

UMR Medical Policy Update Bulletin: January 2025

In This Issue

Take Note

| | Page |
|--------------------------------------|------|
| • Annual CPT/HCPCS Code Updates..... | 2 |

Medical Policy Updates

Updated

| | |
|---|---|
| • Interspinous Fusion and Decompression Devices – Effective Feb. 1, 2025..... | 5 |
| • Obstetrical Ultrasound – Effective Jan. 1, 2025..... | 5 |
| • Vertebral Body Tethering for Scoliosis – Effective Feb. 1, 2025..... | 5 |

Revised

| | |
|--|----|
| • Airway Clearance Devices – Effective Mar. 1, 2025..... | 5 |
| • FDA Cleared or Approved Companion Diagnostic Testing – Effective Mar. 1, 2025..... | 6 |
| • Hysterectomy – Effective Mar. 1, 2025..... | 9 |
| • Obstructive and Central Sleep Apnea Treatment – Effective Feb. 1, 2025..... | 10 |
| • Radiation Therapy: Fractionation, Image-Guidance, and Special Services – Effective Feb. 1, 2025..... | 13 |
| • Stereotactic Body Radiation Therapy and Stereotactic Radiosurgery – Effective Feb. 1, 2025..... | 18 |
| • Total Artificial Disc Replacement for the Spine – Effective Feb. 1, 2025..... | 21 |
| • Treatment of Temporomandibular Joint Disorders – Effective Feb. 1, 2025..... | 21 |
| • Vagus and External Trigeminal Nerve Stimulation – Effective Feb. 1, 2025..... | 22 |

Medical Benefit Drug Policy Updates

Revised

| | |
|---|----|
| • Adakveo® (Crizanlizumab-Tmca) – Effective Feb. 1, 2025..... | 24 |
| • Cimzia® (Certolizumab Pegol) – Effective Feb. 1, 2025..... | 25 |
| • Ophthalmologic Vascular Endothelial Growth Factor (VEGF) Inhibitors – Effective Feb. 1, 2025..... | 27 |
| • Provider Administered Drugs – Site of Care – Effective Feb. 1, 2025..... | 32 |
| • Roctavian® (Valoctocogene Roxaparvovec-Rvox) – Effective Feb. 1, 2025..... | 37 |

Take Note

Annual CPT/HCPCS Code Updates

Effective **Jan. 1, 2025**, the following Medical Policies and Medical Benefit Drug Policies have been updated to reflect the 2025 Current Procedural Terminology (CPT®) and Healthcare Common Procedure Coding System (HCPCS) code additions, revisions, and deletions. Refer to the following sources for information on the code updates:

- [American Medical Association: Current Procedural Terminology: CPT®](#)
- [Centers for Medicare & Medicaid Services: Healthcare Common Procedure Coding System \(HCPCS\) Quarterly Update](#)

| Policy Title | Policy Type | Summary of Changes |
|--|-----------------------------|--|
| Airway Clearance Devices | Medical Policy | <ul style="list-style-type: none"> • Revised description for HCPCS code E0483 |
| Cardiac Event Monitoring | Medical Policy | <p>Cardiac Self-Monitoring Devices</p> <ul style="list-style-type: none"> • Added CPT code 0902T |
| Category III Codes | Medical Policy | <ul style="list-style-type: none"> • Added CPT codes 0903T, 0904T, 0905T, 0906T, 0907T, 0908T, 0909T, 0910T, 0911T, 0912T, 0915T, 0916T, 0917T, 0918T, 0919T, 0920T, 0921T, 0922T, 0923T, 0924T, 0925T, 0926T, 0927T, 0928T, 0929T, 0930T, 0931T, 0933T, 0934T, 0935T, 0936T, 0941T, 0942T, 0943T, 0944T, 0946T, and 0947T • Removed CPT codes 0564T, 0615T, 0616T, 0617T, and 0618T |
| Catheter Ablation for Atrial Fibrillation | Medical Policy | <ul style="list-style-type: none"> • Revised description for CPT code 93656 |
| Complement Inhibitors (PiaSky®, Soliris®, & Ultomiris®) | Medical Benefit Drug Policy | <ul style="list-style-type: none"> • Replaced HCPCS codes C9399, J3490, and J3590 with J1307 |
| Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes | Medical Policy | <ul style="list-style-type: none"> • Added HCPCS codes G0564 and G0565 |
| Cosmetic and Reconstructive Procedures | Medical Policy | <ul style="list-style-type: none"> • Removed CPT code 15819 |
| Gender Dysphoria Treatment | Medical Policy | <ul style="list-style-type: none"> • Removed CPT code 15819 |
| Gene Therapies for Hemophilia B | Medical Benefit Drug Policy | <ul style="list-style-type: none"> • Removed HCPCS code C9172 • Replaced HCPCS codes J3490 and J3590 with J1414 |
| Genetic Testing for Hereditary Cancer | Medical Policy | <ul style="list-style-type: none"> • Removed CPT codes 81433, 81436, and 81438 • Revised description for CPT codes 81432, 81435, and 81437 |
| Immune Globulin (IVIG and SCIG) | Medical Benefit Drug Policy | <ul style="list-style-type: none"> • Added HCPCS code J1552 |
| Mechanical Stretching Devices | Medical Policy | <ul style="list-style-type: none"> • Added HCPCS codes E1803, E1804, E1807, E1808, E1813, E1814, E1822, E1823, E1826, E1827, E1828, and E1829 • Revised description for HCPCS codes E1800, E1810, E1815, and E1830 |

Take Note

| Policy Title | Policy Type | Summary of Changes |
|---|----------------|--|
| Molecular Oncology Testing for Hematologic Cancer Diagnosis, Prognosis, and Treatment Decisions | Medical Policy | <ul style="list-style-type: none"> Added CPT code 81195 |
| Molecular Oncology Testing for Solid Tumor Cancer Diagnosis, Prognosis, and Treatment Decisions | Medical Policy | <ul style="list-style-type: none"> Added CPT codes 0523U and 0530U Removed CPT code 0428U |
| Neurophysiologic Testing and Monitoring | Medical Policy | <ul style="list-style-type: none"> Removed CPT code 96003 |
| Omnibus Codes | Medical Policy | <p>Eye-Movement Analysis Without Spatial Calibration</p> <ul style="list-style-type: none"> Revised description for CPT code 0615T <p>Fallopian Tube Occlusion With a Degradable Biopolymer Implant</p> <ul style="list-style-type: none"> Replaced CPT code 0567T with 58999 <p>Implantable Wireless Pulmonary Artery Pressure (PAP) Sensor</p> <ul style="list-style-type: none"> Added HCPCS code G0555 <p>Insertion of Iris Prosthesis</p> <ul style="list-style-type: none"> Added CPT code 66683 Removed CPT codes 0616T, 0617T, and 0618T <p>Magnetic Resonance Image Guided High Intensity Focused Ultrasound (MRgFUS) Intracranial Stereotactic Ablation</p> <ul style="list-style-type: none"> Added CPT code 61715 Removed CPT code 0398T <p>Sonosalpingography</p> <ul style="list-style-type: none"> Replaced CPT code 0568T with 58999 |
| Pharmacogenetic Panel Testing | Medical Policy | <ul style="list-style-type: none"> Removed CPT codes 0380U and 0456U |
| Preventive Care Services | Medical Policy | <p>Preventive Care Services</p> <p>Genetic Counseling and Evaluation for BRCA Testing; and BRCA Lab Screening</p> <ul style="list-style-type: none"> Added CPT code 96041 Removed CPT code 96040 <p>Cervical Cancer Screening</p> <p>Human Papillomavirus DNA Testing (HPV)</p> <ul style="list-style-type: none"> Added CPT code 87626 Removed CPT code 0500T <p>Statin Use for the Primary Prevention of Cardiovascular Disease in Adults – Cholesterol Screening (Lipid Disorders Screening) and Healthy Diet and</p> |

Take Note

| Policy Title | Policy Type | Summary of Changes |
|---|----------------|---|
| Preventive Care Services (continued) | Medical Policy | <p><i>Physical Activity for Cardiovascular Disease Prevention in Adults with Cardiovascular Risk Factors: Behavioral Counseling Interventions</i> <i>ASCVD Risk Assessment and Risk Management Services</i></p> <ul style="list-style-type: none"> Added HCPCS codes G0537 and G0538 <p><i>Colorectal Cancer Screening</i> <i>Fecal DNA</i></p> <ul style="list-style-type: none"> Added CPT code 0464U <p><i>Screening for Lung Cancer with Low-Dose Computed Tomography</i></p> <ul style="list-style-type: none"> Removed HCPCS codes G9458, G9459, and G9460 <p><i>Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis</i></p> <ul style="list-style-type: none"> Added HCPCS code Q0521 Removed HCPCS codes Q0516, Q0517, Q0518, Q0519, and Q0520 |
| Prostate Surgeries and Interventions | Medical Policy | <ul style="list-style-type: none"> Added CPT codes 53865 and 53866 |
| Stereotactic Body Radiation Therapy and Stereotactic Radiosurgery | Medical Policy | <ul style="list-style-type: none"> Added HCPCS code G0563 |

Medical Policy Updates

| Updated | | | |
|---|----------------|---|--|
| Policy Title | Effective Date | Summary of Changes | |
| Interspinous Fusion and Decompression Devices | Feb. 1, 2025 | <p>Coverage Rationale</p> <ul style="list-style-type: none"> Replaced language indicating: <ul style="list-style-type: none"> “Interspinous <i>bony fusion</i> devices are proven and medically necessary” with “Interspinous <i>Fixation (fusion)</i> Devices are proven and medically necessary” “Interspinous decompression systems (without fusion) for the treatment of spine pain or spinal stenosis are unproven and not medically necessary” with “interspinous decompression <i>and Interlaminar Stabilization</i> systems (without fusion) for the treatment of spine pain or spinal stenosis are unproven and not medically necessary” <p>Applicable Codes</p> <ul style="list-style-type: none"> Removed HCPCS code C1821 <p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>Clinical Evidence</i> and <i>References</i> sections to reflect the most current information | |
| Obstetrical Ultrasound | Jan. 1, 2025 | <p>Definitions</p> <ul style="list-style-type: none"> Updated definition of “Observation Care” <p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>Clinical Evidence</i> and <i>References</i> sections to reflect the most current information | |
| Vertebral Body Tethering for Scoliosis | Feb. 1, 2025 | <p>Applicable Codes</p> <ul style="list-style-type: none"> Added CPT codes 0790T and 22838 Revised description for CPT codes 0657T and 22387 <p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>Description of Services</i>, <i>Clinical Evidence</i>, <i>FDA</i>, and <i>References</i> sections to reflect the most current information | |
| Revised | | | |
| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
| Airway Clearance Devices | Mar. 1, 2025 | <p>Coverage Rationale</p> <ul style="list-style-type: none"> Added language to indicate combination continuous positive expiratory pressure (CPEP), continuous high frequency oscillation (CHFO), and nebulized medication therapy devices for oscillation and lung expansion (OLE) are considered unproven and not medically necessary | <p>A two-month rental trial of a high-frequency chest wall oscillation (HFCWO) system is proven and medically necessary in the management of neuromuscular diseases, Bronchiectasis and cystic fibrosis when criteria have been met. HFCWO is unproven and not medically necessary for any other condition due to insufficient evidence of efficacy. For additional medical necessity clinical coverage criteria, refer to the InterQual® Client Defined, CP: Durable Medical Equipment, Secretion Clearance Devices (Custom) – UHG.</p> <p>Click here to view the InterQual® criteria.</p> |

Medical Policy Updates

| Revised | | | |
|--|----------------|--|---|
| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
| Airway Clearance Devices (continued) | Mar. 1, 2025 | <p>Applicable Codes</p> <ul style="list-style-type: none"> Added HCPCS codes A7021 and E0469 <p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>Clinical Evidence</i> and <i>References</i> sections to reflect the most current information | <p>For all indications for a high-frequency chest wall oscillation system, an initial two-month rental trial must confirm individual tolerance and efficacy in using the device before ongoing medical necessity can be determined. For medical necessity determination to address ongoing use, refer to the InterQual Criteria.</p> <p>Combination continuous positive expiratory pressure (CPEP), continuous high frequency oscillation (CHFO), and nebulized medication therapy devices for oscillation and lung expansion (OLE) are considered unproven and not medically necessary.</p> <p>Intrapulmonary percussive ventilation (IPV) devices for home use are considered unproven and not medically necessary.</p> |
| FDA Cleared or Approved Companion Diagnostic Testing | Mar. 1, 2025 | <p>Title Change</p> <ul style="list-style-type: none"> Previously titled <i>Molecular Oncology Companion Diagnostic Testing</i> <p>Coverage Rationale</p> <ul style="list-style-type: none"> Revised coverage guidelines to indicate: <ul style="list-style-type: none"> Companion Diagnostic Tests are considered proven and medically necessary when the oncology indication has a corresponding diagnostic test and biomarker on the U.S. Food and Drug Administration (FDA) List of Cleared or Approved Companion Diagnostic Devices and all of the following criteria are met: <ul style="list-style-type: none"> The Companion Diagnostic Test must align with the drug, FDA approved indication, and appropriate tissue/ specimen in the FDA List | <p>Companion Diagnostic Tests are considered proven and medically necessary when the oncology indication has a corresponding diagnostic test and biomarker on the U.S. Food and Drug Administration (FDA) List of Cleared or Approved Companion Diagnostic Devices and all of the following criteria are met:</p> <ul style="list-style-type: none"> The Companion Diagnostic Test must align with the drug, FDA-approved indication, and appropriate tissue/specimen in the FDA List of Cleared or Approved Companion Diagnostic Devices; and The use of the Companion Diagnostic Test must be consistent with the label for the Companion Diagnostic-associated drug indicated by requesting provider <p>Repeat Companion Diagnostic Testing on a new tissue or Liquid Biopsy specimen for the purpose of assisting with therapy selection is considered proven and medically necessary up to three times annually when the criteria above for Companion Diagnostic Tests are met and one of the following:</p> <ul style="list-style-type: none"> The individual is experiencing disease recurrence; or The individual's cancer has progressed or did not respond to the most recent systemic therapy <p>Concurrent tissue-based and Liquid Biopsy Companion Diagnostic Testing (ordered within 30 days of each other) is considered proven and medically necessary for the following cancer types when the</p> |

Medical Policy Updates

| Revised | | | |
|--|----------------|---|--|
| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
| FDA Cleared or Approved Companion Diagnostic Testing (continued) | Mar. 1, 2025 | <p style="color: #0070c0;">of Cleared or Approved Companion Diagnostic Devices; and</p> <ul style="list-style-type: none"> ▪ The use of the Companion Diagnostic Test must be consistent with the label for the Companion Diagnostic-associated drug indicated by requesting provider ○ Repeat Companion Diagnostic Testing on a new tissue or Liquid Biopsy specimen for the purpose of assisting with therapy selection is considered proven and medically necessary up to three times annually when the criteria above for Companion Diagnostic Tests are met and one of the following: <ul style="list-style-type: none"> ▪ The individual is experiencing disease recurrence; or ▪ The individual’s cancer has progressed or did not respond to the most recent systemic therapy ○ Concurrent tissue-based and Liquid Biopsy Companion Diagnostic Testing (ordered within 30 days of each other) is considered proven and medically necessary for the following cancer types when the criteria above for | <p>criteria above for Companion Diagnostic Tests are met:</p> <ul style="list-style-type: none"> • Advanced or metastatic (stage IV) breast cancer • Advanced or metastatic (stage IV) non-small cell lung cancer <p>Note: If no cancer/diagnostic test match is found on the U.S. Food and Drug Administration (FDA) List of Cleared or Approved Companion Diagnostic Devices, refer to the Medical Policy titled Molecular Oncology Testing for Solid Tumor Cancer Diagnosis, Prognosis, and Treatment Decisions or Molecular Oncology Testing for Hematologic Cancer Diagnosis, Prognosis, and Treatment Decisions.</p> |

Medical Policy Updates

| Revised | | | |
|--|-----------------------|--|---------------------------|
| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
| FDA Cleared or Approved Companion Diagnostic Testing (continued) | Mar. 1, 2025 | <p>Companion Diagnostic Tests are met:</p> <ul style="list-style-type: none"> ▪ Advanced or metastatic (stage IV) breast cancer ▪ Advanced or metastatic (stage IV) non-small cell lung cancer <p>○ If no cancer/diagnostic test match is found on the U.S. Food and Drug Administration (FDA) List of Cleared or Approved Companion Diagnostic Devices, refer to the following Medical Policies:</p> <ul style="list-style-type: none"> ▪ <i>Molecular Oncology Testing for Solid Tumor Cancer Diagnosis, Prognosis, and Treatment Decisions</i> ▪ <i>Molecular Oncology Testing for Hematologic Cancer Diagnosis, Prognosis, and Treatment Decisions</i> <p>Medical Records Documentation Used for Reviews</p> <ul style="list-style-type: none"> ● Updated list of Medical Records Documentation Used for Reviews: <ul style="list-style-type: none"> ○ Added: <ul style="list-style-type: none"> ▪ Intended drug for which the Companion Diagnostic Test is approved ▪ Diagnosis and clinical stage ▪ Intended tissue source | |

Medical Policy Updates

| Revised | | | |
|--|----------------|---|---|
| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
| FDA Cleared or Approved Companion Diagnostic Testing (continued) | Mar. 1, 2025 | <ul style="list-style-type: none"> ▪ Line of therapy being considered ○ Removed: <ul style="list-style-type: none"> ▪ Cancer type and stage ▪ Proposed treatment based on results of genetic testing (if available) ○ Replaced “results of prior Comprehensive Genomic Profiling, if applicable” with “results of prior <i>Companion Diagnostic Testing</i> Comprehensive Genomic Profiling, if applicable” <p>Definitions</p> <ul style="list-style-type: none"> • Updated definition of “Comprehensive Genomic Profiling (CGP)” <p>Supporting Information</p> <ul style="list-style-type: none"> • Updated <i>Description of Services</i>, <i>Clinical Evidence</i>, and <i>References</i> sections to reflect the most current information | |
| Hysterectomy | Mar. 1, 2025 | <p>Related Policies</p> <ul style="list-style-type: none"> • Added reference link to the Medical Policy titled <i>Gender Dysphoria Treatment</i> <p>Coverage Rationale</p> <ul style="list-style-type: none"> • Removed language indicating hysterectomy is proven and medically necessary for management of chronic pelvic pain <p>Supporting Information</p> <ul style="list-style-type: none"> • Updated <i>Clinical Evidence</i> and <i>References</i> sections to reflect the most current information | <p>Hysterectomy is proven and medically necessary for management of individuals with <i>BRCA1</i> or <i>BRCA2</i> gene mutation.</p> <p>Hysterectomy is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Hysterectomy, +/- Bilateral Salpingo-Oophorectomy (BSO) or Bilateral Salpingectomy.</p> <p>Click here to view the InterQual® criteria.</p> |

Medical Policy Updates

| Revised | | | |
|---|----------------|---|--|
| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
| Obstructive and Central Sleep Apnea Treatment | Feb. 1, 2025 | <p>Coverage Rationale</p> <p>Non-Surgical Treatment</p> <ul style="list-style-type: none"> Replaced reference to “sleep medicine physician” with “physician <i>trained in</i> sleep medicine” Revised list of unproven and not medically necessary devices; replaced “Advanced <i>Lightweight</i> Functional (ALF) appliances” with “Advanced <i>Lightwire</i> Functional (ALF) appliances” <p>Surgical Treatment</p> <ul style="list-style-type: none"> Revised coverage criteria for implantable hypoglossal nerve stimulation with an FDA approved device: <p>Adult Patients With Moderate to Severe OSA</p> <ul style="list-style-type: none"> Replaced criterion requiring: <ul style="list-style-type: none"> “Total AHI < 25% for central + mixed Apneas” with “total AHI < 25% for central + mixed Apneas, <i>as evaluated by attended polysomnography</i>” “Absence of complete concentric collapse <i>at the soft palate level</i>” with “absence of <i>a complete blockage or complete concentric collapse of the soft palate confirmed by drug-induced sleep endoscopy</i>” | <p>Non-Surgical Treatment</p> <p>Removable Oral Appliances are proven and medically necessary for treating Obstructive Sleep Apnea (OSA) as documented by a sleep study (e.g., Polysomnography or Home Sleep Apnea Testing). Refer to the Medical Policy titled Sleep Studies for further information.</p> <p>For many individuals, Oral Appliance therapy (OAT) may be an effective alternative to failed positive airway pressure (PAP) therapy. Documentation of the following is required:</p> <ul style="list-style-type: none"> A patient presenting with symptoms of OSA has been seen in a face-to-face evaluation with a qualified physician (MD or DO) Trained in Sleep Medicine or with an Advanced Practice Provider working under the direct supervision of a physician trained in sleep medicine prior to beginning treatment for OAT (AASM and AADSM, December 2012, AAO-HNS, November 2019) A treating physician (MD or DO) or an advanced practice provider must diagnose OSA and recommend course of treatment (AAO-HNS, November 2019) If PAP therapy results in no therapeutic efficacy or patient intolerance or refusal, documentation from the patient’s treating physician (MD or DO) or an advanced practice provider must be supplied <p>For information on snoring and Oral Appliances, refer to the Medical Policy titled Durable Medical Equipment, Orthotics, Medical Supplies, and Repairs/Replacements.</p> <p>For medical necessity clinical coverage criteria for removable Oral Appliances, refer to the InterQual® CP: Durable Medical Equipment, Noninvasive Airway Assistive Devices.</p> <p>Click here to view the InterQual® criteria.</p> <p>The following are unproven and not medically necessary due to insufficient evidence of efficacy:</p> <ul style="list-style-type: none"> Devices for treating Positional OSA Nasal dilator devices for treating OSA Intranasal expiratory resistance valve (e.g., Bongo Rx) |

Medical Policy Updates

| Revised | | | |
|---|----------------|---|---|
| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
| Obstructive and Central Sleep Apnea Treatment (continued) | Feb. 1, 2025 | <p>Adolescents Aged 10-18 Years With Down Syndrome</p> <ul style="list-style-type: none"> Replaced criterion requiring “absence of a complete blockage or concentric collapse of the soft palate confirmed by a medication induced sleep endoscopy test” with “absence of a complete blockage or concentric collapse of the soft palate <i>level</i> confirmed by drug induced sleep endoscopy” <p>Definitions</p> <ul style="list-style-type: none"> Added definition of “Sleep Medicine Training” Removed definition of: <ul style="list-style-type: none"> Physician or Practitioner Respiratory Disturbance Index (RDI) Respiratory Effort-Related Arousal (RERA) Respiratory Event Index (REI) <p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>Description of Services</i>, <i>Clinical Evidence</i>, <i>FDA</i>, and <i>References</i> sections to reflect the most current information | <ul style="list-style-type: none"> Removable Oral Appliances for treating Central Sleep Apnea Prefabricated Oral Appliance/device Non-surgical electrical muscular training Mandibular vertical repositioning devices (e.g., Slow Wave) Morning repositioning devices Epigenetic appliances [e.g., Homeoblock™, DNA® (Daytime/Nighttime appliance)] Advanced Lightwire Functional (ALF) appliances <p>Surgical Treatment</p> <p>Uvulopalatopharyngoplasty (UPPP), mandibular osteotomy (MO), and maxillomandibular osteotomy and advancement (MMA) are proven and medically necessary in an adult patient when all the following criteria are met:</p> <ul style="list-style-type: none"> Diagnosis of moderate to severe OSA [Apnea Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) ≥ 15] Excessive daytime sleepiness documented with an Epworth Sleepiness Scale (ESS) > 10 or with another validated tool PAP therapy resulted in no therapeutic efficacy or patient refusal or intolerance <p>In addition, the following criteria needs to be met:</p> <ul style="list-style-type: none"> For MMA, craniofacial disproportion, or deformities with evidence of maxillomandibular deficiency For MO, retrolingual or lower pharyngeal function obstruction <p>Implantable hypoglossal nerve stimulation with a U.S. Food and Drug Administration (FDA) approved device is proven and medically necessary in an adult patient with moderate to severe OSA when all the following criteria are met:</p> <ul style="list-style-type: none"> Body Mass Index of (BMI) less than or equal to 40kg/m²; and AHI of ≥ 15 and ≤ 100 as determined with Polysomnography (Attended); and Total AHI < 25% for central + mixed Apneas, as evaluated by attended polysomnography; and Absence of a complete blockage or complete concentric collapse of the |

Medical Policy Updates

| Revised | | | |
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| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
| Obstructive and Central Sleep Apnea Treatment (continued) | Feb. 1, 2025 | | <p>soft palate confirmed by drug-induced sleep endoscopy; and</p> <ul style="list-style-type: none"> • PAP therapy resulted in no therapeutic efficacy or patient refusal or intolerance; and • Used in accordance with FDA guidelines <p>Implantable hypoglossal nerve stimulation with an FDA approved device is proven and medically necessary in adolescents aged 10-18 years with Down Syndrome when all the following criteria are met:</p> <ul style="list-style-type: none"> • Diagnosis of severe OSA (as determined by a Polysomnogram within 24 months and an AHI \geq 10 and RDI \leq 50 events per hour); and • BMI < 95th percentile for age; and • Total AHI < 25% for central + mixed Apneas; and • Contraindication for or not effectively treated with a prior adenotonsillectomy; and • Confirmed failure or intolerance of PAP therapy despite attempts to improve compliance; and • Absence of tracheostomy use during sleep; and • Absence of a complete blockage or concentric collapse of the soft palate level confirmed by drug induced sleep endoscopy; and • Individual and caregiver refusal of an MMA procedure for non-concentric palatal collapse; and • Used in accordance with FDA guidelines <p>Implantable neurostimulation devices for the treatment of Central Sleep Apnea (CSA) are unproven and not medically necessary due to insufficient evidence of safety and/or efficacy.</p> <p>The following surgical procedures are unproven and not medically necessary for treating OSA due to insufficient evidence of efficacy (not an all-inclusive list):</p> <ul style="list-style-type: none"> • Laser-assisted uvulopalatoplasty (LAUP) • Lingual suspension - also referred to as tongue stabilization, tongue stitch, or tongue fixation • Isolated hyoid myotomy • Stand-alone uvulectomy • Palatal implants |

Medical Policy Updates

| Revised | | | |
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| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
| Obstructive and Central Sleep Apnea Treatment (continued) | Feb. 1, 2025 | | <ul style="list-style-type: none"> Radiofrequency ablation of the soft palate and/or tongue base Transoral robotic surgery (TORS) Distraction osteogenesis for maxillary expansion (DOME) |
| Radiation Therapy: Fractionation, Image-Guidance, and Special Services | Feb. 1, 2025 | <p>Coverage Rationale Radiation Therapy Fractionation Breast Adenocarcinoma</p> <ul style="list-style-type: none"> Revised list of medically necessary services when providing external beam radiation therapy (EBRT) for breast adenocarcinoma; added “delivery of up to 5 fractions for accelerated partial breast irradiation (APBI)” <p>Image-Guided Radiation Therapy (IGRT)</p> <ul style="list-style-type: none"> Added language to indicate IGRT may be medically necessary during Definitive Treatment when used with three-dimensional conformal radiation therapy (3D-CRT) for a condition not listed [as medically necessary in the policy] when documentation is provided showing one or more of the following: <ul style="list-style-type: none"> Clinically significant difference in normal tissue sparing between deep inspiration breath hold (DIBH) and free breathing as documented by comparison plans and dose-volume histogram (DVH) (e.g., right-sided breast cancer) | <p>Radiation Therapy Fractionation Bone Metastases</p> <p>When providing palliative external beam radiation therapy (EBRT) for the treatment of a bone metastasis the following are medically necessary:</p> <ul style="list-style-type: none"> Delivery of up to 10 fractions of radiation therapy Delivery of greater than 10 fractions for the treatment of a site that has previously received radiation therapy <p>Breast Adenocarcinoma</p> <p>When providing EBRT for breast adenocarcinoma the following are medically necessary:</p> <ul style="list-style-type: none"> Delivery of up to 5 fractions for accelerated partial breast irradiation (APBI) Delivery of up to 21 fractions (inclusive of a boost to the tumor bed) Delivery of up to 33 fractions (inclusive of a boost to the tumor bed) when any of the following criteria are met: <ul style="list-style-type: none"> Treatment of supraclavicular and/or internal mammary lymph nodes; or Post-mastectomy radiation therapy; or Individual has received previous thoracic radiation therapy; or Individual has a connective tissue disorder such as lupus or scleroderma <p>When providing EBRT for breast cancer, delivery of greater than 33 fractions (inclusive of a boost to the tumor bed) is not medically necessary.</p> <p>Locally Advanced Non-Small Cell Lung Cancer</p> <p>When providing EBRT, with or without chemotherapy, for locally advanced non-small cell lung cancer, the following is medical</p> |

Medical Policy Updates

| Revised | | | |
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| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
| Radiation Therapy: Fractionation, Image-Guidance, and Special Services (continued) | Feb. 1, 2025 | <ul style="list-style-type: none"> ○ Member unable to tolerate immobilization during computed tomography (CT) simulation ○ Significant target motion as documented by imaging ○ Smaller clinical target volume (CTV) margins are required than what is traditionally used for 3D-CRT <p>Medical Records Documentation Used for Reviews</p> <ul style="list-style-type: none"> ● Updated list of Medical Records Documentation Used for Reviews: <ul style="list-style-type: none"> Radiation Therapy Fractionation ○ Added: <ul style="list-style-type: none"> ▪ Radiation oncologist notes ▪ History of prior surgical treatment ○ Replaced” <ul style="list-style-type: none"> ▪ “Diagnosis” with “diagnosis <i>and stage</i>” ▪ “Proposed radiation prescription” with “proposed <i>treatment plan, including</i> radiation prescription” <p>Image-Guided Radiation Therapy (IGRT)</p> <ul style="list-style-type: none"> ○ Added: <ul style="list-style-type: none"> ▪ Radiation oncologist notes | <p>necessary:</p> <ul style="list-style-type: none"> ● Delivery of up to 35 fractions <p>When providing EBRT, with or without chemotherapy, for locally advanced non-small cell lung cancer, delivery of greater than 35 fractions is not medically necessary.</p> <p>Prostate Adenocarcinoma</p> <p>When providing EBRT for prostate adenocarcinoma the following are medically necessary:</p> <ul style="list-style-type: none"> ● Delivery of up to 20 fractions for Definitive Treatment in an individual with Limited Metastatic Disease ● Delivery of up to 28 fractions for localized prostate cancer ● Delivery of up to 45 fractions for localized prostate cancer when any of the following criteria are met: <ul style="list-style-type: none"> ○ Individual with high-risk prostate cancer is undergoing radiation treatment to pelvic lymph nodes; or ○ Radiation therapy is delivered post-prostatectomy; or ○ Individual has a history of inflammatory bowel disease such as ulcerative colitis or Crohn’s disease; or ○ Individual has received previous pelvic radiation therapy <p>When providing EBRT for localized prostate cancer, delivery of greater than 45 fractions is not medically necessary.</p> <p>Image-Guided Radiation Therapy (IGRT)</p> <p>Image guidance for radiation therapy is medically necessary under any of the following circumstances:</p> <ul style="list-style-type: none"> ● When used with intensity modulated radiation therapy (IMRT) (e.g., prostate cancer); or ● When used with proton beam radiation therapy (PBRT); or ● When the target has received prior radiation therapy or abuts previously irradiated area; or ● When implanted fiducial markers are being used for target localization; or ● During Definitive Treatment using three-dimensional conformal radiation therapy (3D-CRT) for the following: |

Medical Policy Updates

| Revised | | | |
|--|----------------|--|--|
| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
| Radiation Therapy: Fractionation, Image-Guidance, and Special Services (continued) | Feb. 1, 2025 | <ul style="list-style-type: none"> ▪ History of prior surgical treatment ▪ Comparison plans, dose-volume histogram, clinical target volume margins, and target motion documented by imaging ○ Replaced” <ul style="list-style-type: none"> ▪ “Diagnosis” with “diagnosis <i>and stage</i>” ▪ “History of present illness” with “history of present illness <i>and conditions</i>” <p>Definitions</p> <ul style="list-style-type: none"> ● Added definition of “Definitive Treatment” <p>Applicable Codes</p> <p>Coding Clarifications</p> <p>CPT Code 77401</p> <ul style="list-style-type: none"> ● Added notation to indicate megavoltage treatment delivery codes should not be reported when superficial radiation therapy (CPT code 77401) is provided, regardless of the number of treatment sites; CPT codes 77261, 77262, 77263, 77332, 77333, 77334, 77306, 77307, 77316, 77317, 77318, 77336, 77370, 77371, 77372, 77373, 77402, 77407, 77412, 77417, 0394T, 0395T, 77427, 77431, 77432, 77435, 77469, 77470, and 77499 should not be reported with 77401 throughout the course of treatment | <ul style="list-style-type: none"> ○ Breast cancer and any of the following: <ul style="list-style-type: none"> ▪ Accelerated partial breast irradiation ▪ Breast boost with the use of photons ▪ Hypofractionated radiation therapy delivered up to five fractions to the whole breast or chest wall ▪ Individual is being treated in prone position ▪ Left breast cancer and deep inspiration breath hold (DIBH) technique is being used ○ During boost treatment of rectal and bladder cancer ○ Esophageal cancer ○ Gastric cancer ○ Head and neck cancer ○ Hepatobiliary cancer ○ Lung cancer ○ Pancreatic cancer ○ Soft tissue sarcoma ○ IGRT when used with 3D-CRT may be medically necessary for a condition not listed above when documentation is provided showing one or more of the following: <ul style="list-style-type: none"> ▪ Clinically significant difference in normal tissue sparing between DIBH and free breathing as documented by comparison plans and dose-volume histogram (DVH) (e.g., right-sided breast cancer) ▪ Member unable to tolerate immobilization during computed tomography (CT) simulation ▪ Significant target motion as documented by imaging ▪ Smaller clinical target volume (CTV) margins are required than what is traditionally used for 3D-CRT <p>When the above criteria are not met, IGRT is not medically necessary including but not limited to any of the following circumstances:</p> <ul style="list-style-type: none"> ● Superficial treatment of skin cancer including superficial radiation therapy or electronic brachytherapy ● To align bony landmarks without implanted fiducials (e.g., during palliative radiation therapy) <p>Note: Refer to the <i>Coding Clarifications</i> section of the policy for special services and use of IGRT with brachytherapy, SRS, and SBRT.</p> |

Medical Policy Updates

| Revised | | | |
|--|-----------------------|---|---------------------------|
| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
| Radiation Therapy: Fractionation, Image-Guidance, and Special Services (continued) | Feb. 1, 2025 | <p>CPT Code 77331</p> <ul style="list-style-type: none"> Added notation to indicate special dosimetry (CPT code 77331) is meant to check the dosimetry in a treatment port that is “outside” the normal calculation parameters of the treatment planning system and calibration of the treatment device such as the following: measuring a dose at abutting fields, unusual anatomic situations, unusually small fields, selected brachytherapy situations, verifying dose under bolus <p>CPT Code 77370</p> <ul style="list-style-type: none"> Updated notation to indicate special medical radiation physics consultation (CPT code 77370) should be reported once under the following circumstances: complex interrelationship of photons and electrons, brachytherapy, stereotactic radiosurgery (SRS) or stereotactic body radiation therapy (SBRT), analysis of customized beam modification devices and special blocking procedures, computing the dose to the fetus of a pregnant individual, specialized brachytherapy equipment developed by the qualified medical physicist (QMP) to treat a specific individual, radioisotope treatment, individuals with | |

Medical Policy Updates

| Revised | | | |
|--|-----------------------|---|---------------------------|
| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
| Radiation Therapy: Fractionation, Image-Guidance, and Special Services (continued) | Feb. 1, 2025 | <p>implanted cardiac devices, fusion by a QMP of 3D image sets from multiple modalities (CT/PET/MRI) in non-IMRT treatment plans</p> <p>CPT Code 77470</p> <ul style="list-style-type: none"> • Updated notation to indicate special treatment procedure (CPT code 77470) should be reported once under the following circumstances: pediatric individuals requiring daily anesthesia, total and hemi body irradiation, per oral or endocavitary irradiation, individuals very difficult to set up, combination of EBRT and brachytherapy, concurrent cytotoxic chemotherapy, and/or targeted therapy, radioimmunotherapy when combined with EBRT, hyperthermia, yttrium microsphere radiotherapy <ul style="list-style-type: none"> ○ Circumstances where routine use of CPT code 77470 should not be reported include but are not limited to contouring for 3D-CRT and IMRT and routine use for SBRT or SRS unless there was cause for extra time/effort with supporting documentation ○ There is no situation in which CPT code 77470 may be routinely used | |

Medical Policy Updates

| Revised | | | |
|--|----------------|---|--|
| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
| Radiation Therapy: Fractionation, Image-Guidance, and Special Services (continued) | Feb. 1, 2025 | <p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>Description of Services</i>, <i>Clinical Evidence</i>, and <i>References</i> sections to reflect the most current information | |
| Stereotactic Body Radiation Therapy and Stereotactic Radiosurgery | Feb. 1, 2025 | <p>Coverage Rationale</p> <ul style="list-style-type: none"> Revised list of proven and medically necessary indications for stereotactic radiation therapy, including stereotactic radiosurgery (SRS) and stereotactic body radiation therapy (SBRT): <p>Definitive Treatment</p> <ul style="list-style-type: none"> Revised coverage criteria for Definitive Treatment; added criterion requiring renal cancer when all the following criteria are met: <ul style="list-style-type: none"> Stage I Individual is non-optimal surgical candidate <p>Extracranial Oligometastatic Disease</p> <ul style="list-style-type: none"> Revised coverage criteria for extracranial Oligometastatic Disease: <ul style="list-style-type: none"> Added criterion requiring “all metastatic lesions are to be treated concurrently in a single episode for care” Replaced criterion requiring “individual has up to three metastatic lesions, and if the | <p>Stereotactic radiation therapy including stereotactic radiosurgery (SRS) and stereotactic body radiation therapy (SBRT) is considered proven and medically necessary for the following indications:</p> <ul style="list-style-type: none"> Acoustic neuroma (vestibular schwannoma) Brain metastasis when one of the following criteria is met: <ul style="list-style-type: none"> Newly diagnosed brain metastasis and all the following criteria are met: <ul style="list-style-type: none"> Individual has a good performance status [Karnofsky Performance Status (KPS) score \geq 70% or Eastern Cooperative Oncology Group (ECOG) performance status of 0-2] Absence of leptomeningeal metastases Individual does not have a diagnosis of lymphoma, germ cell tumor, or small cell carcinoma Has up to 10 lesions or cumulative tumor volume of < 15cc All lesions must be treated in a single treatment for SRS, or in 2 to 5 fractions for SBRT [also known as fractionated stereotactic radiation therapy (FSRT)] Individual is undergoing repeat stereotactic radiation therapy when all the following criteria are met: <ul style="list-style-type: none"> Individual has a good performance status (KPS score \geq 70% or ECOG performance status of 0-2) Absence of leptomeningeal metastases Stable extra-cranial disease as documented on restaging studies dated within the past two months Life expectancy is > 6 months Total number of brain metastases treated in the past 12 months is \leq 13 All lesions must be treated in a single treatment for SRS, or in 2 to 5 fractions for SBRT (also known as FSRT) Retreatment after previous whole brain radiation therapy Chordoma and chondrosarcoma Craniopharyngioma |

Medical Policy Updates

| Revised | | | |
|---|----------------|---|--|
| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
| Stereotactic Body Radiation Therapy and Stereotactic Radiosurgery (continued) | Feb. 1, 2025 | <p>individual has previously received local therapy (e.g., SBRT, surgery, or radiofrequency ablation) for metastatic disease, the treated lesion(s) from that therapy are included in the total count of three lesions” with “individual has <i>a total of</i> up to three metastatic lesions <i>since diagnosis</i>, and if the individual has previously received local therapy (e.g., SBRT, surgery, or radiofrequency ablation) for metastatic disease, the treated lesion(s) from that therapy are included in the total count of three lesions”</p> <ul style="list-style-type: none"> Added language to indicate SBRT for palliative treatment of bone metastases of the spine is proven and medically necessary when all the following criteria are met: <ul style="list-style-type: none"> Using 2 fractions or less Individual has no spinal cord compression or cauda equina compression <p>Definitions</p> <ul style="list-style-type: none"> Added definition of “Definitive Treatment” Updated definition of “Oligometastatic Disease” <p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>Clinical Evidence</i> and | <ul style="list-style-type: none"> Definitive Treatment of the following: <ul style="list-style-type: none"> Hepatocellular carcinoma without evidence of regional or distant metastasis Non-small cell lung cancer when all the following criteria are met: <ul style="list-style-type: none"> Stage I or stage IIA with negative mediastinal lymph nodes Tumor size ≤ 5cm Individual is medically inoperable or refuses to have surgery after thoracic surgery evaluation Pancreatic adenocarcinoma without evidence of distant metastasis Prostate cancer without evidence of distant metastases Renal cancer when all the following criteria are met: <ul style="list-style-type: none"> Stage I Individual is a non-optimal surgical candidate Extracranial Oligometastatic Disease when all the following criteria are met: <ul style="list-style-type: none"> Primary tumor type is any of the following: <ul style="list-style-type: none"> Colorectal cancer Melanoma Non-small cell lung cancer Prostate cancer Renal cancer Sarcoma Controlled primary tumor defined as at least 3 months since original tumor was treated definitively, with no progression at primary site Performance status KPS score ≥ 70% or ECOG performance status of 0-2 Life expectancy is at least 6 months Has a total of up to 3 metastatic lesions since diagnosis, and if the individual has previously received local therapy (e.g., SBRT, surgery, or radiofrequency ablation) for metastatic disease, the treated lesion(s) from that therapy are included in the total count of 3 lesions Each lesion is ≤ 5 cm in size No evidence of malignant pleural effusion, leptomeningeal or peritoneal carcinomatosis All metastatic lesions are to be treated concurrently in a single episode of care SBRT must be completed in 5 fractions for an entire course of |

Medical Policy Updates

| Revised | | | |
|---|----------------|--|--|
| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
| Stereotactic Body Radiation Therapy and Stereotactic Radiosurgery (continued) | Feb. 1, 2025 | <i>References</i> sections to reflect the most current information | <p>treatment regardless of number of lesions treated</p> <ul style="list-style-type: none"> • Glomus jugulare tumors • Hemangiomas of the brain • Intracranial arteriovenous malformations (AVMs) • Meningioma • Pineal gland tumors • Pituitary adenoma • Recurrent gliomas • To treat a previously irradiated field • Trigeminal neuralgia refractory to medical therapy • Uveal melanoma <p>Stereotactic body radiation therapy (SBRT) for palliative treatment of bone metastases of the spine is proven and medically necessary when all the following criteria are met:</p> <ul style="list-style-type: none"> • Using 2 fractions or less • Individual has no spinal cord compression or cauda equina compression |
| Total Artificial Disc Replacement for the Spine | Feb. 1, 2025 | <p>Coverage Rationale</p> <ul style="list-style-type: none"> • Replaced language indicating “lumbar artificial total disc replacement with an FDA-approved prosthetic intervertebral disc is proven and medically necessary for treating single level lumbar degenerative disc disease with symptomatic intractable discogenic low back pain in a Skeletally Mature individual” with “lumbar artificial total disc replacement with an FDA-approved prosthetic intervertebral disc is proven and medically necessary <i>in certain circumstances</i> for treating single level lumbar degenerative disc disease with symptomatic | <p>Cervical artificial total disc replacement with an FDA-approved prosthetic intervertebral disc is proven and medically necessary in certain circumstances for treating one-level or two contiguous levels of cervical degenerative disc disease (C3 to C7) in a Skeletally Mature individual with symptomatic radiculopathy and/or myelopathy.</p> <p>Cervical artificial disc replacement with an FDA-approved prosthetic intervertebral disc is proven and medically necessary for treating one level or two contiguous levels of cervical degenerative disc disease in a Skeletally Mature individual with a history of cervical spinal fusion at another level (adjacent or non-adjacent).</p> <p>Cervical artificial disc replacement at one level combined with cervical spinal fusion surgery at another level (adjacent or non-adjacent), as part of the same surgical plan, is unproven and not medically necessary due to insufficient evidence of efficacy.</p> <p>For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Artificial Disc Replacement, Cervical.</p> |

Medical Policy Updates

| Revised | | | |
|--|----------------|---|---|
| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
| Total Artificial Disc Replacement for the Spine (continued) | Feb. 1, 2025 | <p>intractable discogenic low back pain in a Skeletally Mature individual”</p> <p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>Clinical Evidence</i> and <i>References</i> sections to reflect the most current information | <p>Click here to view the InterQual® criteria.</p> <p>Lumbar artificial total disc replacement with an FDA-approved prosthetic intervertebral disc is proven and medically necessary in certain circumstances for treating single level lumbar degenerative disc disease with symptomatic intractable discogenic low back pain in a Skeletally Mature individual. For medical necessity clinical coverage criteria, refer to the InterQual® Client Defined, CP: Procedures, Artificial Disc Replacement, Lumbar (Custom) - UHG.</p> <p>Click here to view the InterQual® criteria.</p> <p>Lumbar artificial total disc replacement is unproven and not medically necessary at more than one spinal level due to insufficient evidence of efficacy.</p> |
| Treatment of Temporomandibular Joint Disorders | Feb. 1, 2025 | <p>Coverage Rationale</p> <ul style="list-style-type: none"> Revised list of unproven and not medically necessary services: <ul style="list-style-type: none"> Replaced “<i>passive rehabilitation therapy devices</i> (e.g., TheraBite Jaw Motion Rehabilitation System®) and <i>low-load prolonged-duration stretch devices</i> (e.g., Jaw Dynasplint® System)” with “<i>jaw mobility mechanical stretching devices</i> (e.g., Therabite Jaw Motion Rehabilitation System®, Jaw Dynasplint® System)” Revised list of examples of epigenetic appliances; added “Advanced Lightwire Functional (ALF) appliances” <p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>Description of Services</i>, <i>Benefit Considerations</i>, <i>Clinical</i> | <p>The following non-surgical services are proven and medically necessary for treating disorders of the temporomandibular joint (TMJ):</p> <ul style="list-style-type: none"> Arthrocentesis Intra-articular injections of corticosteroids Trigger point injections Physical therapy Occlusal splint (stabilization and repositioning splints) <p>The following TMJ surgical services are proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the:</p> <ul style="list-style-type: none"> InterQual® CP: Procedures: <ul style="list-style-type: none"> Arthroscopy, Temporomandibular Joint (TMJ) Discectomy, Temporomandibular Joint (TMJ) Reconstruction, Temporomandibular Joint (TMJ) InterQual® Client Defined, CP: Procedures, Arthroplasty, Temporomandibular Joint (TMJ) (Custom) - UHG <p>Click here to view the InterQual® criteria.</p> <p>The following services are unproven and not medically necessary for treating disorders of the temporomandibular joint (TMJ) due to</p> |

Medical Policy Updates

| Revised | | | |
|--|----------------|--|---|
| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
| Treatment of Temporomandibular Joint Disorders (continued) | Feb. 1, 2025 | <i>Evidence, and References</i> sections to reflect the most current information | <p>insufficient evidence of efficacy (this list is not all-inclusive):</p> <ul style="list-style-type: none"> Biofeedback Craniosacral manipulation/therapy Jaw mobility mechanical stretching devices (e.g., Therabite Jaw Motion Rehabilitation System®, Jaw Dynasplint® System) Multiple occlusal splints (i.e., daytime and nighttime splints, maxillary and mandibular splints) Epigenetic appliances [e.g., Homeoblock™, DNA® (Daytime/Nighttime appliance), Advanced Lightwire Functional (ALF) appliance] <p>For information regarding intra-articular injections of sodium hyaluronate for temporomandibular joint disorders, refer to the Medical Benefit Drug Policies titled Sodium Hyaluronate (for Commercial Only) and Sodium Hyaluronate (for Individual Exchange Only).</p> <p>For information regarding botulinum toxin injections for temporomandibular joint disorders, refer to the Medical Benefit Drug Policies titled Botulinum Toxins A and B (for Commercial Only) and Botulinum Toxins A and B (for Individual Exchange Only).</p> |
| Vagus and External Trigeminal Nerve Stimulation | Feb. 1, 2025 | <p>Coverage Rationale</p> <ul style="list-style-type: none"> Replaced language indicating “conventional implantable vagus nerve stimulators, also known as non-responsive or open loop stimulators, are proven and medically necessary for treating epilepsy in individuals with all of the [listed conditions]” with “implantable vagus nerve stimulators are proven and medically necessary for treating epilepsy in individuals with all of the [listed conditions]” Revised list of unproven and not medically necessary devices: <ul style="list-style-type: none"> Removed “responsive vagus nerve stimulation implants | <p>Implantable vagus nerve stimulators are proven and medically necessary for treating epilepsy in individuals with all of the following:</p> <ul style="list-style-type: none"> Medically refractory epileptic seizures with failure of two or more trials of single or combination antiepileptic drug therapy or intolerable side effects of antiepileptic drug therapy; and The individual is not a candidate for epilepsy surgery, has failed epilepsy surgery, or refuses epilepsy surgery after Shared Decision Making discussion; and No history of left or bilateral cervical vagotomy. The U.S. Food and Drug Administration (FDA) identifies a history of left or bilateral cervical vagotomy as a contraindication to vagus nerve stimulation. <p>Implantable vagus nerve stimulators are unproven and not medically necessary for treating all other conditions due to insufficient evidence of efficacy. These conditions include but are not limited to:</p> <ul style="list-style-type: none"> Alzheimer's disease Anxiety disorder |

Medical Policy Updates

| Revised | | | |
|---|----------------|--|--|
| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
| Vagus and External Trigeminal Nerve Stimulation (continued) | Feb. 1, 2025 | <p>(closed loop technology) that allow detection and stimulation based upon increased heart rate (e.g., AspireSR™ Model 106, SenTiva™ Model 1000) for treating epilepsy”</p> <ul style="list-style-type: none"> ○ Replaced “transcutaneous (non-implantable) vagus nerve stimulation (e.g., <i>gammaCore® for headaches</i>)” with “transcutaneous (non-implantable) vagus nerve stimulation <i>devices</i>” ○ Removed list of examples of external or transcutaneous (non-implantable) trigeminal nerve stimulation devices: Monarch® eTNS System, Cefaly® <p>Supporting Information</p> <ul style="list-style-type: none"> ● Updated <i>Description of Services, Clinical Evidence, FDA, and References</i> sections to reflect the most current information | <ul style="list-style-type: none"> ● Autism spectrum disorder ● Autoimmune disorders ● Back and neck pain ● Bipolar disorder ● Bulimia ● Cerebral palsy ● Chronic pain syndrome ● Cluster headaches ● Depression ● Fibromyalgia ● Heart failure ● Migraines ● Morbid obesity ● Musculoskeletal disorders ● Narcolepsy ● Obsessive-compulsive disorder ● Paralysis agitans ● Sleep disorders ● Tourette's syndrome ● Upper limb impairment related to stroke <p>The following devices are unproven and not medically necessary due to insufficient evidence of efficacy:</p> <ul style="list-style-type: none"> ● Transcutaneous (non-implantable vagus nerve stimulation devices) for preventing or treating all indications. ● External or transcutaneous (non-implantable) trigeminal nerve stimulation devices for preventing or treating all conditions including but not limited to: <ul style="list-style-type: none"> ○ Attention deficit hyperactivity disorder (ADHD) ○ Depression ○ Epilepsy ○ Headache <p>Note: For vagus nerve blocking for the treatment of obesity, refer to the Medical Policy titled Bariatric Surgery.</p> |

Medical Benefit Drug Policy Updates

| Revised | | | |
|----------------------------------|----------------|--|--|
| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
| Adakveo® (Crizanlizumab-Tmca) | Feb. 1, 2025 | <p>Coverage Rationale</p> <ul style="list-style-type: none"> Revised coverage criteria for initial therapy; added criterion allowing coverage when the patient is transitioning from treatment with Oxbryta (voxelotor) to Adakveo <p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>References</i> section to reflect the most current information | <p>Adakveo is proven and/or medically necessary to reduce the frequency of vasoocclusive crises in patients with sickle cell disease who meet all of the following criteria:</p> <ul style="list-style-type: none"> Initial Therapy <ul style="list-style-type: none"> Patient is 16 years of age or older; and Diagnosis of a sickle cell disease, including, but not limited to, homozygous hemoglobin S (HbSS), sickle hemoglobin C disease (HbSC), sickle beta⁰ thalassemia, and sickle beta⁺ thalassemia; and One of the following: <ul style="list-style-type: none"> Patient is transitioning from treatment with Oxbryta (voxelotor) to Adakveo; or Patient has previously experienced 2 or more sickle cell-related vasoocclusive crises within the previous 12 months and One of the following: <ul style="list-style-type: none"> Patient is currently receiving hydroxyurea therapy; or Patient has a history of treatment failure, intolerance, or contraindication to hydroxyurea therapy and Patient is not receiving concomitant chronic, prophylactic blood transfusion therapy; and Patient is not receiving concomitant Oxbryta (voxelotor) therapy; and Adakveo is prescribed by, or in consultation with, a hematologist, or other specialist with expertise in the diagnosis and management of sickle cell disease; and Adakveo initial dosing is in accordance with the United States Food and Drug Administration approved labeling; and Initial authorization will be for no more than 12 months Continuation Therapy <ul style="list-style-type: none"> Diagnosis of a sickle cell disease, including, but not limited to, homozygous hemoglobin S (HbSS), sickle hemoglobin C disease (HbSC), sickle beta⁰ thalassemia, and sickle beta⁺ thalassemia; and Patient has experienced a reduction in sickle cell-related vasoocclusive crises and/or a decrease in severity of sickle cell-related vasoocclusive crises from pretreatment baseline while on Adakveo; and Patient is not receiving concomitant chronic, prophylactic blood |

Medical Benefit Drug Policy Updates

| Revised | | | |
|---|----------------|---|--|
| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
| Adakveo® (Crizanlizumab-Tmca) (continued) | Feb. 1, 2025 | | <p>transfusion therapy; and</p> <ul style="list-style-type: none"> ○ Patient is not receiving concomitant Oxbryta (voxelotor) therapy; and ○ Adakveo is prescribed by, or in consultation with, a hematologist, or other specialist with expertise in the diagnosis and management of sickle cell disease; and ○ Adakveo maintenance dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Reauthorization will be for no more than 12 months <p>Adakveo is not proven or medically necessary for the treatment of:</p> <ul style="list-style-type: none"> • Pediatric patients less than 16 years of age with sickle cell disease • Myelofibrosis |
| Cimzia® (Certolizumab Pegol) | Feb. 1, 2025 | <p>Coverage Rationale</p> <ul style="list-style-type: none"> • Added language to indicate Cimzia is medically necessary for the treatment of polyarticular juvenile idiopathic arthritis when all of the following criteria are met: <ul style="list-style-type: none"> Initial Therapy <ul style="list-style-type: none"> ○ Diagnosis of active polyarticular juvenile idiopathic arthritis (PJIA) ○ Cimzia is initiated and titrated according to U.S. Food and Drug Administration (FDA)-labeled dosing for polyarticular juvenile idiopathic arthritis ○ Patient is not receiving Cimzia in combination with a targeted immunomodulator [e.g., Enbrel (etanercept), Orencia (abatacept), Simponi (golimumab), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq | <p>This policy refers to Cimzia (certolizumab pegol) injection. Cimzia (certolizumab pegol) for self-administered subcutaneous injection is obtained under the pharmacy benefit.</p> <p>Refer to the policy for complete details.</p> |

Medical Benefit Drug Policy Updates

| Revised | | | |
|--|----------------|--|--------------------|
| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
| Cimzia® (Certolizumab Pegol) (continued) | Feb. 1, 2025 | <p>(upadacitinib)]</p> <ul style="list-style-type: none"> ○ Prescribed by or in consultation with a rheumatologist ○ Initial authorization is for no more than 12 months <p>Continuation of Therapy</p> <ul style="list-style-type: none"> ○ Patient has previously received Cimzia injection for intravenous infusion ○ Documentation of positive clinical response ○ Cimzia is dosed according to FDA-labeled dosing for polyarticular juvenile idiopathic arthritis ○ Patient is not receiving Cimzia in combination with a targeted immunomodulator [e.g., Enbrel (etanercept), Orencia (abatacept), Simponi (golimumab), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)] ○ Authorization is for no more than 12 months <p>Applicable Codes</p> <ul style="list-style-type: none"> ● Added ICD-10 diagnosis codes M08.00, M08.011, M08.012, M08.019, M08.021, M08.022, M08.029, M08.031, M08.032, M08.039, M08.041, M08.042, M08.049, M08.051, M08.052, M08.059, M08.061, M08.062, M08.069, M08.071, M08.072, M08.079, M08.08, M08.09, | |

Medical Benefit Drug Policy Updates

| Revised | | | |
|---|----------------|--|--|
| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
| Cimzia® (Certolizumab Pegol) (continued) | Feb. 1, 2025 | <p>M08.0A, M08.20, M08.211, M08.212, M08.219, M08.221, M08.222, M08.229, M08.231, M08.232, M08.239, M08.241, M08.242, M08.249, M08.251, M08.252, M08.259, M08.261, M08.262, M08.269, M08.271, M08.272, M08.279, M08.28, M08.29, M08.2A, M08.3, M08.80, M08.811, M08.812, M08.819, M08.821, M08.822, M08.829, M08.831, M08.832, M08.839, M08.841, M08.842, M08.849, M08.851, M08.852, M08.859, M08.861, M08.862, M08.869, M08.871, M08.872, M08.879, M08.88, M08.89, M08.90, M08.911, M08.912, M08.919, M08.921, M08.922, M08.929, M08.931, M08.932, M08.939, M08.941, M08.942, M08.949, M08.951, M08.952, M08.959, M08.961, M08.962, M08.969, M08.971, M08.972, M08.979, M08.98, M08.99, and M08.9A</p> <ul style="list-style-type: none"> Removed content addressing maximum dosage requirements <p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>Clinical Evidence</i>, <i>FDA</i>, and <i>References</i> sections to reflect the most current information | |
| Ophthalmologic Vascular Endothelial Growth Factor (VEGF) Inhibitors | Feb. 1, 2025 | <p>Title Change</p> <ul style="list-style-type: none"> Previously titled <i>Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors</i> | Pavblu™ (aflibercept-ayyh) has been added to the Review at Launch program. Some members may not be eligible for coverage of this medication at this time. Refer to the Medical Benefit Drug Policy titled Review at Launch for New to Market Medications for additional details. |

Medical Benefit Drug Policy Updates

| Revised | | | |
|---|----------------|--|---|
| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
| Ophthalmologic Vascular Endothelial Growth Factor (VEGF) Inhibitors (continued) | Feb. 1, 2025 | <p>Coverage Rationale</p> <ul style="list-style-type: none"> Revised list of applicable vascular endothelial growth factor (VEGF) inhibitors and dual VEGF/angiopoietin-2 (Ang-2) inhibitors; added Pavblu™ (aflibercept-ayyh) Added language to indicate: <ul style="list-style-type: none"> Pavblu™ (aflibercept-ayyh) has been added to the Review at Launch program and some members may not be eligible for coverage of this medication at this time; refer to the Medical Benefit Drug Policy titled <i>Review at Launch for New to Market Medications</i> for additional details Pavblu (aflibercept-ayyh) is proven and medically necessary for the treatment of: <ul style="list-style-type: none"> Diabetic macular edema (DME) Diabetic retinopathy (DR) Macular edema following retinal vein occlusion (RVO) Neovascular age-related macular degeneration (nAMD) <p>Applicable Codes</p> <ul style="list-style-type: none"> Added HCPCS codes C9399, J3490, and J3590 for Pavblu Updated list of ICD-10 diagnosis codes to specify the diagnoses | <p>This policy provides information about the use of certain specialty pharmacy medications administered by the intravitreal route for ophthalmologic conditions.</p> <p>This policy refers to the following vascular endothelial growth factor (VEGF) inhibitors and dual VEGF/angiopoietin-2 (Ang-2) inhibitors:</p> <ul style="list-style-type: none"> Avastin® (bevacizumab) Beovu® (brolucizumab-dbll) Byooviz™ (ranibizumab-nuna) Cimerli™ (ranibizumab-eqrn) Eylea® (aflibercept) Eylea® HD (aflibercept) Lucentis® (ranibizumab) Pavblu™ (aflibercept-ayyh) Vabysmo™ (faricimab-svoa) <p>Beovu® and Byooviz™ are typically excluded from coverage. Coverage reviews may be in place if required by law or the benefit plan. Refer to the Medical Benefit Drug Policy titled Medical Benefit Therapeutic Equivalent Medications – Excluded Drugs and the corresponding excluded drug list with preferred alternatives.</p> <p>Note: For requests that require medical necessity review, also refer to the General Requirements and Diagnosis-Specific Requirements sections below. (For Medicare reviews, refer to the <i>CMS</i> section of the policy.*)</p> <p>Coverage for Avastin®, Cimerli™, Eylea®, Lucentis®, and Vabysmo™ is contingent on criteria in the General Requirements and Diagnosis-Specific Requirements sections.</p> <p>General Requirements (Applicable to all Medical Necessity Requests)</p> <ul style="list-style-type: none"> For initial therapy, both of the following: <ul style="list-style-type: none"> Diagnosis; and Intravitreal VEGF or dual VEGF/Ang-2 inhibitor administration is no more than 12 doses per year per eye, regardless of diagnosis |

Medical Benefit Drug Policy Updates

| Revised | | | |
|---|----------------|---|--|
| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
| Ophthalmologic Vascular Endothelial Growth Factor (VEGF) Inhibitors (continued) | Feb. 1, 2025 | <p>that apply to Pavblu</p> <ul style="list-style-type: none"> Revised list of <i>Maximum Allowed Frequencies</i>: <ul style="list-style-type: none"> Added Pavblu (aflibercept-ayyh) Updated list applicable diagnoses for Vabysmo (faricimab); added macular edema following retinal vein occlusion (RVO) <p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>Clinical Evidence</i>, <i>FDA</i>, <i>CMS</i>, and <i>References</i> sections to reflect the most current information | <ul style="list-style-type: none"> For continuation of therapy, both of the following: <ul style="list-style-type: none"> Documentation of positive clinical response to anti-VEGF therapy; and Intravitreal VEGF or dual VEGF/Ang-2 inhibitor administration is no more than 12 doses per year per eye, regardless of diagnosis <p>Diagnosis-Specific Requirements</p> <p>The information below indicates the list of proven and medically necessary indications.</p> <p>Avastin (bevacizumab) is proven and medically necessary for the treatment of:</p> <ul style="list-style-type: none"> Choroidal neovascularization secondary to pathologic myopia, angioid streaks/pseudoxanthoma elasticum, or ocular histoplasmosis syndrome (OHS) Diabetic macular edema (DME) Macular edema secondary to branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO) Neovascular age-related macular degeneration (nAMD) Neovascular glaucoma Neovascularization of the iris (NVI) (rubeosis iridis) Proliferative diabetic retinopathy Type I Retinopathy Of Prematurity <p>Beovu (brolucizumab) is proven and medically necessary for the treatment of:</p> <ul style="list-style-type: none"> Neovascular age-related macular degeneration (nAMD) Diabetic macular edema (DME) <p>Byooviz (ranibizumab-nuna) is proven and medically necessary for the treatment of:</p> <ul style="list-style-type: none"> Neovascular age-related macular degeneration (nAMD) Macular edema following retinal vein occlusion (RVO) Myopic choroidal neovascularization (mCNV) |

Medical Benefit Drug Policy Updates

| Revised | | | |
|---|-----------------------|---------------------------|--|
| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
| Ophthalmologic Vascular Endothelial Growth Factor (VEGF) Inhibitors (continued) | Feb. 1, 2025 | | <p>Cimerli (ranibizumab-eqrn) is proven and medically necessary for the treatment of:</p> <ul style="list-style-type: none"> • Myopic choroidal neovascularization (mCNV) • Diabetic macular edema (DME) • Diabetic retinopathy (DR) • Macular edema following retinal vein occlusion (RVO) • Neovascular age-related macular degeneration (nAMD) <p>Eylea (aflibercept) is proven and medically necessary for the treatment of:</p> <ul style="list-style-type: none"> • Diabetic macular edema (DME) • Diabetic retinopathy (DR) • Macular edema secondary to branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO) • Neovascular age-related macular degeneration (nAMD) • Retinopathy of prematurity (ROP) <p>Eylea HD (aflibercept) is proven and medically necessary for the treatment of:</p> <ul style="list-style-type: none"> • Diabetic macular edema (DME) • Diabetic retinopathy (DR) • Neovascular age-related macular degeneration (nAMD) <p>Lucentis (ranibizumab) is proven and medically necessary for the treatment of:</p> <ul style="list-style-type: none"> • Choroidal neovascularization secondary to pathologic myopia, angioid streaks/pseudoxanthoma elasticum, or ocular histoplasmosis syndrome (OHS) • Diabetic macular edema (DME) • Diabetic retinopathy (DR) • Macular edema secondary to branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO) • Neovascular age-related macular degeneration (nAMD) <p>Pavblu (aflibercept-ayyh) is proven and medically necessary for the treatment of:</p> |

Medical Benefit Drug Policy Updates

| Revised | | | |
|---|----------------|--------------------|--|
| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
| Ophthalmologic Vascular Endothelial Growth Factor (VEGF) Inhibitors (continued) | Feb. 1, 2025 | | <ul style="list-style-type: none"> Diabetic macular edema (DME) Diabetic retinopathy (DR) Macular edema following retinal vein occlusion (RVO) Neovascular age-related macular degeneration (nAMD) <p>Vabysmo (faricimab-svoa) is proven and medically necessary for the treatment of:</p> <ul style="list-style-type: none"> Neovascular age-related macular degeneration (nAMD) Diabetic macular edema (DME) Macular edema following retinal vein occlusion (RVO) <p>Additional Information</p> <p>Avastin (bevacizumab) is supplied in sterile vials containing a solution of 25 mg/mL. Doses utilized in ophthalmic conditions generally range from 6.2 mcg to 2.5 mg. Therefore, bevacizumab in vials is often divided into single-dose, prefilled syringes for intravitreal use by compounding pharmacies. Compounding pharmacies must comply with United States Pharmacopeia (USP) Chapter 797, which sets standards for the compounding, transportation, and storage of compounded sterile products (CSP). The Pharmacy Compounding Accreditation Board can verify that the pharmacy is adhering to these standards.</p> <p>The American Society of Retinal Specialists (ASRS) is committed to ensuring that retina specialists have access to compounded drugs (such as Avastin) that are prepared with high-quality material following good quality controls and sound engineering design by appropriately trained personnel. Refer to their information page at https://www.asrs.org/advocacy-practice/access-to-safe-compounded-agents for resources pertaining to access of safe compounded agents.</p> <p>Refer to the <i>U.S. Food and Drug Administration (FDA)</i> section of the policy for information related to contamination of compounded bevacizumab. In an effort to guard against contamination during the compounding process, the United States Veterans Health Administration (USVHA) requires that only USVHA pharmacies may dispense bevacizumab for intravitreal administration to Veterans Administration beneficiaries. The medication must</p> |

Medical Benefit Drug Policy Updates

| Revised | | | |
|---|----------------|--|--|
| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
| Ophthalmologic Vascular Endothelial Growth Factor (VEGF) Inhibitors (continued) | Feb. 1, 2025 | | be dispensed directly to the VA ophthalmologist, who will then be responsible for preparing and administering the bevacizumab dose for each patient. In addition to strict labeling and storage requirements, the ophthalmologist is required to prepare only one dose of medication from each vial; if both eyes are to be treated, a separate vial and syringe must be utilized. |
| Provider Administered Drugs – Site of Care | Feb. 1, 2025 | <p>Related Policies</p> <ul style="list-style-type: none"> Added reference link to the Medical Benefit Drug Policy titled <i>Tremfya® (Guselkumab)</i> <p>Coverage Rationale</p> <ul style="list-style-type: none"> Replaced language indicating “outpatient hospital facility-based <i>intravenous medication infusion</i> is medically necessary for individuals who meet at least one of the [listed] criteria (submission of medical records <i>is required</i>)” with “submission of medical records <i>documenting that</i> outpatient hospital facility-based <i>administration</i> is medically necessary for individuals who meet at least one of the [listed] criteria” Revised coverage criteria: <ul style="list-style-type: none"> Added criterion requiring: <ul style="list-style-type: none"> The patient is medically unstable and is at risk of requiring medical services and equipment available only in an outpatient hospital setting (e.g., endotracheal tube, chest tube insertion equipment, cricothyroidotomy set, mechanical ventilator) | <p>This policy addresses the criteria for consideration of allowing hospital outpatient facility infusion services for specialty medications and intravenous Immune Globulin (IVIG) and subcutaneous Immune Globulin (SCIG) therapy. This includes claim submission for hospital-based services with the following CMS/AMA place of service codes:</p> <ul style="list-style-type: none"> 19 Off Campus-Outpatient Hospital; and 22 On Campus-Outpatient Hospital <p>Alternative Sites of Care, such as non-hospital outpatient infusion, physician office, ambulatory infusion suites, or home infusion services are well accepted places of service for medication infusion therapy. If an individual does not meet criteria for outpatient hospital facility infusion, alternative sites of care may be used.</p> <p>Submission of medical records documenting that outpatient hospital facility-based administration is medically necessary for individuals who meet at least one of the following criteria:</p> <ul style="list-style-type: none"> The patient is medically unstable and is at risk of requiring medical services and equipment available only in an outpatient hospital setting (e.g., endotracheal tube, chest tube insertion equipment, cricothyroidotomy set, mechanical ventilator) during administration of the requested drug based on one of the following: <ul style="list-style-type: none"> History of cardiopulmonary conditions that cause an increased risk of severe adverse reactions during or immediately following infusion; or An inability to tolerate fluid volume load (for intravenous infusions only) despite using the minimum amount of fluid required for infusion (e.g., unstable renal function) or Treatment at an alternative Site of Care presents a health risk due to a clinically significant physical or cognitive impairment; or Severe patent vascular access issues (for intravenous infusions only) that require specialized equipment only available in an outpatient |

Medical Benefit Drug Policy Updates

| Revised | | | |
|---|----------------|--|--|
| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
| Provider Administered Drugs – Site of Care (continued) | Feb. 1, 2025 | <p>during administration of the requested drug based on one of the following:</p> <ul style="list-style-type: none"> – History of cardiopulmonary conditions that cause an increased risk of severe adverse reactions during or immediately following infusion – An inability to tolerate fluid volume load (for intravenous infusions only) despite using the minimum amount of fluid required for infusion (e.g., unstable renal function) <ul style="list-style-type: none"> ▪ Severe patent vascular access issues (for intravenous infusions only) that require specialized equipment only available in an outpatient hospital setting (e.g., ultrasound guidance) and member is not a viable candidate for long-term vascular access devices such as picc line or port-a-cath <ul style="list-style-type: none"> ○ Removed criterion requiring: <ul style="list-style-type: none"> ▪ Documentation that the individual is medically unstable for | <p>hospital setting (e.g., ultrasound guidance) and member is not a viable candidate for long-term vascular access devices such as picc line or port-a-cath; or</p> <ul style="list-style-type: none"> ● Previous episode(s) of severe or potentially life-threatening adverse events (e.g., anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure), not including the first or second infusion, that have occurred while receiving requested therapy that was unresponsive to acetaminophen, steroids, diphenhydramine, fluids, infusion rate reductions, or other pre-medications, thereby increasing risk to the individual while administering at alternative Sites of Care; or ● Initial infusion or re-initiation of previous therapy after more than 6 months (excludes drugs dosed at an interval of 6 months or greater) for a short duration of time (e.g., 4 weeks); or ● For IVIG or SCIG only: Individual has immunoglobulin A (IgA) deficiency with anti-IgA antibodies; or ● All of the following: <ul style="list-style-type: none"> ○ Homecare or home infusion provider has deemed that the individual or home environment is not suitable for home infusion therapy; and ○ The prescriber is unable to administer in the office setting; and ○ There are no ambulatory infusion suite options available for this member <p>Ongoing outpatient hospital facility-based infusion duration of therapy will be no more than 6 months to allow for reassessment of the individual’s ability to receive therapy at an alternative Site of Care.</p> <p>Note: If more than one of the above criteria are met, then the greatest of the applicable approval time periods will be allowed.</p> <p>This policy applies to these medications that require healthcare provider administration:</p> <ul style="list-style-type: none"> ● Actemra® (tocilizumab) ● Adakveo® (crizanlizumab-tmca) ● Adzynma (ADAMTS13, recombinant-krhn) ● Aldurazyme® (laronidase) ● Alyglo™ (IV) ● Amondys 45™ (casimersen) |

Medical Benefit Drug Policy Updates

| Revised | | | |
|--|----------------|--|--|
| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
| Provider Administered Drugs – Site of Care (continued) | Feb. 1, 2025 | <p>administration of the prescribed medication at the alternative Sites of Care as determined by any of the following:</p> <ul style="list-style-type: none"> – The individual’s complex medical status or therapy requires enhanced monitoring and potential intervention above and beyond the capabilities of the alternate Site of Care – The individual’s documented history of a significant comorbidity (e.g., cardiopulmonary disorder or fluid overload) status that precludes treatment at an alternative Site of Care <ul style="list-style-type: none"> ▪ Treatment at an alternate Site of Care setting presents a health risk due to difficulty establishing and maintaining patent vascular access ○ Replaced criterion requiring: <ul style="list-style-type: none"> ▪ “Documentation (e.g., infusion records, medical records) of episodes of severe or potentially life-threatening adverse events (e.g., anaphylaxis, | <ul style="list-style-type: none"> • Amvuttra™ (vutrisiran) • Apretude™ (cabotegravir) • Aralast NP® (A1-PI) • Asceniv™ (IV) • Avsola™ (infliximab-axxq) • Benlysta® (belimumab) • Bivigam® (IV) • Briumvi® (ublituximab-xiiv) • Carimune® NF (IV) • Cerezyme® (imiglucerase) • Cimzia® (certolizumab pegol) • Cinqair® (reslizumab) • Cosentyx® (secukinumab) • Crysvita® (burosumab-twza) • Cutaquig® (SC) • Cuvitru® (SC) • Elaprase® (idursulfase) • Elelyso® (taliglucerase) • Elfabrio® (pegunigalsidase alfa-iwxj) • Enjaymo™ (sutimlimab-jome) • Entyvio® (vedolizumab) • Evkeeza® (evinacumab) • Exondys 51® (eteplirsen) • Fabrazyme® (agalsidase beta) • Fasenra® (benralizumab) • Flebogamma® DIF (IV) • Gammagard® Liquid (IV, SC) • Gammagard® S/D (IV) • Gammaked™ (IV, SC) • Gammaplex® (IV) • Gamunex®-C (IV, SC) • Givlaari® (givosiran) • Glassia® (A1-PI) • Hizentra® (SC) • HyQvia® (SC) |

Medical Benefit Drug Policy Updates

| Revised | | | |
|---|----------------|--|--|
| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
| Provider Administered Drugs – Site of Care (continued) | Feb. 1, 2025 | seizure, thromboembolism, myocardial infarction, renal failure), not including the first or second infusion, and while receiving requested therapy that <i>have not been responsive</i> to acetaminophen, steroids, diphenhydramine, fluids, infusion rate reductions, or other pre-medications, thereby increasing risk to the individual <i>when administration</i> at an alternate Site of Care” with “ <i>previous episode(s)</i> of severe or potentially life-threatening adverse events (e.g., anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure), not including the first or second infusion, <i>that have occurred</i> while receiving requested therapy that <i>was unresponsive</i> to acetaminophen, steroids, diphenhydramine, fluids, infusion rate reductions, or other pre-medications, thereby increasing risk to the individual <i>while</i> | <ul style="list-style-type: none"> • Ilaris® (canakinumab) • Ilumya® (tildrakizumab-asmn) • Inflectra® (infliximab-dyyb) • Kanuma® (sebelipase alfa) • Lamzede® (velmanase alfa-tycv) • Lumizyme® (alglucosidase alfa) • Mepsevii™ (vestronidase alfa-vjvk) • Naglazyme® (galsulfase) • Nexviazyme™ (avalglucosidase alfa-ngpt) • Nucala® (mepolizumab) • Nulibry™ (fosdenopterin) • Ocrevus® (ocrelizumab) • Octagam® (IV) • Omvoh™ (mirikizumab-mrkz) • Onpattro® (patisiran) • Orencia® (abatacept) • Oxlumo® (lumasiran) • Panzyga® (IV) • Pombiliti™ (cipaglucosidase alfa-atga) • Privigen® (IV) • Prolastin®-C™ (A1-PI) • Radicava® (edaravone) • Remicade® (infliximab) • Renflexis® (infliximab-abda) • Revcovi® (elapegedemase-lvlr) • Rivfloza™ (Nedosiran) • Ryplazim® (plasminogen, human-tvmh) • Rystiggo® (rozanolixizumab-noli) • Saphnelo™ (anifrolumab-fnia) • Simponi Aria® (golimumab) • Skyrizi® (risankizumab-rzaa) • Soliris® (eculizumab) • Spevigo® (spesolimab-sbzo) (SC) • Stelara® (ustekinumab) • Tepezza® (teprotumumab-trbw) |

Medical Benefit Drug Policy Updates

| Revised | | | |
|---|----------------|--|---|
| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
| Provider Administered Drugs – Site of Care (continued) | Feb. 1, 2025 | <p><i>administering at alternative Sites of Care</i></p> <ul style="list-style-type: none"> ▪ “Initial infusion or re-initiation of therapy after more than 6 months for a short duration of time (e.g., 4 weeks)” with “initial infusion or re-initiation of <i>previous</i> therapy after more than 6 months (<i>excludes drugs dosed at an interval of 6 months or greater</i>) for a short duration of time (e.g., 4 weeks)” ▪ “The homecare or infusion provider has deemed that the individual, <i>home caregiver</i>, or home environment is not suitable for home infusion therapy” with “the homecare or <i>home</i> infusion provider has deemed that the individual or home environment is not suitable for home infusion therapy” <ul style="list-style-type: none"> • Revised list of applicable medications that require healthcare provider administration; added: <ul style="list-style-type: none"> ○ Alyglo™ (IV) ○ Tremfya® (guselkumab) (IV) | <ul style="list-style-type: none"> • Tezspire™ (tezepelumab-ekko) • Tremfya® (Guselkumab) (IV) • Tzield™ (teplizumab-mzww) • Ultomiris® (ravulizumab-cwvz) • Uplizna® (inebilizumab-cdon) • Veopoz™ (pozelimab-bbfg) • Viltepso™ (viltolarsen) • Vimizim® (elosulfase alfa) • VPRIV® (velaglucerase) • Vyepti® (eptinezumab-jjmr) • Vyjuvek™ (beramagene geperpavec-svdt) • Vyondys 53™ (golodirsen) • Vyvgart® (efgartigimod) • Vyvgart® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) • Xembify® (SC) • Xenpozyme™ (olipudase alfa-rpcp) • Xolair® (Omalizumab) • Zemaira® (A1-PI) |

Medical Benefit Drug Policy Updates

| Revised | | | |
|---|----------------|---|---|
| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
| Provider Administered Drugs – Site of Care (continued) | Feb. 1, 2025 | <p>Documentation Requirements</p> <ul style="list-style-type: none"> Revised list of specialty medications with associated documentation requirements; added: <ul style="list-style-type: none"> Alyglo™ (IV) (HCPCS code J1552) Tremfya® (guselkumab) (IV) (HCPCS code J1628) <p>Applicable Codes</p> <ul style="list-style-type: none"> Added HCPCS codes J1552, J1599, and J1628 <p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>References</i> section to reflect the most current information | |
| Roctavian® (Valoctocogene Roxaparvovec-Rvox) | Feb. 1, 2025 | <p>Coverage Rationale</p> <ul style="list-style-type: none"> Revised coverage criteria; replaced criterion allowing coverage when the “patient is currently receiving chronic prophylactic Hemlibra (emicizumab) therapy” with “patient is currently receiving chronic prophylactic Hemlibra (emicizumab-kxwh) therapy or Hymravzi (marstacimab-hncq)” <p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>References</i> section to reflect the most current information | <p>Hemophilia A (i.e., factor VIII Deficiency, Classical Hemophilia)</p> <p>Roctavian is proven and medically necessary for the treatment of Hemophilia A (factor VIII Deficiency) when all of the following criteria are met:</p> <ul style="list-style-type: none"> Patient is 18 years of age or older; and Both of the following: <ul style="list-style-type: none"> Diagnosis of severe hemophilia A; and Documentation of endogenous factor VIII levels less than 1% of normal factor VIII (< 0.01 IU/mL, < 1 IU/dL); and One of the following: <ul style="list-style-type: none"> Patient is currently receiving chronic prophylactic Hemlibra (emicizumab-kxwh) therapy or Hymravzi (marstacimab-hncq); or Both of the following: <ul style="list-style-type: none"> Patient currently uses factor VIII prophylaxis therapy; and Patient has had a minimum of 150 exposure days to a factor VIII agent <p>or</p> <ul style="list-style-type: none"> Patient has been determined to be an appropriate candidate for Roctavian by the Hemophilia Treatment Center based on willingness |

Medical Benefit Drug Policy Updates

| Revised | | | |
|--|----------------|--------------------|--|
| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
| Roctavian® (Valoctocogene Roxaparvovec-Rvox) | Feb. 1, 2025 | | <p style="text-align: center;">to adhere to initial and long-term monitoring and management</p> <p>and</p> <ul style="list-style-type: none"> • Patient does not have a history of inhibitors to factor VIII greater than or equal to 0.6 Bethesda units [BU]; and • Patient does not screen positive for active factor VIII inhibitors as defined as greater than or equal to 0.6 Bethesda units [BU] prior to administration of Roctavian; and • Patient does not have pre-existing immunity to the AAV5 capsid as detected by the FDA-approved companion diagnostic test AAV5 DetectCDx®; and • Patient has not gone through Immune Tolerance Induction (ITI); and • Liver health assessments including enzyme testing [alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP) and total bilirubin] and hepatic ultrasound and elastography are performed to rule out radiological liver abnormalities and/or sustained liver enzyme elevations; and • One of the following: <ul style="list-style-type: none"> ○ Patient is not HIV positive; or ○ Patient is HIV positive and is virally suppressed with anti-viral therapy (i.e., < 200 copies of HIV per mL) <p>and</p> <ul style="list-style-type: none"> • The patient’s hepatitis B surface antigen is negative; and • One of the following: <ul style="list-style-type: none"> ○ Patient’s hepatitis C virus (HCV) antibody is negative; or ○ Patient’s HCV antibody is positive, and the patient’s HCV RNA is negative <p>and</p> <ul style="list-style-type: none"> • The patient is not currently using antiviral therapy for hepatitis B or C; and • Patient has not previously received treatment with Roctavian or other gene therapy product for the treatment of hemophilia A in the patient’s lifetime; and • Roctavian is administered within a Hemophilia Treatment Center (HTC) that holds Federal designation as evidenced by being listed within the CDC’s HTC directory; and • Prescriber attests that the patient’s ALT and factor VIII activity will be monitored weekly for at least 26 weeks following administration of |

Medical Benefit Drug Policy Updates

| Revised | | | |
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| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
| Roctavian® (Valoctocogene Roxaparvovec-Rvox) (continued) | Feb. 1, 2025 | | <p>Roctavian and regularly thereafter per the monitoring schedule recommended in the prescribing information; and</p> <ul style="list-style-type: none"> Prescriber attests that counseling has been provided to the patient to abstain from consuming alcohol for at least one year following administration of Roctavian and regarding how much alcohol may be acceptable for the patient in the longer term; and Roctavian dosing is in accordance with the United States Food and Drug Administration approved labeling; and Authorization will be issued for no more than one treatment per lifetime and for no longer than 45 days from approval <p>Additional information relevant to the review process but not impacting the determination of medical necessity:</p> <ul style="list-style-type: none"> Prescriber attests that the patient, while under the care of the prescriber, will be assessed for treatment efficacy including, but not limited to evaluation of factor VIII expression, breakthrough bleeding episodes, factor VIII product utilization, inhibitor development*; and Prescriber acknowledges that UnitedHealthcare may request documentation, not more frequently than biannually, and not for a period to exceed 5 years of follow-up patient assessment(s) including, but not necessarily limited to, evaluation of factor VIII expression, breakthrough bleeding episodes, factor VIII product utilization, inhibitor development while the patient is under the care of the prescriber* <p>*For quality purposes only, this information will not be considered as part of the individual coverage decision.</p> <p>Roctavian is not proven or medically necessary for:</p> <ul style="list-style-type: none"> The treatment of hemophilia B The treatment of mild or moderate hemophilia A The repeat administration of Roctavian for the treatment of hemophilia A The treatment of hemophilia A after previously receiving another factor VIII gene therapy product The routine combination treatment with chronically administered prophylactic therapy for hemophilia A The treatment of hemophilia A in patients less than 18 years of age The treatment of hemophilia A in patients with elevated AAV5 antibodies |

General Information

The inclusion of a health service (e.g., test, drug, device, or procedure) in this bulletin indicates only that UnitedHealthcare is adopting a new policy and/or updated, revised, replaced, or retired an existing policy; it does not imply that UnitedHealthcare provides coverage for the health service. Note that most benefit plan documents exclude from benefit coverage health services identified as investigational or unproven/not medically necessary. Physicians and other health care professionals may not seek or collect payment from a member for services not covered by the applicable benefit plan unless first obtaining the member's written consent, acknowledging that the service is not covered by the benefit plan and that they will be billed directly for the service.

Note: The absence of a policy does not automatically indicate or imply coverage. As always, coverage for a health service must be determined in accordance with the member's benefit plan and any applicable federal or state regulatory requirements. Additionally, UnitedHealthcare reserves the right to review the clinical evidence supporting the safety and effectiveness of a medical technology prior to rendering a coverage determination.

UnitedHealthcare respects the expertise of the physicians, health care professionals, and their staff who participate in our network. Our goal is to support you and your patients in making the most informed decisions regarding the choice of quality and cost-effective care, and to support practice staff with a simple and predictable administrative experience. The Medical Policy Update Bulletin was developed to share important information regarding changes to our Medical Policies and Medical Benefit Drug Policies. When information in this bulletin conflicts with applicable state and/or federal law, UnitedHealthcare follows such applicable federal and/or state law.

UMR is a wholly owned subsidiary of UnitedHealthcare, a part of UnitedHealth Group. UMR is a third-party administrator (TPA) for self-funded plans.

Policy Update Classifications

New

New clinical coverage criteria have been adopted for a health service (e.g., test, drug, device, or procedure)

Updated

An existing policy has been reviewed and changes have not been made to the clinical coverage criteria; however, items such as the clinical evidence, FDA information, and/or list(s) of applicable codes may have been updated

Revised

An existing policy has been reviewed and revisions have been made to the clinical coverage criteria

Replaced

An existing policy has been replaced with a new or different policy

Retired

The health service(s) addressed in the policy are no longer being managed or are considered to be proven/medically necessary and are therefore not excluded as unproven/not medically necessary services, unless coverage guidelines or criteria are otherwise documented in another policy



The complete library of UMR Medical Policies and Medical Benefit Drug Policies is available at UHCprovider.com/policies > For Commercial Plans > [UnitedHealthcare](#) | [UMR Medical & Drug Policies](#).