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Medical Policy Update Bulletin: April 2025

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In This Issue

Quarterly CPT/HCPCS Code Updates

Effective **Apr. 1, 2025**, the following Medical Policies and Medical Benefit Drug Policies have been updated to reflect the quarterly 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
Cell-Free Fetal DNA Testing	Medical Policy	• Added CPT code 0536U
Complement Inhibitors (PiaSky®, Soliris®, & Ultomiris®)	Medical Benefit Drug Policy	• Added HCPCS code J1299 • Removed HCPCS code J1300
Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes	Medical Policy	• Removed HCPCS codes G0564 and G0565
FDA Cleared or Approved Companion Diagnostic Testing	Medical Policy	• Added CPT code 0543U
Lower Extremity Prosthetics	Medical Policy	• Added HCPCS code L5827
Maximum Dosage and Frequency	Medical Benefit Drug Policy	• Added HCPCS code J1299 • Removed HCPCS code J1300
Mechanical Stretching Devices	Medical Policy	• Added HCPCS code E1832 • Revised description for HCPCS codes E1801, E1811, E1816, E1818, and E1841
Molecular Oncology Testing for Solid Tumor Cancer Diagnosis, Prognosis, and Treatment Decisions	Medical Policy	• Added CPT codes 0537U, 0538U, 0539U, and 0549U
Ocrevus® (Ocrelizumab) and Ocrevus Zunovo™ (Ocrelizumab and Hyaluronidase-Ocsq)	Medical Benefit Drug Policy	• Replaced HCPCS codes C9399, J3490, and J3590 with J2351
Ophthalmologic Vascular Endothelial Growth Factor (VEGF) Inhibitors	Medical Benefit Drug Policy	• Replaced HCPCS codes C9399, J3490, and J3590 with Q5147
Pharmacogenetic Panel Testing	Medical Policy	• Added CPT code 0533U
Provider Administered Drugs – Site of Care	Medical Benefit Drug Policy	• Added HCPCS codes J1299 and J2351 • Removed HCPCS code J1300
Upper Extremity Prosthetic Devices	Medical Policy	• Added HCPCS codes L6028, L6029, L6030, L6031, L6032, L6033, L6037, L6700, and L7406 • Revised description for HCPCS code L6698

Take Note

Policy Title	Policy Type	Summary of Changes
White Blood Cell Colony Stimulating Factors	Medical Benefit Drug Policy	• Replaced HCPCS code C9173 with Q5148
Whole Exome and Whole Genome Sequencing (Non-Oncology Conditions)	Medical Policy	• Added CPT code 0532U

Medical Policy Updates

Updated		
Policy Title	**Effective Date**	**Summary of Changes**
Ambulance Services	May 1, 2025	**Template Update** • Created shared policy version to support application to Rocky Mountain Health Plans membership **Applicable Codes** • Added modifier QL • Added notation to indicate modifier QL must be billed in place of the origin/destination combination ***Ground/Other Ambulance*** • Removed HCPCS code A0999
Category III Codes	May 1, 2025	**Template Update** • Created shared policy version to support application to Rocky Mountain Health Plans membership **Related Policies** • Removed reference link to the Medical Policy title *Omnibus Codes* **Applicable Codes** • Removed CPT codes 0234T, 0235T, 0236T, 0237T, 0347T, 0348T, 0349T, 0350T, 0494T, 0495T, 0572T, 0573T, 0574T, 0575T, 0576T, 0577T, 0578T, 0579T, 0580T, 0594T, 0600T, 0601T, 0607T, 0608T, 0615T, 0659T, 0695T, 0696T, 0737T, 0870T, 0871T, 0872T, 0873T, 0874T, and 0875T • Revised description for CPT codes 0733T and 0734T **Supporting Information** • Updated *Description of Services* section to reflect the most current information

Rhinoplasty and Other Nasal Procedures	May 1, 2025	**Template Update**
		• Created shared policy version to support application to Rocky Mountain Health Plans membership
		Medical Records Documentation Used for Reviews
		• Updated list of Medical Records Documentation Used for Reviews:
		  ○ Added "relevant surgical history, including dates"
		  ○ Replaced:
		  ▪ "Detailed history of nasal symptoms *for the date of service and the note for the day the decision to perform surgery was made*" with "detailed history of nasal symptoms *including detailed notes with specific date(s) related to evaluation and management*"
		  ▪ "Evidence of *chronic sinusitis with treatment, response, and duration*" with "evidence of *rhinosinusitis*"
		  ▪ "History of treatments tried, failed, or contraindicated" with "history of treatments tried, failed, or contraindicated; *include the dates, duration of treatment, and reason for discontinuation*"
		  ▪ "High-quality color *image(s)* (full face photos *in cases of post-traumatic nasal deformity*)" with "high-quality color *photographs, including but not limited to full face, that clearly show the deformity/dynamic collapse/complication being treated*"
		  ○ Removed reference link to the Medical Policy titled *Cosmetic and Reconstructive Procedures* for CPT code 30560

Medical Policy Updates

Updated

Policy Title	Effective Date	Summary of Changes
Rhinoplasty and Other Nasal Procedures (continued)	May 1, 2025	**Applicable Codes** • Removed CPT code 30999 **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information
Transcatheter Procedures for Heart Valve Conditions	May 1, 2025	**Title Change** • Previously titled *Transcatheter Heart Valve Procedures* **Template Update** • Created shared policy version to support application to Rocky Mountain Health Plans membership **Applicable Codes** • Removed CPT code 33999 **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Cardiovascular Disease Risk Tests	May 1, 2025	**Template Update** • Created shared policy version to support application to Rocky Mountain Health Plans membership **Coverage Rationale** • Revised list of unproven and not medically necessary services: ○ Removed "long-chain omega-3 fatty acids as method to determine risk for cardiovascular disease" ○ Replaced "lipoprotein-associated phospholipase A2 (Lp-PLA2) enzyme *and other human A2 phospholipases such as secretory phospholipase A2 (sPLA2-IIA)* as method to determine	**The following are unproven and not medically necessary due to insufficient evidence of efficacy:** • Arterial compliance testing, using waveform analysis as a method to determine risk for cardiovascular disease • Carotid intima-media thickness (CIMT) measurement as an effective screening tool for the management of cardiovascular disease • Advanced lipoprotein analysis [e.g., lipoprotein(a), subfractions or particle size] as method to determine risk for cardiovascular disease • Lipoprotein-associated phospholipase A2 (Lp-PLA2) enzyme as a method to determine risk for cardiovascular disease or ischemic stroke • Endothelial function assessment using tools such as peripheral arterial tonometry (PAT) or brachial artery pressure ultrasound as a prognostic indicator to determine risk of cardiovascular disease • Multi-protein diagnostic biomarker: ○ Analysis of protein biomarkers by aptamer-based microarray and algorithm ○ 3 proteins [high sensitivity (hs) troponin, adiponectin, and kidney injury molecule-1 (KIM-1)] with algorithm and reported as a risk score

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Cardiovascular Disease Risk Tests (continued)	May 1, 2025	risk for cardiovascular disease or ischemic stroke" with "lipoprotein-associated phospholipase A2 (Lp-PLA2) enzyme as *a* method to determine risk for cardiovascular disease or ischemic stroke ○ Updated list of examples of advanced lipoprotein analysis; removed "apolipoproteins" **Applicable Codes** • Removed CPT codes 82172 and 84999 **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	○ 4 proteins [NT-proBNP, osteopontin, tissue inhibitor of metalloproteinase-1 (TIMP-1), and KIM-1] with algorithm and reported as a risk score ○ 7 proteins (IL-16, FAS, FASLigand, HGF, CTACK, EOTAXIN, and MCP-3) with algorithm and reported as a risk score
Implantable Loop Recorders and Wearable Heart Rhythm Monitors	May 1, 2025	**Title Change** • Previously titled *Cardiac Event Monitoring* **Template Update** • Created shared policy version to support application to Rocky Mountain Health Plans membership **Coverage Rationale** • Removed language indicating the following are proven and medically necessary for evaluating suspected cardiac arrhythmias: ○ Ambulatory Event Monitoring ▪ Holter Monitor	**Implantable Loop Recorders are proven and medically necessary for evaluating suspected cardiac arrhythmias when noninvasive cardiac event recording is contraindicated or yielded non-diagnostic results after at least two weeks of monitoring in one or more of the following circumstances:** • Suspected paroxysmal atrial fibrillation in the setting of a cryptogenic stroke or another documented systemic thromboembolic event • Suspected or known ventricular arrhythmia • High risk for arrhythmia secondary to structural or infiltrative heart disease such as aortic stenosis, hypertrophic cardiomyopathy, cardiac sarcoidosis, congenital heart disease, family history, dilated ischemic or nonischemic cardiomyopathy, or use of medications known to cause malignant arrhythmias such as those prolonging the QT interval • Recurrent or unexplained infrequent syncope, after modification of potentially syncope-causing medications or associated with autonomic dysfunction • Abnormal tests such as electrophysiology study or tilt table testing

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Implantable Loop Recorders and Wearable Heart Rhythm Monitors (continued)	May 1, 2025	▪ Event Monitor ▪ Patch-type monitor ○ Outpatient Cardiac Telemetry • Replaced language indicating "wearable heart rhythm monitors (Cardiac Self-Monitoring Devices) commercially available to the general public and purchased for home use are not medically necessary" with "wearable heart rhythm monitors *or* Cardiac Self-Monitoring Devices commercially available to the general public and purchased for home use are not medically necessary" **Definitions** • Removed definition of: ○ Ambulatory Event Monitoring/ Electrocardiography (ECG) ○ Attended Surveillance ○ Outpatient Cardiac Telemetry • Updated definition of "Implantable Loop Recorder" **Applicable Codes** • Removed CPT codes 93224, 93225, 93226, 93227, 93228, 93229, 93241, 93242, 93243, 93244, 93245, 93246, 93247, 93248, 93268, 93270, 93271, and 93272 **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information	**Replacement of Implantable Loop Recorders is considered medically necessary for an individual who continues to meet all initial criteria for insertion described above and the existing device is beyond its useful life span, is irreparable, or no longer operating.** **Wearable heart rhythm monitors or Cardiac Self-Monitoring Devices commercially available to the general public and purchased for home use are not medically necessary due to insufficient evidence of efficacy and are considered a convenience item.** Such items include (but are not limited to): • A self-monitoring device that includes an ECG monitor combined with a personal electronic device such as a cellular telephone or watch • Hardware or software required for downloading ECG data to a device such as personal computer, tablet, or smart phone

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale

Infertility Diagnosis, Treatment, and Fertility Preservation	May 1, 2025	**Template Update**
		• Created shared policy version to support application to Rocky Mountain Health Plans membership
		Definitions
		• Revised definition of "Infertility"
		Benefit Considerations
		• Modified language addressing state/plan specific benefit coverage requirements to clarify certain plans do not cover Infertility services; legislative mandates and the member specific benefit plan document must be reviewed when determining benefit coverage for Infertility services
		Infertility Services
		• Revised list of services that are eligible for benefit coverage when provided by or under the care or supervision of a physician; added "pharmaceutical products for the treatment of Infertility that are administered on an outpatient basis in a hospital, alternate facility, physician's office, or in your home"
		• Revised eligibility criteria; removed criterion requiring the member must not be able to become pregnant after one year, if the member is a female under age 35, or six months, if the member is a female age 35 or
			For medical necessity reviews, refer to the Clinical Guideline titled Fertility Solutions Medical Necessity Clinical Guideline: Infertility.
			
			The following tests or procedures are proven and medically necessary for diagnosing or treating Infertility:
			• Antisperm antibodies
			• Antral follicle count
			• Cryopreservation of sperm, semen, or embryos for individuals who are undergoing treatment with assisted reproductive technologies or are planning to undergo therapies that threaten their reproductive health, such as cancer chemotherapy
			• Cryopreservation of surgically derived sperm
			• Cryopreservation of *mature* oocytes (eggs) for women who are undergoing treatment with assisted reproductive technologies or are planning to undergo therapies that threaten their reproductive health, such as cancer chemotherapy
			• Cryopreservation of supernumerary embryos or in the setting where the intent is to freeze all embryos for the purpose of an elective single embryo transfer
			• Genetic screening tests:
			  ○ Cystic fibrosis gene mutations
			  ○ Karyotyping for chromosomal abnormalities
			  ○ Y-chromosome microdeletion testing
			• Hormone level tests:
			  ○ Antimüllerian hormone (AMH)
			  ○ Estradiol
			  ○ Follicle-stimulating hormone (FSH)
			  ○ Luteinizing hormone (LH)
			  ○ Progesterone
			  ○ Prolactin
			  ○ Testosterone (total and free)
			  ○ Thyroid-stimulating hormone (TSH)
			• Hysterosalpingogram (HSG)
			• Diagnostic hysteroscopy
			• Diagnostic laparoscopy with or without chromotubation
			• Leukocyte count in semen
			• Pelvic ultrasound (transabdominal or transvaginal)

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Infertility Diagnosis, Treatment, and Fertility Preservation (continued)	May 1, 2025	older, of regular, unprotected intercourse or Therapeutic Donor Insemination ***Fertility Preservation for Iatrogenic Infertility*** • Revised list of coverage limitations and exclusions; added language to indicate benefits are not available for elective fertility preservation **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	• Post-ejaculatory urinalysis • Scrotal, testicular or transrectal ultrasound • Semen analysis • Sonohysterogram or saline infusion ultrasound • Testicular biopsy • Vasography **Due to insufficient evidence of efficacy, the following are unproven and not medically necessary for diagnosing or treating Infertility:** • Co-culture of embryos • Computer-assisted sperm analysis (CASA) • Cryopreservation of immature oocytes (eggs), ovarian tissue, or testicular tissue • EmbryoGlue® • Hyaluronan binding assay (HBA) • In vitro maturation (IVM) of oocytes • Inhibin B • Post-coital cervical mucus penetration test • Reactive oxygen species (ROS) test • Sperm acrosome reaction test • Sperm capacitation test • Sperm DNA integrity/fragmentation tests [e.g., sperm chromatin structure assay (SCSA), single-cell gel electrophoresis assay (Comet), deoxynucleotidyl transferase-mediated dUTP nick end labeling assay (TUNEL), sperm chromatin dispersion (SCD), or Sperm DNA Decondensation™ Test (SDD)] • Sperm penetration assays • Uterine/endometrial receptivity testing • Treatments to improve uterine/endometrial receptivity (e.g., immunotherapy, endometrial scratching, uterine artery vasodilation) • **Note**: For eligibility of Infertility benefits, refer to the member specific benefit plan document. Benefits are available for fertility preservation for medical reasons that cause irreversible Infertility such as chemotherapy, radiation treatment, and bilateral

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Infertility Diagnosis, Treatment, and Fertility Preservation (continued)	May 1, 2025		oophorectomy due to cancer; refer to the member specific benefit plan document. For coding associated with fertility preservation for Iatrogenic Infertility benefit, refer to the Applicable Codes section of this policy; codes are identified with an asterisk (*).

Retired

Policy Title	Effective Date	Summary of Changes
Athletic Pubalgia	Apr. 1, 2025	• Retired policy; treatment of athletic pubalgia no longer requires clinical review
Fecal Microbiota Transplantation	Apr. 1, 2025	• Retired policy; fecal microbiota transplantation no longer requires clinical review
Transanal Minimally Invasive Surgical Procedures	Apr. 1, 2025	• Retired policy; transanal minimally invasive surgical procedures no longer require clinical review
Transpupillary Thermotherapy	Apr. 1, 2025	• Retired policy; transpupillary thermotherapy no longer requires clinical review

New

Policy Title	Effective Date	Coverage Rationale

Niktimvo™ (Axatilimab-Csfr)	May 1, 2025	**Niktimvo™ (axatilimab-csfr) 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.**
		
		Niktimvo (axatilimab-csfr) is proven for the treatment of chronic graft-versus-host disease (cGVHD) after failure of at least two prior lines of systemic therapy. Niktimvo is medically necessary for the treatment of chronic graft-versus-host disease (cGVHD) in patients who meet all of the following criteria:
		• For **initial therapy**, **all** of the following:
		  ○ Diagnosis of chronic graft-versus-host disease (cGVHD) as defined by **all** of the following:
		  ▪ Patient has undergone allogenic hematopoietic cell transplantation (HCT); **and**
		  ▪ Clinical symptoms and signs that are components of the National Institutes of Health (NIH) consensus criteria for diagnosis of cGVHD; **and**
		  ▪ cGVHD is classified as moderate or severe based on grading scale (e.g., NIH disease grade, CIBMTR score)
		  and
		  ○ Patient has history of failure with **both** of the following:
		  ▪ Corticosteroid (e.g., prednisone, methylprednisolone); **and**
		  ▪ **One** of the following:
		  – Bortezomib; **or**
		  – Imbruvica (ibrutinib); **or**
		  – Immunosuppressant agent (e.g., cyclosporine, mycophenolate, tacrolimus); **or**
		  – Jakafi (ruxolitinib); **or**
		  – Rezurock (belumosudil); **or**
		  – Rituximab
		  and
		  ○ Patient weighs at least 40 kg; **and**
		  ○ Prescribed by or in consultation with a transplant specialist; **and**
		  ○ Niktimvo dosing is in accordance with the United States Food and Drug Administration approved labeling; **and**
		  ○ Authorization will be issued for no more than 12 months
		• For **continuation of therapy**, **all** of the following:
		  ○ Documentation of a positive clinical response to Niktimvo therapy; **and**
		  ○ Prescribed by or in consultation with a transplant specialist; **and**
		  ○ Niktimvo dosing is in accordance with the United States Food and Drug Administration approved labeling; **and**
		  ○ Reauthorization will be issued for no more than 12 months
		
		Niktimvo (axatilimab-csfr) is unproven and not medically necessary for prevention and/or treatment for all other indications, including but not limited to acute graft-versus-host disease (aGVHD), due to insufficient evidence of efficacy.

Updated

Policy Title	Effective Date	Summary of Changes
Complement Inhibitors (PiaSky®, Soliris®, & Ultomiris®)	Apr. 1, 2025	**Coverage Rationale** • Removed reference link to the Medical Benefit Drug Policy titled *Review at Launch for New to Market Medications* for PiaSky® (crovalimab-akkz) **Applicable Codes** • Updated list of applicable HCPCS codes to reflect quarterly edits: ○ Added J1299 ○ Removed J1300
Enjaymo® (Sutimlimab-Jome)	Apr. 1, 2025	**Coverage Rationale** • Updated list of examples of complement inhibitors the patient must not be receiving in combination with Enjaymo; added PiaSky (crovalimab) **Supporting Information** • Updated *References* section to reflect the most current information
Parsabiv® (Etelcalcetide)	May 1, 2025	**Applicable Codes** • Added list of applicable ICD-10 diagnosis codes: E21.1, N18.1, N18.2, N18.30, N18.31, N18.32, N18.4, N18.5, N18.9, and N25.81

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Amondys 45® (Casimersen)	May 1, 2025	**Coverage Rationale** • Revised coverage criteria: ○ Replaced criterion requiring "the patient has achieved a time to rise *from the floor (Gower's test)* of less than 7 seconds" with "the patient has achieved a time to rise *(TTR)* of less than 7 seconds" ○ Added list of examples of exon skipping therapies that cannot be used concomitantly with Amondys 45: Exondys 51 (eteplirsen), Viltepso (viltolarsen), and Vyondys 53 (golodirsen) • Replaced language indicating "Amondys 45 *will not be covered*	**Amondys 45 (casimersen) may be covered for the treatment of Duchenne muscular dystrophy (DMD) in patients who meet all of the following criteria:** **Initial Therapy** • Diagnosis of Duchenne muscular dystrophy by, or in consultation with, a neurologist with expertise in the diagnosis of DMD; **and** • Submission of medical records (e.g., chart notes, laboratory values) confirming the mutation of the DMD gene is amenable to exon 45 skipping; **and** • **One** of the following: ○ Submission of medical records (e.g., chart notes, laboratory values) confirming that the patient has a 6-Minute Walk Test (6MWT) ≥ 300 meters while walking independently (e.g., without side-by-side assist, cane, walker, wheelchair, etc.) prior to beginning Amondys 45 therapy; **or** ○ **Both** of the following:

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Amondys 45® (Casimersen) (continued)	May 1, 2025	for other forms of muscular dystrophy" with "Amondys 45 *is unproven and not medically necessary* for *the treatment* of other forms of muscular dystrophy *(e.g., Becker muscular dystrophy)*" **Supporting Information** • Updated *Background*, *Clinical Evidence*, and *References* sections to reflect the most current information	▪ Submission of medical records (e.g., chart notes) confirming that the patient is ambulatory **without** needing an assistive device (e.g., without side-by-side assist, cane, walker, wheelchair, etc.); **and** ▪ **One** of the following: – Patient has achieved a score of greater than 17 on the North Star Ambulatory Assessment (NSAA); **or** – Patient has achieved a time to rise (TTR) of less than 7 seconds **and** • Amondys 45 is not used concomitantly with other exon skipping therapies for DMD [e.g., Exondys 51 (eteplirsen), Viltepso (viltolarsen), Vyondys 53 (golodirsen)]; **and** • Prescribed by, or in consultation with, a neurologist with expertise in the treatment of DMD; **and** • 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** • Submission of medical records (e.g., chart notes) confirming that the patient is ambulatory **without** needing an assistive device (e.g., without side-by-side assist, cane, walker, wheelchair, etc.); **and** • Amondys 45 is not used concomitantly with other exon skipping therapies for DMD [e.g., Exondys 51 (eteplirsen), Viltepso (viltolarsen), Vyondys 53 (golodirsen)]; **and** • Prescribed by, or in consultation with, a neurologist with expertise in the treatment of DMD; **and** • Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** • Reauthorization will be for no more than 12 months **Unproven** **Amondys 45 is unproven and not medically necessary for the treatment of other forms of muscular dystrophy (e.g., Becker muscular dystrophy).**

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale

Exondys 51® (Eteplirsen)	May 1, 2025	**Coverage Rationale**
		• Revised coverage criteria:
		  ○ Replaced criterion requiring "the patient has achieved a time to rise *from the floor (Gower's test)* of less than 7 seconds" with "the patient has achieved a time to rise *(TTR)* of less than 7 seconds"
		  ○ Updated list of examples of exon skipping therapies that cannot be used concomitantly with Exondys 51; added Amondys (casimersen) and Viltepso (viltolarsen)
		• Replaced language indicating "Exondys 51 *will not be covered* for other forms of muscular dystrophy" with "Exondys 51 *is unproven and not medically necessary* for *the treatment* of other forms of muscular dystrophy *(e.g., Becker muscular dystrophy)*"
		Supporting Information
		• Updated *Background*, *Clinical Evidence*, and *References* sections to reflect the most current information
			Exondys 51® (eteplirsen) may be covered for the treatment of Duchenne muscular dystrophy (DMD) in patients who meet all of the following criteria:
			Initial Therapy
			• Diagnosis of Duchenne muscular dystrophy by, or in consultation with, a neurologist with expertise in the diagnosis of DMD; **and**
			• Submission of medical records (e.g., chart notes, laboratory values) confirming the mutation of the DMD gene is amenable to exon 51 skipping; **and**
			• **One** of the following:
			  ○ Submission of medical records (e.g., chart notes, laboratory values) confirming that the patient has a 6-Minute Walk Test (6MWT) ≥ 300 meters while walking independently (e.g., without side-by-side assist, cane, walker, wheelchair, etc.) prior to beginning Exondys 51 therapy; **or**
			  ○ **Both** of the following:
			  ▪ Submission of medical records (e.g., chart notes) confirming that the patient is ambulatory **without** needing an assistive device (e.g., without side-by-side assist, cane, walker, wheelchair, etc.); **and**
			  ▪ **One** of the following:
			  – Patient has achieved a score of greater than 17 on the North Star Ambulatory Assessment (NSAA); **or**
			  – Patient has achieved a time to rise (TTR) of less than 7 seconds
			and
			• Exondys 51 is not used concomitantly with other exon skipping therapies for DMD [e.g., Amondys (casimersen), Viltepso (viltolarsen), Vyondys 53 (golodirsen)]; **and**
			• Exondys 51 is prescribed by, or in consultation with, a neurologist with expertise in the treatment of DMD; **and**
			• 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

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Exondys 51® (Eteplirsen) (continued)	May 1, 2025		**Continuation Therapy** • Submission of medical records (e.g., chart notes) confirming that the patient is ambulatory **without** needing an assistive device (e.g., without side-by-side assist, cane, walker, wheelchair, etc.); **and** • Exondys 51 is not used concomitantly with other exon skipping therapies for DMD [e.g., Amondys (casimersen), Viltepso (viltolarsen), Vyondys 53 (golodirsen)]; **and** • Prescribed by, or in consultation with, a neurologist with expertise in the treatment of DMD; **and** • Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** • Reauthorization will be for no more than 12 months **Unproven** **Exondys 51 is unproven and not medically necessary for the treatment of other forms of muscular dystrophy (e.g., Becker muscular dystrophy).**
Ketalar® (Ketamine) and Spravato® (Esketamine)	May 1, 2025	**Coverage Rationale** • Revised coverage criteria for **Spravato (esketamine) nasal spray**: ***Treatment-Resistant Depression (TRD)*** ○ Updated list of applicable clinical assessments for depression: ▪ Added Beck Depression Inventory (BDI) ▪ Removed specific number of items listed for the following rating scales: – Hamilton Rating Scale for Depression (HAMD) – Montgomery-Asberg	This policy refers to the following ketamine products: • Ketalar (ketamine) • Spravato (esketamine) **Spravato (Esketamine) Nasal Spray** **Spravato is proven for the treatment of treatment-resistant depression (TRD) when all of the following criteria are met:** • **Initial Therapy** ○ Diagnosis of major depressive disorder (treatment-resistant); **and** ○ Patient has not experienced a clinically meaningful improvement after treatment with at least two different antidepressants; **and** ○ Provider and/or the provider's healthcare setting is certified in the Spravato REMS program; **and** ○ Spravato dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** ○ Initial authorization will be for no longer than 12 months • **Continuation of Therapy** ○ Documentation of positive clinical response to Spravato therapy; **and** ○ Provider and/or the provider's healthcare setting is certified in the

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Ketalar® (Ketamine) and Spravato® (Esketamine) (continued)	May 1, 2025	Depression Rating Scale (MADRS) – Quick Inventory of Depressive Symptomatology (QIDS) Initial Therapy ○ Removed criterion requiring the patient is to receive Spravato therapy in conjunction with an oral antidepressant ○ Replaced criterion requiring: ▪ "Diagnosis of major depressive disorder *according to the current DSM (i.e., DSM-5-TR), by a mental health professional*" with "diagnosis of major depressive disorder" ▪ "The patient has not experienced a clinically meaningful improvement after treatment with at least two different antidepressants *of adequate dose and duration (at least 6 weeks) in the current depressive episode (must document medications, doses, and durations)*" with "the patient has not experienced a clinically meaningful improvement after treatment with at	Spravato REMS program; **and** ○ Spravato dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** ○ Reauthorization will be for no longer than 12 months **Spravato is medically necessary for the treatment of treatment-resistant depression (TRD) when all of the following criteria are met:** • **Initial Therapy** ○ Diagnosis of major depressive disorder (treatment-resistant), according to the current DSM (i.e., DSM-5-TR), by a mental health professional; **and** ○ Submission of medical records (e.g., chart notes, laboratory values) documenting baseline scoring (prior to starting Spravato) on at least **one** of the following clinical assessments has been completed: ▪ Beck Depression Inventory (BDI) ▪ Hamilton Rating Scale for Depression (HAMD) ▪ Montgomery-Asberg Depression Rating Scale (MADRS) ▪ 9-item Patient Health Questionnaire (PHQ-9) ▪ Quick Inventory of Depressive Symptomatology (QIDS) **and** ○ History of failure of a trial of at least two different antidepressants or treatment regimens for a duration of at least 8 weeks each (document medication, date, and duration of trial): ▪ An antidepressant or treatment regimen would include any of the following classes or combinations: – Selective serotonin reuptake inhibitors (e.g., citalopram, fluoxetine, paroxetine, sertraline) – Serotonin norepinephrine reuptake inhibitors (e.g., duloxetine, venlafaxine, etc.) – Bupropion – Tricyclic antidepressants (e.g., amitriptyline, clomipramine, nortriptyline, etc.) – Mirtazapine – Monoamine oxidase inhibitors (e.g., selegiline, tranylcypromine, etc.) – Serotonin modulators (e.g., nefazodone, trazodone, etc.) – Augmentation with antipsychotics, lithium, or thyroid hormone

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Ketalar® (Ketamine) and Spravato® (Esketamine) (continued)	May 1, 2025	least two different antidepressants" ▪ "The patient has *not experienced a clinically meaningful improvement after treatment with* at least *three* different antidepressants or treatment regimens *of adequate dose (maximally tolerated)* and duration (at least 8 weeks) *in the current depressive episode*" with "the patient has *a history of failure of a trial of* at least *two* different antidepressants or treatment regimens for a duration of at least 8 weeks *each*" ▪ "[Treatment with] an antidepressant or treatment regimen of augmentation with antipsychotics, lithium, Cytomel (liothyronine), or anticonvulsants" with "[treatment with] an antidepressant or treatment regimen of augmentation with antipsychotics, lithium, or thyroid hormone" Continuation of Therapy ○ Removed criterion requiring:	**and** ○ Provider and/or the provider's healthcare setting is certified in the Spravato REMS program; **and** ○ Prescribed by or in consultation with a psychiatrist; **and** ○ Spravato dosing is in accordance with the United States Food and Drug Administration (FDA) approved labeling; **and** ○ Initial authorization will be for no longer than 12 months • **Continuation of Therapy** ○ Documentation of remission or a positive clinical response to Spravato therapy; **and** ○ Submission of medical records (e.g., chart notes, laboratory values) documenting baseline and recent (within the last month) scoring on at least **one** of the following assessments demonstrating remission or clinical response (e.g., score reduction from baseline) as defined by the: ▪ BDI ▪ HAMD ▪ MADRS ▪ PHQ-9 ▪ QIDS **and** ○ Provider and/or the provider's healthcare setting is certified in the Spravato REMS program; **and** ○ Prescribed by or in consultation with a psychiatrist; **and** ○ Spravato dosing is in accordance with the United States FDA approved labeling; **and** ○ Reauthorization will be for no longer than 12 months **Spravato is proven for the treatment of depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior when all of the following criteria are met:** • **Initial Therapy** ○ Diagnosis of major depressive disorder; **and** ○ Patient is experiencing an acute suicidal ideation or behavior; **and** ○ Provider and/or the provider's healthcare setting is certified in the Spravato REMS program; **and** ○ Spravato dosing is in accordance with the United States Food and

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Ketalar® (Ketamine) and Spravato® (Esketamine) (continued)	May 1, 2025	▪ The patient has previously been treated with Spravato ▪ The patient is to receive Spravato therapy in conjunction with an oral antidepressant ○ Removed specific dosage requirements for Spravato (esketamine); refer to the applicable U.S. FDA approved labeling ***Major Depressive Disorder (MDD)*** Initial Therapy ○ Replaced criterion requiring "diagnosis of major depressive disorder *according to the current DSM (i.e., DSM-5-TR), by a mental health professional*" with "diagnosis of major depressive disorder" **Supporting Information** • Updated *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	Drug Administration approved labeling; **and** ○ Initial authorization will be for no longer than 12 months **Spravato is medically necessary for the treatment of depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior when all of the following criteria are met:** • **Initial Therapy** ○ Diagnosis of major depressive disorder according to the current DSM (i.e., DSM-5-TR), by a mental health professional; **and** ○ Patient is experiencing an acute suicidal ideation or behavior; **and** ○ Patient is to receive Spravato therapy in conjunction with a newly initiated or optimized oral antidepressant; **and** ○ Provider and/or the provider's healthcare setting is certified in the Spravato REMS program; **and** ○ Spravato dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** ○ Initial authorization will be for no longer than 12 months **Spravato is unproven and not medically necessary for the following:** • Anesthetic agent • Chronic pain (including but not limited to nonmalignant pain, Fibromyalgia, neuropathic pain, Complex Regional Pain Syndrome, Reflex Sympathetic Dystrophy) • Migraine headaches **Ketalar (Ketamine) Injection** **Ketamine injection is considered medically necessary and may be covered for the following:** • Anesthesia for diagnostic and surgical procedures that do not require skeletal muscle relaxation • The induction of anesthesia prior to administration of other anesthesia agents • As supplemental anesthesia for low-potency agents, such as nitrous oxide **Ketamine injection is investigational, and therefore not proven or medically necessary for the following:**

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Ketalar® (Ketamine) and Spravato® (Esketamine) (continued)	May 1, 2025		• Psychiatric disorders (including but not limited to depression, bipolar disorder, and posttraumatic stress disorder) • Chronic pain (including but not limited to nonmalignant pain, Fibromyalgia, neuropathic pain, Complex Regional Pain Syndrome, Reflex Sympathetic Dystrophy) • Migraine headaches
Maximum Dosage and Frequency	Apr. 1, 2025	**Notice of Revision**: The following summary of changes has been modified. Revisions to the previous policy update announcement are outlined in red below. Please take note of the additional updates to be applied on **Apr. 1, 2025**. **Coverage Rationale** • Revised list of applicable drug products; added: ○ aflibercept (Eylea® HD) ○ crovalimab-akkz (PiaSky™) ○ guselkumab (Tremfya®) • Added language to indicate continued use of a medication or dosages used beyond labeled indication or other published clinical evidence [e.g., well-designed systematic reviews (with or without meta-analyses) of multiple well-designed randomized controlled trials, NCCN guidelines] is considered not medically necessary • Added examples of published clinical evidence used to support medication use: ○ Well-designed systematic reviews (with or without meta-analyses) of multiple well-	This policy provides information about the maximum dosage per administration and dosing frequency for certain medications administered by a medical professional. Most medications have a maximum dosage and frequency based upon body surface area or patient weight or a set maximal dosage and frequency independent of patient body size. **Drug Products** • abatacept (Orencia®) • abobotulinumtoxinA (Dysport®) • aflibercept (Eylea®) • aflibercept (Eylea® HD) • atezolizumab (Tecentriq®) • avelumab (Bavencio®) • benralizumab (Fasenra®) • bevacizumab (Avastin®) • bevacizumab-adcd (Vegzelma®) • bevacizumab-awwb (Mvasi™) • bevacizumab-bvzr (Zirabev®) • bevacizumab-maly (Alymsys®) • brolucizumab-dbll (Beovu®) • canakinumab (Ilaris®) • cemiplimab-rwlc (Libtayo®) • certolizumab pegol (Cimzia®) • crovalimab-akkz (PiaSky™) • daxibotulinumtoxina-lanm (Daxxify®) • denosumab (Prolia® & Xgeva®) • durvalumab (Imfinzi®) • eculizumab (Soliris®) • pegfilgrastim (Neulasta®) • pegfilgrastim-apgf (Nyvepria™) • pegfilgrastim-cbqv (Udenyca®) • pegfilgrastim-fpgk (Stimufend®) • pegfilgrastim-jmdb (Fulphila™) • pegfilgrastim-pbbk (Fylnetra®) • pegfilgrastim-bmez (Ziextenzo®) • pegloticase (Krystexxa®) • pembrolizumab (Keytruda®) • ranibizumab (Lucentis®) • ranibizumab-nuna (Byooviz™) • ranibizumab-eqrn (Cimerli™) • ravulizumab-cwvz (Ultomiris®) • reslizumab (Cinqair®) • rimabotulinumtoxinB (Myobloc®) • risankizumab-rzaa (Skyrizi®) • rituximab (Rituxan®) • rituximab-pvvr (Ruxience™) • rituximab-abbs (Truxima®) • rituximab-arrx (Riabni™)

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Maximum Dosage and Frequency (continued)	Apr. 1, 2025	designed randomized controlled trials ○ The National Comprehensive Cancer Network (NCCN) guidelines ***Maximum Allowed Quantities by HCPCS Units*** • Revised list of HCPCS codes with maximum allowed quantities: ○ Added: ▪ PiaSky (crovalimab-akkz) ▪ Tremfya (guselkumab) ○ Updated list of applicable HCPCS codes for Soliris (eculizumab): ▪ Added J1299 ▪ Removed J1300 ○ Updated maximum dosage/maximum allowed units for Soliris (eculizumab); replaced: ▪ "*10* mg per unit" with "*2* mg per unit" ▪ "*120* HCPCS units" with "*600* HCPCS units" ***Maximum Allowed Quantities for National Drug Code (NDC) Billing*** • Revised list of NDCs with maximum allowed quantities: ○ Added: ▪ PiaSky (crovalimab-akkz): 50242-0115-01 ▪ Tremfya (guselkumab): 57894-0650-02	• edaravone (Radicava®) • efgartigimod alfa-fcab (Vyvgart®) • efgartigimod alfa and hyaluronidase-qvfc (Vyvgart® Hytrulo) • eflapegrastim-xnst (Rolvedon™) • emicizumab-kxwh (Hemlibra®) • eptinezumab-jjmr (Vyepti®) • faricimab-svoa (Vabysmo™) • golimumab (Simponi Aria®) • guselkumab (Tremfya®) • inclisiran (Leqvio®) • incobotulinumtoxinA (Xeomin®) • infliximab (Remicade®) • infliximab-axxq (Avsola™) • infliximab-dyyb (Inflectra®) • infliximab-abda (Renflexis®) • ipilimumab (Yervoy®) • mepolizumab (Nucala®) • mirikizumab-mrkz (Omvoh®) • nivolumab (Opdivo®) • ocrelizumab (Ocrevus®) • omalizumab (Xolair®) • onabotulinumtoxinA (Botox®) • patisiran (Onpattro®) • pegcetacoplan (Syfovre™) • rituximab and hyaluronidase (Rituxan Hycela®) • rozanolixizumab-noli (Rystiggo®) • spesolimab-sbzo (Spevigo®) • testosterone cypionate (Depo-Testosterone®) • testosterone enanthate • testosterone pellets (Testopel®) • testosterone undecanoate (Aveed®) • tezepelumab-ekko (Tezspire®) • tildrakizumab-asmn (Ilumya™) • tocilizumab (Actemra®) • tofersen (Qalsody™) • trastuzumab (Herceptin®) • trastuzumab-anns (Kanjinti™) • trastuzumab-dkst (Ogivri™) • trastuzumab-dttb (Ontruzant®) • trastuzumab-pkrb (Herzuma®) • trastuzumab-qyyp (Trazimera™) • ustekinumab (Stelara®) • vedolizumab (Entyvio®) • vutrisiran (Amvuttra™) • zoledronic acid (zoledronic acid, Reclast®) **The use of medications included in this policy when given within the maximum dosage and/or frequency based upon body surface area or patient weight or a set of maximal dosage and/or frequency independent of patient body size are proven when used according to labeled indications or when otherwise supported by published clinical evidence [e.g., well-designed systematic reviews (with or without meta-analyses) of multiple well-designed randomized controlled trials, the National Comprehensive Cancer Network (NCCN) guidelines].**

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Maximum Dosage and Frequency (continued)	Apr. 1, 2025	○ Removed Daxxify (daxibotulinumtoxinA-lanm): 72960-111-01 ***Maximum Allowed Frequencies*** • Revised list of drug products with maximum frequencies: ○ Added: ▪ Eylea HD (aflibercept) for the diagnosis of: – Diabetic macular edema (DME) and neovascular age-related macular degeneration (nAMD): The recommended dose is 8 mg (0.07 mL) into affected eye(s) every 4 weeks (approximately every 28 days +/- 7 days) for the first 3 doses, then 8 mg every 8 to 16 weeks +/- 1 week; maximum of 12 doses per year per eye – Diabetic retinopathy (DR): The recommended dose is 8 mg (0.7 mL) into affected eye(s) every 4 weeks (approximately every 28 days +/- 7 days) for the first 3 doses, followed by 8 mg	**The use of medications included in this policy when given beyond maximum dosages and/or frequency based upon body surface area or patient weight or a set maximal dosage independent of patient body size are not supported by package labeling or published clinical evidence and are unproven.** **Continued use of a medication or dosages used beyond labeled indication or other published clinical evidence [e.g., well-designed systematic reviews (with or without meta-analyses) of multiple well-designed randomized controlled trials, NCCN guidelines] is considered not medically necessary.** This policy creates an upper dose limit based on the clinical evidence and the 95th percentile for adult body weight (140 kg) and body surface area (2.71 meters^2) in the U.S. (adult male, 30 to 39 years, Fryar, 2021). In some cases, the maximum allowed units and/or vials may exceed the upper level limit as defined within this policy due to an individual patient body weight > 140 kg or body surface area > 2.71 meters^2. Refer to the policy for complete details.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Maximum Dosage and Frequency (continued)	Apr. 1, 2025	once every 8 to 12 weeks +/- 1 week; maximum of 12 doses per year per eye ▪ PiaSky (crovalimab-akkz) for the diagnosis of paroxysmal nocturnal hemoglobinuria (PNH): One loading dose administered intravenously on day 1, followed by four additional weekly loading doses administered subcutaneously (on days 2, 8, 15, and 22); the maintenance dose starts on day 29 and is then administered every 4 weeks subcutaneously ▪ Tremfya (guselkumab) for the diagnosis of ulcerative colitis: Administered intravenously initially at week 0, week 4, and week 8, then administered subcutaneously every 4 or 8 weeks thereafter ○ Updated list of applicable diagnoses for: ▪ Eylea (aflibercept): Added diagnosis of retinopathy of prematurity (ROP) with the recommended dose	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Maximum Dosage and Frequency (continued)	Apr.1, 2025	of 0.4 mg (0.01 mL) per affected eye(s) and may be given bilaterally on the same day, and injections may be repeated in each eye; the treatment interval between doses injected into the same eye should be at least 10 days ▪ Vabysmo (faricimab): Added diagnosis of macular edema following retinal vein occlusion (RVO) with the recommended dose of 6 mg (0.05 mL) by intravitreal injection every 4 weeks (approximately every 28 ±7 days, monthly) for 6 months **Applicable Codes** • Updated list of applicable HCPCS codes: ○ Added J0177, J0178, J0179, J1299*, J1307, J1628, J2777, J2778, Q5124, and Q5128 ○ Removed J1300* *(*quarterly edit)* • Updated list of applicable NDCs: ○ Added 50242-0115-01 and 57894-0650-02 ○ Removed 72960-0111-01 **Supporting Information** • Updated *References* section to reflect the most current information	

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Omvoh® (Mirikizumab-Mrkz)	May 1, 2025	**Coverage Rationale** • Added language to indicate: ○ Omvoh is proven for the treatment of Crohn's disease (CD) when all of the following criteria are met: ▪ Diagnosis of moderately to severely active CD ▪ Omvoh is to be administered as three intravenous induction doses ▪ Omvoh induction dosing is in accordance with the U.S. FDA labeled dosing for CD ▪ Patient is not receiving Omvoh in combination with another targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Xeljanz (tofacitinib)] ▪ Authorization will be issued for 3 induction doses ○ Omvoh is medically necessary for the treatment of CD when all of the following criteria are met:	This policy refers to Omvoh (mirikizumab-mrkz) injection. Omvoh (mirikizumab-mrkz) for self-administered subcutaneous injection is obtained under the pharmacy benefit. **Ulcerative Colitis (UC)** **Omvoh is proven for the treatment of ulcerative colitis when all of the following criteria are met:** • Diagnosis of moderately to severely active ulcerative colitis; **and** • Omvoh is to be administered as three intravenous induction doses; **and** • Omvoh induction dosing is in accordance with the United States Food and Drug Administration (FDA) labeled dosing for UC; **and** • Patient is not receiving Omvoh in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Stelara (ustekinumab), Skyrizi (risankizumab)]; **and** • Authorization will be issued for 3 induction doses **Omvoh is medically necessary for the treatment of ulcerative colitis when all of the following criteria are met:** • Diagnosis of moderately to severely active ulcerative colitis; **and** • **One** of the following: ○ Patient has had prior or concurrent inadequate response to a therapeutic course of oral corticosteroids and/or immunosuppressants (e.g., azathioprine, 6-mercaptopurine); **or** ○ Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ulcerative colitis [e.g., adalimumab, infliximab, Entyvio (vedolizumab), Rinvoq (upadacitinib) Simponi (golimumab), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Xeljanz (tofacitinib)] **and** • Omvoh is to be administered as three intravenous induction doses; **and** • Omvoh induction dosing is in accordance with the U.S FDA labeled dosing for UC; **and** • Patient is not receiving Omvoh in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Xeljanz

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Omvoh® (Mirikizumab-Mrkz) (continued)	May 1, 2025	▪ Diagnosis of moderately to severely active CD ▪ One of the following: – History of failure to one of the following conventional therapies at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced: • Corticosteroids (e.g., prednisone, methylpredni-solone, budesonide) • 6-mercaptopurine (Purinethol) • Azathioprine (Imuran) • Methotrexate (Rheumatrex, Trexall) – Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of CD [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib),	(tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Stelara (ustekinumab), Skyrizi (risankizumab)]; **and** • Prescribed by or in consultation with a gastroenterologist; **and** • Authorization will be issued for 3 induction doses **Crohn's Disease (CD)** **Omvoh is proven for the treatment of Crohn's disease (CD) when all of the following criteria are met:** • Diagnosis of moderately to severely active Crohn's disease; **and** • Omvoh is to be administered as three intravenous induction doses; **and** • Omvoh induction dosing is in accordance with the United States Food and Drug Administration (FDA) labeled dosing for CD; **and** • Patient is not receiving Omvoh in combination with another targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Xeljanz (tofacitinib)] **and** • Authorization will be issued for 3 induction doses **Omvoh is medically necessary for the treatment of Crohn's disease (CD) when all of the following criteria are met:** • Diagnosis of moderately to severely active Crohn's disease; **and** • One of the following: ○ History of failure to **one** of the following conventional therapies at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced: ▪ Corticosteroids (e.g., prednisone, methylprednisolone, budesonide) ▪ 6-mercaptopurine (Purinethol) ▪ Azathioprine (Imuran) ▪ Methotrexate (Rheumatrex, Trexall) **or** ○ Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of Crohn's disease [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq

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Omvoh® (Mirikizumab-Mrkz) (continued)	May 1, 2025	Simponi (golimumab), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Xeljanz (tofacitinib)] ▪ Omvoh is to be administered as three intravenous induction doses ▪ Omvoh induction dosing is in accordance with the U.S. FDA labeled dosing for CD ▪ Patient is not receiving Omvoh in combination with another targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Xeljanz (tofacitinib)] ▪ Prescribed by or in consultation with a gastroenterologist ▪ Authorization will be issued for 3 induction doses **Applicable Codes** • Added ICD-10 diagnosis codes K50.00, K50.011, K50.012, K50.013, K50.014, K50.018,	(upadacitinib), Simponi (golimumab), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Xeljanz (tofacitinib)] **and** • Omvoh is to be administered as three intravenous induction doses; **and** • Omvoh induction dosing is in accordance with the United States Food and Drug Administration (FDA) labeled dosing for CD; **and** • Patient is not receiving Omvoh in combination with another targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Olumiant (baricitinib), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab-rzaa), Stelara (ustekinumab), Xeljanz (tofacitinib)]; **and** • Prescribed by or in consultation with a gastroenterologist; **and** • Authorization will be issued for 3 induction doses

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Omvoh® (Mirikizumab-Mrkz) (continued)	May 1, 2025	K50.019, K50.10, K50.111, K50.112, K50.113, K50.114, K50.118, K50.119, K50.80, K50.811, K50.812, K50.813, K50.814, K50.818, K50.819, K50.90, K50.911, K50.912, K50.913, K50.914, K50.918, and K50.919 **Supporting Information** • Updated *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information • Removed *CMS* section	
Ophthalmologic Vascular Endothelial Growth Factor (VEGF) Inhibitors	May 1, 2025	**Coverage Rationale** • Removed reference link to the Medical Benefit Drug Policy titled *Review at Launch for New to Market Medications* for Pavblu™ (aflibercept-ayyh) • Removed list of *Maximum Allowed Frequencies*; refer to the Medical Benefit Drug Policy titled *Maximum Dosage and Frequency*	This policy provides information about the use of certain specialty pharmacy medications administered by the intravitreal route for ophthalmologic conditions. This policy refers to the following vascular endothelial growth factor (VEGF) inhibitors and dual VEGF/angiopoietin-2 (Ang-2) inhibitors: • Avastin® (bevacizumab) • Beovu® (brolucizumab-dbll) • Byooviz™ (ranibizumab-nuna) • Cimerli™ (ranibizumab-eqrn) • Eylea® (aflibercept) • Eylea® HD (aflibercept) • Lucentis® (ranibizumab) • Pavblu™ (aflibercept-ayyh) • Vabysmo™ (faricimab-svoa) **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. **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 *CMS* section of the policy).

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Ophthalmologic Vascular Endothelial Growth Factor (VEGF) Inhibitors (continued)	May 1, 2025		**Coverage for Avastin®, Cimerli™, Eylea®, Lucentis®, and Vabysmo™ is contingent on criteria in the General Requirements and Diagnosis-Specific Requirements sections.**
			
			General Requirements (Applicable to all Medical Necessity Requests)
			• For **initial therapy**, **both** of the following:
			  ○ Diagnosis; **and**
			  ○ Intravitreal VEGF or dual VEGF/Ang-2 inhibitor administration is no more than 12 doses per year per eye, regardless of diagnosis
			• For **continuation of therapy**, **both** of the following:
			  ○ 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
			
			Diagnosis-Specific Requirements
			The information below indicates the list of proven and medically necessary indications.
			
			Avastin (bevacizumab) is proven and medically necessary for the treatment of:
			• 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
			
			Beovu (brolucizumab) is proven and medically necessary for the treatment of:

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Ophthalmologic Vascular Endothelial Growth Factor (VEGF) Inhibitors (continued)	May 1, 2025		• Neovascular age-related macular degeneration (nAMD) • Diabetic macular edema (DME) **Byooviz (ranibizumab-nuna) is proven and medically necessary for the treatment of:** • Neovascular age-related macular degeneration (nAMD) • Macular edema following retinal vein occlusion (RVO) • Myopic choroidal neovascularization (mCNV) **Cimerli (ranibizumab-eqrn) is proven and medically necessary for the treatment of:** • Myopic choroidal neovascularization (mCNV) • Diabetic macular edema (DME) • Diabetic retinopathy (DR) • Macular edema following retinal vein occlusion (RVO) • Neovascular age-related macular degeneration (nAMD) **Eylea (aflibercept) is proven and medically necessary for the treatment of:** • 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) **Eylea HD (aflibercept) is proven and medically necessary for the treatment of:** • Diabetic macular edema (DME) • Diabetic retinopathy (DR) • Neovascular age-related macular degeneration (nAMD) **Lucentis (ranibizumab) is proven and medically necessary for the treatment of:** • Choroidal neovascularization secondary to pathologic myopia, angioid streaks/pseudoxanthoma elasticum, or ocular histoplasmosis syndrome (OHS)

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Ophthalmologic Vascular Endothelial Growth Factor (VEGF) Inhibitors (continued)	May 1, 2025		• 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) **Pavblu (aflibercept-ayyh) is proven and medically necessary for the treatment of:** • Diabetic macular edema (DME) • Diabetic retinopathy (DR) • Macular edema following retinal vein occlusion (RVO) • Neovascular age-related macular degeneration (nAMD) **Vabysmo (faricimab-svoa) is proven and medically necessary for the treatment of:** • Neovascular age-related macular degeneration (nAMD) • Diabetic macular edema (DME) • Macular edema following retinal vein occlusion (RVO) **Additional Information** 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. 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.

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Ophthalmologic Vascular Endothelial Growth Factor (VEGF) Inhibitors (continued)	May 1, 2025		Refer to the US Food and Drug Administration (FDA) section of this 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 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	Apr. 1, 2025	**Notice of Revision**: The following summary of changes has been modified. Revisions to the previous policy update announcement are outlined in red below. Please take note of the additional updates to be applied on **Apr. 1, 2025**. **Coverage Rationale** • Revised list of applicable medications that require healthcare provider administration; added: ○ Ocrevus Zunovo™ (ocrelizumab and hyaluronidase-ocsq) ○ PiaSky® (crovalimab-akkz) ○ Pyzchiva® (ustekinumab-ttwe) ○ Selarsdi™ (ustekinumab-aekn) ○ Tofidence™ (tocilizumab-bavi) ○ Tyenne® (tocilizumab-aazg) ○ Wezlana™ (ustekinumab-auub)	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: • 19 Off Campus-Outpatient Hospital; and • 22 On Campus-Outpatient Hospital 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. **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:** • 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: ○ History of cardiopulmonary conditions that cause an increased risk of severe adverse reactions during or immediately following infusion; **or**

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Provider Administered Drugs – Site of Care (continued)	Apr. 1, 2025	**Documentation Requirements** • Revised list of specialty medications with associated documentation requirements: ○ Added: ▪ Ocrevus Zunovo™ (ocrelizumab and hyaluronidase-ocsq) (HCPCS code J2351) ▪ PiaSky® (crovalimab-akkz) (HCPCS code J1307) ▪ Pyzchiva® (ustekinumab-ttwe) (HCPCS codes Q9996 and Q9997) ▪ Selarsdi™ (ustekinumab-aekn) (HCPCS code Q9998) ▪ Tofidence™ (tocilizumab-bavi) (HCPCS code Q5133) ▪ Tyenne® (tocilizumab-aazg) (HCPCS code Q5135) ▪ Wezlana™ (ustekinumab-auub) (HCPCS codes Q5137 and Q5138) ○ Updated list of applicable HCPCS codes for Soliris® (eculizumab) to reflect quarterly edits: ▪ Added J1299 ▪ Removed J1300 **Applicable Codes** • Updated list of applicable HCPCS codes:	○ 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 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** • 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: ○ 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 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. **Note**: If more than one of the above criteria are met, then the greatest of the applicable approval time periods will be allowed.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Provider Administered Drugs – Site of Care (continued)	Apr. 1, 2025	○ Added J1299*, J1307, J2351, Q5133, Q5135, Q5137, Q5138, Q9996, Q9997, and Q9998 ○ Removed J1300* *(*quarterly edit)*	Refer to the policy for complete details.
Provider Administered Drugs – Site of Care	May 1, 2025	**Related Policies** • Removed reference link to the Medical Benefit Drug Policy titled *Tzield® (Teplizumab-Mzwv)* **Coverage Rationale** • Revised list of medications that require healthcare provider administration; removed: ○ Apretude™ (cabotegravir) ○ Tzield™ (teplizumab-mzwv) **Documentation Requirements** • Revised list of specialty medications with associated documentation requirements; removed: ○ Apretude™ (cabotegravir) (HCPCS code J0739) ○ Tzield™ (teplizumab-mzwv) (HCPCS code J9381) **Applicable Codes** • Removed HCPCS codes J0739 and J9381	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: • 19 Off Campus-Outpatient Hospital; and • 22 On Campus-Outpatient Hospital 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. **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:** • 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: ○ 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**

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Provider Administered Drugs – Site of Care (continued)	May 1, 2025		• 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; **or**
			• 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:
			  ○ 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
			
			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.
			
			Note: If more than one of the above criteria are met, then the greatest of the applicable approval time periods will be allowed.
			
			Refer to the policy for complete details.

Repository Corticotropin Injections	May 1, 2025	**Coverage Rationale** • Removed specific dosage requirements for Acthar Gel (repository corticotropin injection) and Purified Cortrophin Gel	This policy refers to the following drug products: • Acthar® Gel (repository corticotropin injection) • Purified Cortrophin Gel™ (repository corticotropin injection USP)

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Repository Corticotropin Injections (continued)	May 1, 2025	(repository corticotropin injection USP); refer to the applicable U.S. FDA approved labeling **Supporting Information** • Updated *Background*, *Clinical Evidence*, and *References* sections to reflect the most current information	**Acthar Gel (repository corticotropin injection) and Purified Cortrophin Gel (repository corticotropin injection USP) are proven and medically necessary for the treatment of:** • **Infantile spasm** (i.e., West Syndrome) for up to 4 weeks when **all** of the following criteria are met: ○ Diagnosis of infantile spasms (i.e., West Syndrome); **and** ○ Patient is less than 2 years old; **and** ○ Provider attestation that the caregiver is not able to be trained or is physically unable to administer the drug; **and** ○ Provider must submit explanation; **and** ○ Dosing is in accordance with the United States Food and Drug Administration (FDA) approved labeling; **and** ○ Authorizations will be for no longer than 1 month • **Opsoclonus-myoclonus syndrome** (i.e., Kinsbourne Syndrome) when **both** of the following criteria are met: ○ Diagnosis of opsoclonus-myoclonus syndrome (i.e., Kinsbourne Syndrome); **and** ○ Provider attestation that the caregiver is not able to be trained or is physically unable to administer the drug; provider must submit explanation; **and** ○ Authorizations will be for no longer than 3 months **Acthar Gel and Purified Cortrophin Gel are not medically necessary for treatment of acute exacerbations of multiple sclerosis.** For non-medical necessity plans, Acthar Gel and Purified Cortrophin Gel may be covered for the treatment of acute exacerbation of multiple sclerosis (MS). **Acthar Gel and Purified Cortrophin Gel are unproven and not medically necessary for treatment of the following disorders and diseases:** • Allergic States: Serum sickness and atopic dermatitis • Collagen Diseases: Systemic lupus erythematosus and systemic dermatomyositis (polymyositis) • Dermatologic Diseases: Severe erythema multiforme, Stevens-Johnson syndrome, and severe psoriasis • Edematous State: To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus

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Repository Corticotropin Injections (continued)	May 1, 2025		• Ophthalmic Diseases: Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, and anterior segment inflammation • Respiratory Diseases: Symptomatic sarcoidosis • Rheumatic Disorders: Psoriatic arthritis, rheumatoid arthritis, including juvenile rheumatoid arthritis, ankylosing spondylitis, and acute gouty arthritis • Any indication outside of the proven indications above
Tremfya® (Guselkumab)	May 1, 2025	**Coverage Rationale** • Added language to indicate: ○ Tremfya is proven for the treatment of Crohn's disease (CD) when all of the following criteria are met: ▪ Diagnosis of moderately to severely active CD ▪ Tremfya is to be administered as three intravenous induction doses ▪ Tremfya induction dosing is in accordance with the U.S. FDA labeled dosing for CD ▪ Patient is not receiving Tremfya in combination with another targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Skyrizi (risankizumab), Stelara (ustekinumab)] ▪ Authorization will be	This policy refers to Tremfya (guselkumab) injection for intravenous use. Tremfya (guselkumab) for self-administered subcutaneous injection is obtained under the pharmacy benefit. **Ulcerative Colitis (UC)** **Tremfya is proven for the treatment of ulcerative colitis when all of the following criteria are met:** • Diagnosis of moderately to severely active ulcerative colitis; **and** • Tremfya is to be administered as three intravenous induction doses; **and** • Tremfya induction dosing is in accordance with the U.S FDA labeled dosing for UC; **and** • Patient is not receiving Tremfya in combination with another targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Entyvio (vedolizumab), Olumiant (baricitinib), Omvoh (mirikizumab-mrkz), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), ustekinumab, Xeljanz (tofacitinib)]; **and** • Authorization will be issued for 3 induction doses **Tremfya is medically necessary for the treatment of ulcerative colitis when all of the following criteria are met:** • Diagnosis of moderately to severely active ulcerative colitis; **and** • **One** of the following: ○ Patient has had prior or concurrent inadequate response to a therapeutic course of oral corticosteroids and/or immunosuppressants (e.g., azathioprine, 6-mercaptopurine); **or** ○ Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ulcerative

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Tremfya® (Guselkumab) (continued)	May 1, 2025	issued for 3 induction doses ○ Tremfya is medically necessary for the treatment of CD when all of the following criteria are met: ▪ Diagnosis of moderately to severely active CD ▪ One of the following: – History of failure to one of the following conventional therapies at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced: ● Corticosteroids (e.g., prednisone, methylpredni-solone, budesonide) ● 6-mercaptopurine (Purinethol) ● Azathioprine (Imuran) ● Methotrexate (Rheumatrex, Trexall) – Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of CD [e.g.,	colitis [e.g., adalimumab, Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), ustekinumab, Xeljanz (tofacitinib)] **and** ● Tremfya is to be administered as three intravenous induction doses; **and** ● Tremfya induction dosing is in accordance with the U.S FDA labeled dosing for UC; **and** ● Patient is not receiving Tremfya in combination with another targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Enbrel (etanercept), Entyvio (vedolizumab), Olumiant (baricitinib), Omvoh (mirikizumab-mrkz), Orencia (abatacept), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), ustekinumab, Xeljanz (tofacitinib)]; **and** ● Prescribed by or in consultation with a gastroenterologist; **and** ● Authorization will be issued for 3 induction doses **Crohn's Disease (CD)** **Tremfya is proven for the treatment of Crohn's disease (CD) when all of the following criteria are met:** ● Diagnosis of moderately to severely active Crohn's disease; **and** ● Tremfya is to be administered as three intravenous induction doses; **and** ● Tremfya induction dosing is in accordance with the United States Food and Drug Administration (FDA) labeled dosing for CD; **and** ● Patient is not receiving Tremfya in combination with another targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Skyrizi (risankizumab), ustekinumab]; **and** ● Authorization will be issued for 3 induction doses **Tremfya is medically necessary for the treatment of Crohn's disease (CD) when all of the following criteria are met:** ● Diagnosis of moderately to severely active Crohn's disease; **and** ● One of the following: ○ History of failure to **one** of the following conventional therapies at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced:

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Tremfya® (Guselkumab) (continued)	May 1, 2025	adalimumab, Cimzia (certolizumab), Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Skyrizi (risankizumab), Stelara (ustekinumab)] ▪ Tremfya is to be administered as three intravenous induction doses ▪ Tremfya induction dosing is in accordance with the U.S. FDA labeled dosing for CD ▪ Patient is not receiving Tremfya in combination with another targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Skyrizi (risankizumab), Stelara (ustekinumab)] ▪ Prescribed by or in consultation with a gastroenterologist ▪ Authorization will be issued for 3 induction doses	▪ Corticosteroids (e.g., prednisone, methylprednisolone, budesonide) ▪ 6-mercaptopurine (Purinethol) ▪ Azathioprine (Imuran) ▪ Methotrexate (Rheumatrex, Trexall) **or** ○ Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of Crohn's disease [e.g., adalimumab, Cimzia (certolizumab), Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Skyrizi (risankizumab), ustekinumab] **and** ● Tremfya is to be administered as three intravenous induction doses; **and** ● Tremfya induction dosing is in accordance with the United States Food and Drug Administration (FDA) labeled dosing for CD; **and** ● Patient is not receiving Tremfya in combination with another targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Entyvio (vedolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Skyrizi (risankizumab), ustekinumab]; **and** ● Prescribed by or in consultation with a gastroenterologist; **and** ● Authorization will be issued for 3 induction doses

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Tremfya® (Guselkumab) (continued)	May 1, 2025	**Applicable Codes** • Added ICD-10 diagnosis codes K50.00, K50.011, K50.012, K50.013, K50.014, K50.018, K50.019, K50.10, K50.111, K50.112, K50.113, K50.114, K50.118, K50.119, K50.80, K50.811, K50.812, K50.813, K50.814, K50.818, K50.819, K50.90, K50.911, K50.912, K50.913, K50.914, K50.918, and K50.919 **Supporting Information** • Updated *FDA* section to reflect the most current information	
Viltepso® (Viltolarsen)	May 1, 2025	**Coverage Rationale** • Revised coverage criteria: ○ Replaced criterion requiring "the patient has achieved a time to rise *from the floor (Gower's test)* of less than 7 seconds" with "the patient has achieved a time to rise *(TTR)* of less than 7 seconds" ○ Added list of examples of exon skipping therapies that cannot be used concomitantly with Viltepso: Amondys (casimersen), Exondys 51 (eteplirsen), and Vyondys 53 (golodirsen) ○ Removed criterion for continuation of therapy requiring the patient has previously received Viltepso • Replaced language indicating "Viltepso *will not be covered* for	**Viltepso (viltolarsen) may be covered for the treatment of Duchenne muscular dystrophy (DMD) in patients who meet all of the following criteria:** **Initial Therapy** • Diagnosis of Duchenne muscular dystrophy by, or in consultation with, a neurologist with expertise in the diagnosis of DMD; **and** • Submission of medical records (e.g., chart notes, laboratory values) confirming the mutation of the DMD gene is amenable to exon 53 skipping; **and** • **One** of the following: ○ Submission of medical records (e.g., chart notes, laboratory values) confirming that the patient has a 6-Minute Walk Test (6MWT) ≥ 300 meters while walking independently (e.g., without side-by-side assist, cane, walker, wheelchair, etc.) prior to beginning Viltepso therapy; **or** ○ **Both** of the following: ▪ Submission of medical records (e.g., chart notes) confirming that the patient is ambulatory **without** needing an assistive device (e.g., without side-by-side assist, cane, walker, wheelchair, etc.); **and** ▪ **One** of the following:

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Viltepso® (Viltolarsen) (continued)	May 1, 2025	other forms of muscular dystrophy" with "Viltepso *is unproven and not medically necessary* for *the treatment* of other forms of muscular dystrophy *(e.g., Becker muscular dystrophy)*" **Supporting Information** • Updated *Background*, *Clinical Evidence*, and *References* sections to reflect the most current information	– Patient has achieved a score of greater than 17 on the North Star Ambulatory Assessment (NSAA); or – Patient has achieved a time to rise (TTR) of less than 7 seconds **and** • Viltepso is not used concomitantly with other exon skipping therapies for DMD [e.g., Amondys (casimersen), Exondys 51 (eteplirsen), Vyondys 53 (golodirsen)]; **and** • Viltepso is prescribed by, or in consultation with, a neurologist with expertise in the treatment of DMD; **and** • 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** • Submission of medical records (e.g., chart notes) confirming that the patient is ambulatory **without** needing an assistive device (e.g., without side-by-side assist, cane, walker, wheelchair, etc.); **and** • Viltepso is not used concomitantly with other exon skipping therapies for DMD [e.g., Amondys (casimersen), Exondys 51 (eteplirsen), Vyondys 53 (golodirsen)]; **and** • Prescribed by, or in consultation with, a neurologist with expertise in the treatment of DMD; **and** • Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** • Reauthorization will be for no more than 12 months **Unproven** **Viltepso is unproven and not medically necessary for the treatment of other forms of muscular dystrophy (e.g., Becker muscular dystrophy).**
Vyondys 53® (Golodirsen)	May 1, 2025	**Coverage Rationale** • Revised coverage criteria: ○ Replaced criterion requiring "the patient has achieved a time to rise *from the floor (Gower's test)* of less than 7	**Vyondys 53 (golodirsen) may be covered for the treatment of Duchenne muscular dystrophy (DMD) in patients who meet all of the following criteria:**

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Vyondys 53® (Golodirsen) (continued)	May 1, 2025	seconds" with "the patient has achieved a time to rise *(TTR)* of less than 7 seconds" ○ Added list of examples of exon skipping therapies that cannot be used concomitantly with Vyondys 53: Amondys (casimersen), Exondys 51 (eteplirsen), and Viltepso (viltolarsen) • Replaced language indicating "Vyondys 53 *will not be covered* for other forms of muscular dystrophy" with "Vyondys 53 *is unproven and not medically necessary* for *the treatment* of other forms of muscular dystrophy *(e.g., Becker muscular dystrophy)*" **Supporting Information** • Updated *Background*, *Clinical Evidence*, and *References* sections to reflect the most current information	**Initial Therapy** • Diagnosis of Duchenne muscular dystrophy by, or in consultation with, a neurologist with expertise in the diagnosis of DMD; **and** • Submission of medical records (e.g., chart notes, laboratory values) confirming the mutation of the DMD gene is amenable to exon 53 skipping; **and** • **One** of the following: ○ Submission of medical records (e.g., chart notes, laboratory values) confirming that the patient has a 6-Minute Walk Test (6MWT) ≥ 300 meters while walking independently (e.g., without side-by-side assist, cane, walker, wheelchair, etc.) prior to beginning Vyondys 53 therapy; **or** ○ **Both** of the following: ▪ Submission of medical records (e.g., chart notes) confirming that the patient is ambulatory **without** needing an assistive device (e.g., without side-by-side assist, cane, walker, wheelchair, etc.); **and** ▪ **One** of the following: – Patient has achieved a score of greater than 17 on the North Star Ambulatory Assessment (NSAA); or – Patient has achieved a time to rise (TTR) of less than 7 seconds **and** • Vyondys 53 is not used concomitantly with other exon skipping therapies for DMD [e.g., Amondys (casimersen), Exondys 51 (eteplirsen), Viltepso (viltolarsen)]; **and** • Vyondys 53 is prescribed by, or in consultation with, a neurologist with expertise in the treatment of DMD; **and** • 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** • Submission of medical records (e.g., chart notes) confirming that the patient is ambulatory **without** needing an assistive device (e.g., without side-by-side assist, cane, walker, wheelchair, etc.); **and**

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Vyondys 53® (Golodirsen) (continued)	May 1, 2025		• Vyondys 53 is not used concomitantly with other exon skipping therapies for DMD [e.g., Amondys (casimersen), Exondys 51 (eteplirsen), Viltepso (viltolarsen)]; **and** • Prescribed by, or in consultation with, a neurologist with expertise in the treatment of DMD; **and** • Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** • Reauthorization will be for no more than 12 months **Unproven** **Vyondys 53 is unproven and not medically necessary for the treatment of other forms of muscular dystrophy (e.g., Becker muscular dystrophy).**

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.

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 UnitedHealthcare Medical Policies and Medical Benefit Drug Policies is available at **UHCprovider.com/policies** > For Commercial Plans > Medical & Drug Policies.