosis with current pathological fracture, vertebra(e), initial encounter for fracture
M80.88XD	Other osteoporosis with current pathological fracture, vertebra(e), subsequent encounter for fracture with routine healing
M80.88XG	Other osteoporosis with current pathological fracture, vertebra(e), subsequent encounter for fracture with delayed healing
M80.88XK	Other osteoporosis with current pathological fracture, vertebra(e), subsequent encounter for fracture with nonunion
M80.88XP	Other osteoporosis with current pathological fracture, vertebra(e), subsequent encounter for fracture with malunion
M80.88XS	Other osteoporosis with current pathological fracture, vertebra(e), sequela
M80.8AXA	Other osteoporosis with current pathological fracture, other site, initial encounter for fracture
M80.8AXD	Other osteoporosis with current pathological fracture, other site, subsequent encounter for fracture with routine healing
M80.8AXG	Other osteoporosis with current pathological fracture, other site, subsequent encounter for fracture with delayed healing
M80.8AXK	Other osteoporosis with current pathological fracture, other site, subsequent encounter for fracture with nonunion
M80.8AXP	Other osteoporosis with current pathological fracture, other site, subsequent encounter for fracture with malunion
M80.8AXS	Other osteoporosis with current pathological fracture, other site, sequela
M80.8B1A	Other osteoporosis with current pathological fracture, right pelvis, initial encounter for fracture
M80.8B1D	Other osteoporosis with current pathological fracture, right pelvis, subsequent encounter for fracture with routine healing
M80.8B1G	Other osteoporosis with current pathological fracture, right pelvis, subsequent encounter for fracture with delayed healing
M80.8B1K	Other osteoporosis with current pathological fracture, right pelvis, subsequent encounter for fracture with nonunion
M80.8B1P	Other osteoporosis with current pathological fracture, right pelvis, subsequent encounter for fracture with malunion
M80.8B1S	Other osteoporosis with current pathological fracture, right pelvis, sequela
M80.8B2A	Other osteoporosis with current pathological fracture, left pelvis, initial encounter for fracture
M80.8B2D	Other osteoporosis with current pathological fracture, left pelvis, subsequent encounter for fracture with routine healing
M80.8B2G	Other osteoporosis with current pathological fracture, left pelvis, subsequent encounter for fracture with delayed healing
M80.8B2K	Other osteoporosis with current pathological fracture, left pelvis, subsequent encounter for fracture with nonunion
M80.8B2P	Other osteoporosis with current pathological fracture, left pelvis, subsequent encounter for fracture with malunion

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Diagnosis Code	Description
M80.8B2S	Other osteoporosis with current pathological fracture, left pelvis, sequela
M80.8B9A	Other osteoporosis with current pathological fracture, unspecified pelvis, initial encounter for fracture
M80.8B9D	Other osteoporosis with current pathological fracture, unspecified pelvis, subsequent encounter for fracture with routine healing
M80.8B9G	Other osteoporosis with current pathological fracture, unspecified pelvis, subsequent encounter for fracture with delayed healing
M80.8B9K	Other osteoporosis with current pathological fracture, unspecified pelvis, subsequent encounter for fracture with nonunion
M80.8B9P	Other osteoporosis with current pathological fracture, unspecified pelvis, subsequent encounter for fracture with malunion
M80.8B9S	Other osteoporosis with current pathological fracture, unspecified pelvis, sequela
M81.0	Age-related osteoporosis without current pathological fracture
M81.8	Other osteoporosis without current pathological fracture
Z78.310	Personal history of (healed) osteoporosis fracture

Background

Osteoporosis is characterized by low bone mass, microarchitectural disruption, and increased skeletal fragility. The World Health Organization (WHO) established diagnostic thresholds for bone mineral density (BMD) by dual-energy x-ray absorptiometry (DXA) according to the standard deviation (SD) difference between a patient's BMD and that of a young adult reference population (T-score). A T-score of -2.5 SD or below is defined as osteoporosis, provided that other causes of low BMD have been ruled out, and a T-score between -1 and -2.5 SD is defined as osteopenia. Additionally, guidelines state that osteoporosis can be diagnosed by one of the following: (1) Presence of fragility fractures in the absence of other metabolic bone disorders; (2) T-score ≤ -2.5 SD in the lumbar spine (antero-posterior), femoral neck, total hip, or one-third radius; or (3) T-score between -1.0 and -2.5 and increased fracture risk using the FRAX® (fracture risk assessment tool) country-specific thresholds. The FRAX tool is designed to assist clinicians in predicting the ten-year probability of hip fracture and 10-year probability of a major osteoporotic fracture (spine, forearm, hip or shoulder fracture) with or without the addition of femoral neck BMD. In the United States, a clinical diagnosis of osteoporosis may be made when the FRAX 10-year probability of major osteoporotic fracture (hip, clinical spine, proximal humerus, or forearm) is greater than or equal to 20 percent or the FRAX 10-year probability of hip fracture is greater than or equal to 3 percent.

Romosozumab is a human monoclonal antibody that binds and inhibits sclerostin. Sclerostin is a negative regulator of bone formation that is secreted by osteocytes, inhibiting Wnt pathway signaling, down-regulating the stimulus for osteoblast development and function. When romosozumab binds to sclerostin, sclerostin cannot bind to the LRP-5 and LRP-6 receptors, preventing its inhibitory effect. The therapeutic effect of sclerostin inhibition promotes the dual effect of increasing bone formation and decreasing bone resorption.

Benefit Considerations

Some Certificates of Coverage allow for coverage of experimental/investigational/unproven treatments for life-threatening illnesses when certain conditions are met. The member specific benefit plan document must be consulted to make coverage decisions for this service. Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances when certain conditions are met. Where such mandates apply, they supersede language in the benefit document or in the medical or drug policy.

Clinical Evidence

Cosman et al. evaluated the efficacy and safety of romosozumab for the treatment of osteoporosis in postmenopausal women. The *Fracture Study in Postmenopausal Women with Osteoporosis* (FRAME) study was an international, randomized, double-blind, placebo-controlled parallel-group trial. The study enrolled 7,180 postmenopausal women (age 55 to 90 years of age) with the diagnosis of osteoporosis, who were randomly assigned, in a 1:1 ratio, to receive romosozumab (n = 3,589) subcutaneously once monthly for 12 months, or placebo (n = 3,591), followed by open label denosumab, 60 mg, once every 6 months for an additional 12 months. The primary end points were the cumulative incidences of new vertebral fractures at 12 months and 24 months. Secondary endpoints included clinical and

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nonvertebral fractures. At 12 months, new vertebral fractures had occurred in 16 of 3,321 patients (0.5%) in the romosozumab group, as compared with 59 of 3,322 (1.8%) in the placebo group (representing a 73% lower risk with romosozumab; p < 0.001). Clinical fractures had occurred in 58 of 3,589 patients (1.6%) in the romosozumab group, as compared with 90 of 3,591 (2.5%) in the placebo group (a 36% lower risk with romosozumab; p = 0.008). Nonvertebral fractures had occurred in 56 of 3,589 patients (1.6%) in the romosozumab group and in 75 of 3,591 (2.1%) in the placebo group (p = 0.10). At 24 months, the rates of vertebral fractures were significantly lower in the romosozumab group than in the placebo group after each group made the transition to denosumab [0.6% (21 of 3,325 patients) in the romosozumab group vs 2.5% (84 of 3,327) in the placebo group, a 75% lower risk with romosozumab; p < 0.001]. Adverse events, including instances of hyperostosis, cardiovascular events, osteoarthritis, and cancer, appeared to be balanced between the groups. One atypical femoral fracture and two cases of osteonecrosis of the jaw were observed in the romosozumab group. The authors concluded that in postmenopausal women with osteoporosis, romosozumab was associated with a lower risk of vertebral fracture than placebo at 12 months and, after the transition to denosumab, at 24 months. The lower risk of clinical fracture that was seen with romosozumab was evident at 1 year.

In the FRAME extension study, eligible women continued to receive denosumab, every 6 months for an additional 12 months. Of 7,180 women enrolled, 5,743 (80%) completed the 36-month study (2,851 romosozumab-to-denosumab; 2,892 placebo-to-denosumab). Through 36 months, fracture risk was reduced in subjects receiving romosozumab versus placebo for 12 months followed by 24 months of denosumab for both groups: new vertebral fracture [relative risk reduction (RRR), 66%; incidence, 1.0% versus 2.8%; p < 0.001], clinical fracture (RRR, 27%; incidence, 4.0% versus 5.5%; p = 0.004), and nonvertebral fracture (RRR, 21%; incidence, 3.9% versus 4.9%; p = 0.039). BMD continued to increase for the 2 years with denosumab treatment in both arms. The BMD difference achieved through 12 months of romosozumab treatment versus placebo was maintained through the follow-up period when both treatment arms received denosumab. The authors concluded that, in postmenopausal women with osteoporosis, 12 months of romosozumab led to persistent fracture reduction benefit and ongoing BMD gains when followed by 24 months of denosumab.

In a phase 3, multicenter, international, randomized, double-blind trial, Saag et al. investigated the safety and efficacy of romosozumab in postmenopausal women with osteoporosis and a fragility fracture. The study enrolled 4,093 women, randomly assigned, in a 1:1 ratio, to receive monthly romosozumab 210 mg subcutaneously or weekly oral alendronate for 12 months, followed by open-label alendronate in both groups. The primary end points were the cumulative incidence of new vertebral fracture at 23 months and the cumulative incidence of clinical fracture at the time of the primary analysis. Secondary end points included incidences of nonvertebral and hip fracture at the time of the primary analysis. At 24 months in the romosozumab-to-alendronate group, a 48% lower risk of new vertebral fractures was observed [6.2% (127 of 2,046 patients)], than in the alendronate-to-alendronate group [11.9% (243 of 2,047 patients) (p < 0.001)]. Clinical fractures occurred in 198 of 2,046 patients (9.7%) in the romosozumab-to-alendronate group versus 266 of 2,047 patients (13.0%) in the alendronate-to-alendronate group, representing a 27% lower risk with romosozumab (p < 0.001). The risk of nonvertebral fractures was lower by 19% in the romosozumab-to-alendronate group than in the alendronate-to-alendronate group [178 of 2,046 patients (8.7%) vs 217 of 2,047 patients (10.6%); p = 0.04], and the risk of hip fracture was lower by 38% [41 of 2,046 patients (2.0%) vs 66 of 2,047 patients (3.2%); p = 0.02]. Overall adverse events and serious adverse events were similar between the two groups. During year 1, serious cardiovascular adverse events were observed more often with romosozumab than with alendronate [50 of 2,040 patients (2.5%) vs 38 of 2,014 patients (1.9%)]. During the open-label alendronate period, osteonecrosis of the jaw (1 event each in the romosozumab-to-alendronate and alendronate-to-alendronate groups) and atypical femoral fracture (2 events and 4 events, respectively) were observed. The authors concluded that for postmenopausal women with osteoporosis who were at high risk for fracture, romosozumab treatment for 12 months followed by alendronate resulted in a significantly lower risk of fracture than alendronate alone.

Langdahl et al. evaluated the safety and efficacy of romosozumab versus teriparatide on bone mineral density (BMD) in women with postmenopausal osteoporosis after transitioning from bisphosphonate therapy. The randomized, phase 3, open-label, active-controlled enrolled postmenopausal osteoporosis (n = 436; age 55 through 90 years old) with previous therapy on oral bisphosphonate for at least 3 years before screening and alendronate the year before screening. BMD T-score screening was performed. Women were randomly assigned (1:1 ratio) to receive either romosozumab 210 mg subcutaneously (n = 218), monthly, or subcutaneous teriparatide 20µg (n = 218) once daily. The primary endpoint was percentage change from baseline in areal BMD by dual-energy x-ray absorptiometry at the total hip through month 12 (mean of months 6 and 12). All randomized patients with a baseline measurement and at least one post-baseline measurement were included in the efficacy analysis. Through 12 months, the mean percentage change from baseline in total hip areal BMD was 2.6% (95% CI 2.2 to 3.0) in the romosozumab group and -0.6% (-1.0 to -0.2) in the teriparatide group; difference 3.2% (95% CI 2.7 to 3.8; p < 0.0001). The frequency of adverse events was generally balanced between treatment groups. The most frequently reported adverse events were nasopharyngitis [28 (13%) of 218 in the romosozumab group vs 22 (10%) of 214 in the teriparatide group], hypercalcemia [two (< 1%) vs 22 (10%)], and arthralgia [22 (10%) vs 13 (6%)]. Serious adverse events were reported in 17 (8%) patients on romosozumab and in 23 (11%) on

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teriparatide; none were treatment related. There were six (3%) patients in the romosozumab group compared with 12 (6%) in the teriparatide group with adverse events leading to investigational product withdrawal. The authors concluded that patients transitioning from bisphosphonates to romosozumab experienced increases in hip BMD that were not observed with teriparatide.

McClung et al. reported the results of the study extension of the randomized, double-blind, phase 2, parallel group study evaluating 24 months of treatment with romosozumab, discontinuation of romosozumab, alendronate followed by romosozumab, and romosozumab followed by denosumab. The study enrolled postmenopausal women aged 55 to 85 years with a lumbar spine (LS), total hip (TH), or femoral neck T-score ≤ -2.0 and ≥ -3.5 were enrolled and randomly assigned to placebo, one of five romosozumab regimens (70 mg, 140 mg, 210 mg monthly; 140 mg every 3 months; 210 mg every 3 months) for 24 months, or open-label alendronate for 12 months followed by romosozumab 140 mg monthly for 12 months. Eligible participants were then re-randomized 1:1 within original treatment groups to placebo or denosumab 60 mg every 6 months for an additional 12 months. Percentage change from baseline in BMD and bone turnover markers (BTMs) at months 24 and 36 and safety were evaluated. Of 364 participants initially randomized to romosozumab, placebo, or alendronate, 315 completed 24 months of treatment and 248 completed the extension. Romosozumab markedly increased LS and TH BMD through month 24, with largest gains observed with romosozumab 210 mg monthly (LS = 15.1%; TH = 5.4%). Women receiving romosozumab who transitioned to denosumab continued to accrue BMD, whereas BMD returned toward pretreatment levels with placebo. Romosozumab 210 mg monthly caused bone formation marker P1NP to initially increase after treatment initiation and gradually decrease to below baseline by month 12, remaining below baseline through month 24; bone resorption marker β-CTX rapidly decreased after treatment, remaining below baseline through month 24. Continuing romosozumab treatment for a second year resulted in further increases in BMD; however, these increments were smaller than those observed during the first year, consistent with the BTMs. Although there was incremental benefit in the second year of treatment, the greatest benefit of romosozumab was achieved in the first year of therapy.

Professional Societies

American Association of Clinical Endocrinologists/American College of Endocrinology

In 2020, the American Association of Clinical Endocrinologists/American College of Endocrinology published an update to the *Guidelines for Diagnosis and Treatment of Postmenopausal Osteoporosis*, which recommends abaloparatide, denosumab, romosozumab, teriparatide, and zoledronate be considered for patients unable to use oral therapy and as initial therapy for patients at very high fracture risk. The guidelines define high fracture risk as the following: recent fracture (e.g., within the past 12 months), fractures while on approved osteoporosis therapy, multiple fractures, fractures while on drugs causing skeletal harm (e.g., long-term glucocorticoids), very low T-score (e.g., less than -3.0), high risk for falls or history of injurious falls, and very high fracture probability by FRAX® (fracture risk assessment tool) (e.g., major osteoporosis fracture > 30%, hip fracture > 4.5%) or other validated fracture risk algorithm to be at very high fracture risk.

Endocrine Society

The Endocrine Society 2020 update to the *Pharmacological Management of Osteoporosis in Postmenopausal Women Guideline* recommends romosozumab treatment for up to 1 year to reduce vertebral, hip, and nonvertebral fractures in postmenopausal women with osteoporosis at very high risk of fracture. Patients at high risk of fracture include those with severe osteoporosis (i.e., low T-score < -2.5 and fractures) or multiple vertebral fractures. Additionally, in postmenopausal women with osteoporosis who have completed a course of romosozumab treatment, antiresorptive osteoporosis therapies are recommended to maintain bone mineral density gains and reduce fracture risk.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Evenity (romosozumab-aqqg) is a sclerostin inhibitor indicated for the 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.

The anabolic effect of Evenity wanes after 12 monthly doses of therapy. Therefore, the duration of Evenity use should be limited to 12 monthly doses. If osteoporosis therapy remains warranted, continued therapy with an anti-resorptive agent should be considered.

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Policy History/Revision Information

Date	Summary of Changes

11/01/2026	**Template Update**
	• Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans
	• Added *Application* section to indicate this policy applies to:
	  ○ UnitedHealthcare Commercial benefit plans
	  ○ Individual Exchange benefit plans
	Supporting Information
	• Updated *References* section to reflect the most current information
	• Archived previous policy versions 2025D0080L and IEXD0080.11

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its policies and guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

This Medical Benefit Drug Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Medical Benefit Drug Policies are intended to be used in connection with

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the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

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