ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM

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KATIE HOBBS
GOVERNOR

VIRGINIA ROUNTREE
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Pharmacy and Therapeutics Committee

January 13, 2026 - 12:00PM – 5:00PM

Written Testimony

Name*
Debra Gibson
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Check here if you are representing or speaking on behalf of any company/organization.
Representation
Check here if you are a private practice physician not affiliated with any manufacturer/organization.
Please check the box of the statement that best applies*
I do not have a current or recent (within the last 24 months) financial arrangement or affiliation with any organization that may have a direct interest in the business before the AHCCCS P&T Committee.
If yes, name organizations and roles:
Summary of Testimony *
My name is Debra Gibson, a Psychiatric Mental Health Nurse Practitioner, specializing in Psychiatry for over 16 years. I am writing to request an update to your formulary to include Spravato (esketamine nasal spray) as a monotherapy treatment option for treatment-resistant depression (TRD) in adults. This request is supported by recent FDA approval, as of January 21, 2025, with clinical evidence demonstrating significant therapeutic benefit for patient's who have failed more than 2 antidepressants and who cannot tolerate or do not respond to oral antidepressants. I have had clients who see significant improvement in their depression in as little as 2 weeks after starting Spravato, and continue to have functional improvement and minimal psychiatric decompensation with ongoing Spravato treatment. I have had challenges explaining to prior authorization staff that Spravato is FDA approved as monotherapy, and not requiring a conjunctive antidepressant, as they report the formulary does not indicate Spravato as monotherapy. I ask that you please update your policy for Spravato's FDA label.
Drug/product*
Spravato / Esketamine 56mg and 84mg
Therapeutic Drug Class*

N-methyl-D-aspartate (NMDA) receptor antagonist and a Schedule III controlled substance
Testimony Format **
Written

Name*
Jeffrey Baldwin
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Amgen
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Check here if you are representing or speaking on behalf of any company/organization.
Representation
Check here if you are a private practice physician not affiliated with any manufacturer/organization.
Please check the box of the statement that best applies*
I have a financial interest, affiliation or am employed by an organization that may have a direct interest in the business before the AHCCCS P&T Committee.
If yes, name organizations and roles:
Amgen, Inc.
Sr. Manager, Medical Value & Population Health
Summary of Testimony *
EVENITY® (romosozumab) is indicated for the treatment of osteoporosis in postmenopausal women (PMO) 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.(1)
EVENITY® may increase the risk of myocardial infarction, stroke and cardiovascular death. EVENITY® should not be initiated in patients who have had a myocardial infarction or stroke within the preceding year. Consider whether the benefits outweigh the risks in patients with other cardiovascular risk factors. Monitor for signs and symptoms of myocardial infarction and stroke and instruct patients to seek prompt medical attention if symptoms occur. If a patient experiences a myocardial infarction or stroke during therapy, EVENITY® should be discontinued.
Please see full Prescribing Information for additional Important Safety Information.
Evenity is a monoclonal antibody that inhibits sclerostin and is the only bone-forming agent that exerts a dual effect, increasing bone formation and, to a lesser extent, decreasing bone resorption. EVENITY® improves bone strength and increases bone mineral density (BMD) at the hip and vertebrae, without increases in cortical porosity, and reduces vertebral fracture risk within 1 year.(2-6) The recommended dosage is 210 mg administered subcutaneously once monthly in the abdomen, thigh, or upper arm, for a total treatment duration of 12 months.(1)
The American Society of Bone Mineral Research (ASBMR) and the Bone Health and Osteoporosis Foundation (BHOF) developed a position statement on a goal-directed approach to management of osteoporosis in 2024. This approach ensures selection of the most appropriate initial treatment and emphasizes the importance of treatment sequence to maximize BMD gains. Osteoanabolics like EVENITY® are recommended as initial therapy for patients at very high risk for

fracture, such as those with a very low T-score, a recent fracture (within 2 years), or a history of a vertebral, pelvic, and hip fracture.(7)

Amgen respectfully asks the P&T Committee to revise its existing policy, to enable patients at very high risk for fracture to receive EVENITY® consistent with its approved indication without requiring step therapy with teriparatide. We base our request on the phase 3 randomized open label study which compared 12 months of EVENITY® vs teriparatide in women with PMO transitioning from bisphosphonate therapy. Compared to teriparatide, EVENITY® significantly increased BMD as early as 6 months and at 1 year at all key sites. EVENITY® significantly increased percent change BMD from baseline compared to teriparatide at 12 months at the Total Hip (2.9% vs -0.5%, p<0.0001), Lumbar Spine (9.8% vs 5.4%, p<0.0001), and Femoral Neck (3.2% vs -0.2%, p<0.0001).(5)
Serious adverse events were reported in 17 (8%) patients on EVENITY® and in 23 (11%) on teriparatide; none were judged treatment related. There were six (3%) patients in the EVENITY® group compared with 12 (6%) in the teriparatide group with adverse events leading to investigational product withdrawal.5 For additional safety information, please see Evenity® Full Prescribing Information including Boxed Warning.(1) Unlike PTH analogues, which require daily injections for 18–24 months,(8,9) EVENITY® is administered once monthly and limited to 12 doses.(1)
In the FRAME Extension trial, women who received either EVENITY® or placebo for 12 months followed by open-label denosumab for 12 months received an additional 12 months of denosumab treatment during the extension period. Through 36 months, new vertebral fracture risk was reduced in patients who had initially received EVENITY® vs placebo (66% RRR; 1.8% ARR).10 The final (36 month) analysis was exploratory, and no statistical conclusions can be drawn. BMD at the lumbar spine, total hip, and femoral neck continued to increase for the 24 months of denosumab treatment in both arms, and the increased BMD seen with 12 months of EVENITY® treatment was maintained throughout the follow-up period.(10)
In summary, we respectfully request the P&T Committee to consider revisions to the EVENITY® to allow access to EVENITY® as an option for post-menopausal women at very high risk for fracture (very low T-score, recent fracture, or a history of vertebral, pelvic and hip fracture) without requiring a step through teriparatide or denosumab. Further and as previously discussed, medical societies include EVENITY® as an initial recommended treatment option in women with PMO at very high risk of fracture or unable to use oral therapy.

References
1. EVENITY® (romosozumab) Prescribing Information. 2.Cosman F, Crittenden DB, Adachi JD, et al. N Engl J Med. 2016;375:1532-1543. 3. Saag KG, et al. N Engl J Med. 2017;377:1417-1427. 4. McClung MR, et al. N Engl J Med. 2014;370:412-420. 5. Langdahl BL, et al. Lancet. 2017;390:1585-1594. 6. Keaveny TM, et al. J Bone Miner Res. 2017;32:1956-1962. 7. Cosman F, et al. J Bone Miner Res. 2024;39:1393-1405. 8. Tymlos® (abaloparatide) Prescribing Information. 9. FORTEO® (teriparatide) Prescribing Information. 10. Lewiecki EM et al. J Bone Miner Res. 2019;34:419-428.
Drug/product*
EVENITY (romosozumab)
Therapeutic Drug Class*
Bone Resorption Suppression and Related Agents
Testimony Format **
Written

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Check here if you are representing or speaking on behalf of any company/organization.
Check here if you are a private practice physician not affiliated with any manufacturer/organization.
Affiliation
Please check the box of the statement that best applies*
I do not have a current or recent (within the last 24 months) financial arrangement or affiliation with any organization that may have a direct interest in the business before the AHCCCS P&T Committee.
If yes, name organizations and roles:
Summary of Testimony *
Fensolvi delivers the 30-year reliability of leuprolide acetate with effective suppression for precocious puberty. Fensolvi is the only 6-month subcutaneous injection of leuprolide acetate on the market. Fensolvi has the smallest injection volume at 0.375 ml and has the shortest needle at only 5/8 inch. Fensolvi has proven to be effective and well-tolerated in my practice with my patients. I feel it is important to have options available for my medicaid patients.
Drug/product*
Fensolvi
Therapeutic Drug Class*
GnRH Anaology
Testimony Format **
Written