# *UMR*
# Medical Policy Update Bulletin: June 2026

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# Medical Policy Updates

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| **Policy Title** | **Effective Date** | **Summary of Changes** |
| Ambulance Services | Jun. 1, 2026 | **Definitions**<br>• Added definition of "Independent Freestanding Emergency Department"<br>**Supporting Information**<br>• Updated *Clinical Evidence* and *References* sections to reflect the most current information |
| Category III Codes | Jul. 1, 2026 | **Applicable Codes**<br>• Added CPT codes 0877T, 0878T, 0879T, 0880T, 0913T, and 0914T |
| Chromosome Microarray Testing (Non-Oncology Conditions) | Jun. 1, 2026 | **Related Policies**<br>• Added reference link to the Medical Policy titled *Genetic Testing for Cardiac Disease*<br>• Removed reference link to the Medical Policy titled:<br>  ○ *FDA Cleared or Approved Companion Diagnostic Testing*<br>  ○ *Molecular Oncology Testing for Hematologic Cancer Diagnosis, Prognosis, and Treatment Decisions*<br>**Coverage Rationale**<br>• Replaced reference to:<br>  ○ "Multiple anomalies" with "multiple *Congenital* Anomalies"<br>  ○ "Developmental Delay" with "*Global* Developmental Delay"<br>**Definitions**<br>• Added definition of:<br>  ○ Autism Spectrum Disorder<br>  ○ Congenital Anomaly<br>• Removed definition of "Prenatal Diagnosis"<br>• Updated definition of:<br>  ○ Global Developmental Delay<br>  ○ Intellectual Disability<br>  ○ Well-Delineated Genetic Syndrome<br>**Supporting Information**<br>• Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information |
| Cosmetic and Reconstructive Procedures | Jun. 1, 2026 | **Definitions**<br>• Updated definition of:<br>  ○ Cosmetic Procedures<br>  ○ Functional Impairment<br>  ○ Reconstructive Procedures<br>**Supporting Information**<br>• Updated *References* section to reflect the most current information |

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| **Policy Title** | **Effective Date** | **Summary of Changes** |
| Epidural Steroid Injections for Spinal Pain | Jun. 1, 2026 | **Coverage Rationale**<br>• Replaced references to “Radicular Pain” with “Radicular *Back* Pain”<br>**Supporting Information**<br>• Updated *Clinical Evidence* and *References* sections to reflect the most current information |
| Gastrointestinal Disorders Diagnostic Procedures | Jun. 1, 2026 | **Definitions**<br>• Updated definition of “Magnetic Resonance Imaging Defecography”<br>**Supporting Information**<br>• Updated *Clinical Evidence* and *References* sections to reflect the most current information |
| Infertility Diagnosis, Treatment, and Fertility Preservation | Jun. 1, 2026 | **Coverage Rationale**<br>• Replaced reference to “deoxynucleotidyl transferase-*mediated* dUTP nick end labeling assay (TUNEL)” with “*terminal* deoxynucleotidyl transferase dUTP nick end labeling assay (TUNEL)”<br>**Definitions**<br>• Removed definition of:<br>  ○ Preimplantation Genetic Testing (PGT)<br>  ○ Therapeutic Donor Insemination (TDI)<br>**Applicable Codes**<br>• Removed HCPCS code J3355<br>**Supporting Information**<br>• Updated *Benefit Considerations*, *Clinical Evidence*, and *References* sections to reflect the most current information |
| Manipulative Therapy | Jun. 1, 2026 | **Definitions**<br>• Removed definition of “Upledger Technique”<br>**Supporting Information**<br>• Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information |
| Surgery of the Knee | Jun. 1, 2026 | **Definitions**<br>• Updated definition of “BioCartilage”<br>**Supporting Information**<br>• Updated *Clinical Evidence* and *References* sections to reflect the most current information |

# Medical Policy Updates

**Revised**

| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| Beds and Mattresses | Jul. 1, 2026 | **Coverage Rationale**<br>***Indications for Coverage***<br>Safety Enclosure With Beds<br>• Updated list of examples of safety enclosure beds:<br>  ○ Added "Safety Sleeper®"<br>  ○ Removed "Posey"<br>• Added language to indicate enclosed bed systems are not covered when the purpose is to restrain the beneficiary due to behavioral conditions, caregiver need, or convenience<br>**Supporting Information**<br>• Updated *Description of Services*, *Benefit Considerations*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information | **Indications for Coverage**<br>**Hospital beds and accessories are proven and medically necessary in certain circumstances.** For medical necessity clinical coverage criteria, refer to the InterQual® CP: Durable Medical Equipment:<br>• Support Surfaces<br>• Hospital Beds, Cribs, and Accessories<br><br>Click here to view the InterQual® criteria.<br><br>***Safety Enclosure With Beds***<br>Safety enclosure with beds (e.g., pediatric enclosed bed, adult bed, safety enclosure) is covered as durable medical equipment for individuals who have a risk for safety in bed when **all** the following criteria are met:<br>• Use of equipment is required due to a diagnosis related to cognitive impairment (e.g., traumatic brain injury, cerebral palsy, seizure disorder), or a severe behavioral disorder<br>• Medications to address seizures and/or disruptive or harmful behaviors have been optimized or are not appropriate<br>• There is a safety risk that includes but is not limited to any of the following:<br>  ○ Claustrophobia<br>  ○ High risk of falls due to a clinical condition<br>  ○ Uncontrolled movements<br>  ○ Violent or self-destructive behaviors such as uncontrolled head banging<br>• Less intensive alternative methods such as the following have been tried, as appropriate, and have not been successful or are contraindicated:<br>  ○ Mattress placed on the floor<br>  ○ Medical helmet<br>  ○ Removal of all safety hazards<br>  ○ Side rails<br>  ○ Weighted blankets<br><br>**Notes**:<br>• Safety enclosure with beds (e.g., Safety Sleeper®) should be coded with HCPCS code E0316. |

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| **Policy Title** | **Effective Date** | **Summary of Changes** | **Coverage Rationale** |
| Beds and Mattresses (continued) | Jul. 1, 2026 | | • Enclosed bed systems are not covered when the purpose is to restrain the beneficiary due to behavioral conditions, caregiver need, or convenience. |
| Minimally Invasive Procedures for the Treatment of Upper Gastrointestinal Diseases | Aug. 1, 2026 | **Coverage Rationale**<br>• Replaced language indicating "endoluminal therapy with GERDx® is *investigational*, unproven, and not medically necessary for treating Gastroesophageal Reflux Disease *as it has not received U.S. Food and Drug Administration (FDA) approval*" with "endoluminal therapy with GERDx® is unproven and not medically necessary for treating Gastroesophageal Reflux Disease"<br>**Supporting Information**<br>• Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information | **Gastric electrical stimulation therapy is proven and medically necessary for treating refractory Gastroparesis that has failed other therapies or chronic, intractable (drug-refractory) nausea and vomiting secondary to Gastroparesis of diabetic or idiopathic etiology.**<br>Refer to the *U.S. Food and Drug Administration (FDA)* section of the policy for information regarding FDA labeling and Humanitarian Device Exemption for gastric electrical stimulation.<br><br>**Surgical pyloroplasty (open or laparoscopic) is proven and medically necessary for treating refractory Gastroparesis that has failed other therapies or chronic, intractable (drug-refractory) nausea and vomiting secondary to Gastroparesis of diabetic or idiopathic etiology.**<br><br>**The peroral endoscopic myotomy (POEM) procedure is proven and medically necessary for treating individuals with Achalasia or Diffuse Esophageal Spasm.**<br><br>**POEM is unproven and not medically necessary for all other indications (e.g., Zenker diverticula) due to insufficient evidence of efficacy.**<br><br>**Gastric POEM (G-POEM) is unproven and not medically necessary for the treatment of Gastroparesis.**<br><br>**The following are unproven and not medically necessary for treating Gastroesophageal Reflux Disease due to insufficient evidence of efficacy:**<br>• Endoscopic therapies<br>• Injection or implantation techniques<br>• LINX™ Reflux Management System<br><br>**Endoluminal therapy with GERDx™ is unproven and not medically necessary for treating Gastroesophageal Reflux Disease.**<br><br>Refer to the Medical Policy titled Bariatric Surgery for information regarding endoscopic therapies for the treatment of obesity. |

# Medical Policy Updates

## Revised

| Policy Title | Effective Date | Summary of Changes / Coverage Rationale |
|---|---|---|
| Preventive Care Services | Jul. 1, 2026 | **Coverage Rationale**<br>• Added language to indicate a vaccine (immunization) is generally covered under the preventive care services benefit when it is listed in the applicable immunization schedule of the Centers for Disease Control and Prevention (CDC) and has explicit ACIP recommendations published in the Morbidity and Mortality Weekly Report (MMWR) of the CDC; for age limits and additional information, refer to *Preventive Care Services: Vaccine Codes*<br>• Replaced language indicating "a vaccine (immunization) is not covered if it *does not meet company vaccine policy requirements for FDA labeling and if it* does not have explicit ACIP recommendations *for routine use* published in the MMWR of the CDC and is not listed on the applicable immunization schedule *of ACIP*; refer to *Preventive Care Services: Vaccine Codes*" with "a vaccine (immunization) is generally not covered when it is not listed on the applicable *CDC* immunization schedule or when it does not have explicit ACIP recommendations published in the MMWR of the CDC"<br>**Frequently Asked Questions (FAQ)**<br>• Changed question 14 from "Does the *preventive care services* benefit include prescription or over the counter (OTC) items?" to "Does the *pharmacy* benefit include *preventive benefits for* prescriptions and over the counter (OTC) items?"<br>**Applicable Codes**<br>***Preventive Care Services***<br>Chlamydia Infection Screening, Gonorrhea Screening, Hepatitis B Virus Infection Screening, HIV (Human Immunodeficiency Virus) Screening for Adolescents and Adults, *and* Syphilis Screening<br>• Added ICD-10 diagnosis codes Z01.411 and Z01.419<br>Screening for Pre-Diabetes and Type 2 Diabetes: Pre-Diabetes Preventive Interventions<br>• Added HCPCS code G9887<br>Healthy Diet and Physical Activity for Cardiovascular Disease Prevention in Adults with Cardiovascular Risk Factors: Behavioral Counseling Interventions, Weight Loss to Prevent Obesity-Related Morbidity and Mortality in Adults: Behavioral Interventions, *and* High Body Mass Index in Children and Adolescents<br>• Added HCPCS code G9887<br>• Revised preventive benefit instructions; added language to indicate HCPCS code G9887 requires one of the diagnosis codes listed [in the policy for the preventive benefit to apply]<br>Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis<br>• Revised preventive benefit instructions; removed language indicating prior authorization requirements may apply, depending on plan<br><br>Refer to the policy for complete details. |

# Medical Benefit Drug Policy Updates

| Updated | | |
|---|---|---|
| **Policy Title** | **Effective Date** | **Summary of Changes** |
| Korsuva® (Difelikefalin) | Jul. 1, 2026 | **Template Update**<br>• Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans<br>• Added *Application* section to indicate this policy applies to:<br>  ○ UnitedHealthcare Commercial benefit plans<br>  ○ Individual Exchange benefit plans<br>**Applicable Codes**<br>• Added list of applicable ICD-10 diagnosis codes: L29.89 and 29.9 |
| Oxlumo® (Lumasiran) and Rivfloza® (Nedosiran) | Jun. 1, 2026 | **Template Update**<br>• Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans<br>• Added *Application* section to indicate this policy applies to:<br>  ○ UnitedHealthcare Commercial benefit plans<br>  ○ Individual Exchange benefit plans |
| RNA-Targeted Therapies (Amvuttra® and Onpattro®) | Jun. 1, 2026 | **Template Update**<br>• Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans<br>• Added *Application* section to indicate this policy applies to:<br>  ○ UnitedHealthcare Commercial benefit plans<br>  ○ Individual Exchange benefit plans<br>**Supporting Information**<br>• Updated *CMS* and *References* sections to reflect the most current information |
| Spevigo® (Spesolimab-Sbzo) | Jun. 1, 2026 | **Template Update**<br>• Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans<br>• Added *Application* section to indicate this policy applies to:<br>  ○ UnitedHealthcare Commercial benefit plans<br>  ○ Individual Exchange benefit plans |
| Trogarzo® (Ibalizumab-Uiyk) | Jun. 1, 2026 | **Template Update**<br>• Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans<br>• Added *Application* section to indicate this policy applies to:<br>  ○ UnitedHealthcare Commercial benefit plans<br>  ○ Individual Exchange benefit plans |

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| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| Entyvio® (Vedolizumab) | Aug. 1, 2026 | **Template Update**<br>• Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans<br>• Added *Application* section to indicate this policy applies to:<br>  ○ UnitedHealthcare Commercial benefit plans<br>  ○ Individual Exchange benefit plans<br>**Coverage Rationale**<br>• Added language to indicate Entyvio (vedolizumab) for self-administered subcutaneous injection is obtained under the pharmacy benefit, unless otherwise specified in the member's benefit plan documents; exception: for members enrolled in UnitedHealthcare of California plans with a delegated provider group conducting the prior authorization review, the self-administered Entyvio may be obtained under the medical benefit<br>• Replaced references to "targeted immunomodulator" with "*systemic* targeted immunomodulator"<br>• Revised coverage criteria for:<br>***Crohn's Disease (CD)***<br>Initial Therapy<br>  ○ Added **medical necessity** criterion requiring: | This policy refers to Entyvio (vedolizumab) injection for intravenous infusion. Entyvio (vedolizumab) for self-administered subcutaneous injection is obtained under the pharmacy benefit, unless otherwise specified in the member's benefit plan documents. Exception: For members enrolled in UnitedHealthcare of California plans with a delegated provider group conducting the prior authorization review, the self-administered Entyvio may be obtained under the medical benefit.<br>**Crohn's Disease (CD)**<br>**Entyvio is proven for the treatment of Crohn's disease (CD) when all of the following criteria are met:**<br>• For **initial therapy**, **all** of the following:<br>  ○ Diagnosis of moderately to severely active Crohn's disease; **and**<br>  ○ Entyvio is initiated and titrated according to U.S. Food and Drug Administration (FDA) labeled dosing for Crohn's disease; **and**<br>  ○ Patient is not receiving Entyvio in combination with another systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Skyrizi (risankizumab), Tremfya (guselkumab), ustekinumab] for treatment of the same indication; **and**<br>  ○ Initial authorization will be for no more than 12 months<br>• For continuation of therapy, all of the following:<br>  ○ Documentation of positive clinical response to Entyvio; **and**<br>  ○ Entyvio dosing for Crohn's disease is in accordance with the FDA labeled dosing; **and**<br>  ○ Patient is not receiving Entyvio in combination with another systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Skyrizi (risankizumab), Tremfya (guselkumab), ustekinumab] for treatment of the same indication; **and**<br>  ○ Reauthorization will be for no more than 12 months<br>**Entyvio is medically necessary for the treatment of Crohn's disease (CD) when all of the following criteria are met:**<br>• For **initial therapy**, **all** of the following:<br>  ○ Diagnosis of moderately to severely active Crohn's disease; **and**<br>  ○ One of the following: |

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| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
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| Entyvio® (Vedolizumab) (continued) | Aug. 1, 2026 | ▪ One of the following:<br>– 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:<br>• Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)<br>• 6-mercaptopurine (Purinethol)<br>• Azathioprine (Imuran)<br>• Methotrexate (Rheumatrex, Trexall)<br>– The patient has been previously treated with a systemic targeted immunomodulator U.S. FDA-approved for the treatment of Crohn's disease [e.g., adalimumab, Cimzia (certolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Skyrizi (risankizumab), Tremfya | ▪ 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:<br>– Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)<br>– 6-mercaptopurine (Purinethol)<br>– Azathioprine (Imuran)<br>– Methotrexate (Rheumatrex, Trexall)<br>**or**<br>▪ Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of Crohn's disease [e.g., adalimumab, Cimzia (certolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Skyrizi (risankizumab), Tremfya (guselkumab), ustekinumab]; **or**<br>▪ Patient is currently on Entyvio therapy<br>**and**<br>○ Entyvio is initiated and titrated according to U.S. Food and Drug Administration (FDA) labeled dosing for Crohn's disease; **and**<br>○ Patient is not receiving Entyvio in combination with another systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Skyrizi (risankizumab), Tremfya (guselkumab), ustekinumab] for treatment of the same indication; **and**<br>○ Prescribed by or in consultation with a gastroenterologist; **and**<br>○ Initial authorization will be for no more than 12 months<br>• For **continuation of therapy**, **all** of the following:<br>○ Documentation of positive clinical response to Entyvio; **and**<br>○ Entyvio dosing for Crohn's disease is in accordance with the FDA labeled dosing; **and**<br>○ Patient is not receiving Entyvio in combination with another systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Skyrizi (risankizumab), Tremfya (guselkumab), ustekinumab] for treatment of the same indication; **and**<br>○ Reauthorization will be for no more than 12 months |

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| Entyvio® (Vedolizumab) (continued) | Aug. 1, 2026 | (guselkumab), ustekinumab]<br>– The patient is currently on Entyvio therapy<br>▪ Entyvio is prescribed by or in consultation with a gastroenterologist<br>○ Removed **proven/medically necessary** criterion requiring:<br>▪ History of failure, contraindication, or intolerance to at least one of the following conventional therapies:<br>– Tumor necrosis factor (TNF) blocker<br>– Immunomodulator<br>– Corticosteroid<br>▪ The patient is corticosteroid dependent (e.g., unable to successfully taper corticosteroids without a return of the symptoms of CD)<br>▪ Updated list of examples of systemic targeted immunomodulator the patient must not be receiving in combination with Entyvio for treatment of the same indication; removed:<br>– Simponi (golimumab)<br>– Tysabri (natalizumab)<br>– Xeljanz (tofacitinib) | **Ulcerative Colitis (UC)**<br>**Entyvio is proven for the treatment of ulcerative colitis (UC) when all of the following criteria are met:**<br>• For **initial therapy**, **all** of the following:<br>○ Diagnosis of moderately to severely active ulcerative colitis; **and**<br>○ Entyvio is initiated and titrated according to U.S. Food and Drug Administration (FDA) labeled dosing for ulcerative colitis; **and**<br>○ Patient is not receiving Entyvio in combination with another systemic targeted immunomodulator [e.g., adalimumab, Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab, Zeposia (ozanimod)] for treatment of the same indication; **and**<br>○ Initial authorization will be for no more than 12 months<br>• For **continuation of therapy**, **all** of the following:<br>○ Documentation of positive clinical response to Entyvio; **and**<br>○ Entyvio dosing for ulcerative colitis is in accordance with the FDA labeled dosing; **and**<br>○ Patient is not receiving Entyvio in combination with another systemic targeted immunomodulator [e.g., adalimumab, Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab, Zeposia (ozanimod)] for treatment of the same indication; **and**<br>○ Reauthorization will be for no more than 12 months<br>**Entyvio is medically necessary for the treatment of ulcerative colitis (UC) when all of the following criteria are met:**<br>• For **initial therapy**, **all** of the following:<br>○ Diagnosis of moderately to severely active ulcerative colitis; **and**<br>○ **One** of the following:<br>▪ Patient has had prior or concurrent inadequate response to a therapeutic course of oral corticosteroids and/or immunosuppressants (e.g., azathioprine, 6-mercaptopurine); **or**<br>▪ Patient has been previously treated with a systemic targeted immunomodulator FDA-approved for the treatment of ulcerative colitis [e.g., adalimumab, Omvoh (mirikizumab-mrkz), Rinvoq |

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| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| Entyvio® (Vedolizumab) (continued) | Aug. 1, 2026 | Continuation of Therapy<br>○ Added **proven/medically necessary** criterion requiring the patient is not receiving Entyvio in combination with another systemic targeted immunomodulator [e.g., adalimumab, Cimzia (certolizumab), Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Skyrizi (risankizumab), Tremfya (guselkumab), ustekinumab] for treatment of the same indication<br>***Ulcerative Colitis (UC)***<br>Initial Therapy<br>○ Added **medical necessity** criterion requiring:<br>▪ One of the following:<br>– The patient has had prior or concurrent inadequate response to a therapeutic course of oral corticosteroids and/or immunosuppressants (e.g., azathioprine, 6-mercaptopurine)<br>– The patient has been previously treated with a systemic targeted immunomodulator U.S. FDA-approved for the treatment of ulcerative colitis [e.g., | (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab, Zeposia (ozanimod)]; **or**<br>▪ Patient is currently on Entyvio therapy<br>**and**<br>○ Entyvio is initiated and titrated according to U.S. Food and Drug Administration (FDA) labeled dosing for ulcerative colitis; **and**<br>○ Patient is not receiving Entyvio in combination with another systemic targeted immunomodulator [e.g., adalimumab, Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab, Zeposia (ozanimod)] for treatment of the same indication; **and**<br>○ Prescribed by or in consultation with a gastroenterologist; **and**<br>○ Initial authorization will be for no more than 12 months<br>• For **continuation of therapy**, **all** of the following:<br>○ Documentation of positive clinical response to Entyvio; **and**<br>○ Entyvio dosing for ulcerative colitis is in accordance with the FDA labeled dosing; **and**<br>○ Patient is not receiving Entyvio in combination with another systemic targeted immunomodulator [e.g., adalimumab, Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab, Zeposia (ozanimod)] for treatment of the same indication; **and**<br>○ Reauthorization will be for no more than 12 months<br>**Immune Checkpoint Inhibitor-Related Toxicities**<br>**Entyvio is proven and medically necessary for the treatment of Immune checkpoint inhibitor-related toxicities when all of the following criteria are met:**<br>• For **initial therapy**, **all** of the following:<br>○ **One** of the following immunotherapy-related diagnosis:<br>▪ Moderate to severe esophagitis, gastritis, or duodenitis if no improvement on corticosteroids or budesonide<br>▪ Mild (G1) diarrhea or colitis if persistent or progressive symptoms and positive lactoferrin/calprotectin |

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| Entyvio® (Vedolizumab) (continued) | Aug. 1, 2026 | adalimumab, Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab, Zeposia (ozanimod)]<br>– Patient is currently on Entyvio therapy<br>▪ Entyvio is prescribed by or in consultation with a gastroenterologist<br>○ Removed **proven/medically necessary** criterion requiring:<br>▪ History of failure, contraindication, or intolerance to at least one of the following conventional therapies:<br>– Tumor necrosis factor (TNF) blocker<br>– Immunomodulator<br>– Corticosteroid<br>▪ The patient is corticosteroid dependent (e.g., unable to successfully taper corticosteroids without a return of the symptoms of CD)<br>▪ Updated list of examples of systemic targeted | ▪ Moderate (G2) or severe (G3-4) immunotherapy-related diarrhea or colitis<br>**and**<br>○ Patient is receiving a checkpoint inhibitor [e.g., Keytruda (Pembrolizumab), Opdivo (Nivolumab)]; **and**<br>○ One of the following:<br>▪ History of failure, contraindication, or intolerance to infliximab<br>▪ Patient has immune-related hepatitis<br>**and**<br>○ Initial authorization will be for no more than 3 doses of Entyvio<br>• For **continuation of therapy**, **all** of the following:<br>○ Documentation of positive clinical response; **and**<br>○ Patient continues to experience checkpoint inhibitor-related toxicities; **and**<br>○ Reauthorization will be for no more than 3 doses of Entyvio<br><br>**Gastrointestinal (GI) Acute Graft-Versus-Host Disease**<br>**Entyvio is proven and medically necessary for the treatment of GI acute graft-versus-host disease (aGVHD) when all of the following criteria are met:**<br>• For **initial therapy**, **all** of the following:<br>○ Diagnosis of steroid-refractory acute GI aGVHD; **and**<br>○ **One** of the following:<br>▪ Patient is receiving Entyvio in combination with systemic corticosteroids<br>▪ Patient is intolerant to systemic corticosteroid therapy<br>**and**<br>○ Initial authorization will be for no more than 4 doses<br>• For **continuation of therapy**, **all** of the following:<br>○ Documentation of positive clinical response; **and**<br>○ Patient continues to experience acute GI aGVHD; **and**<br>○ Reauthorization will be for no more than 4 doses |

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| Entyvio® (Vedolizumab) (continued) | Aug. 1, 2026 | immunomodulator the patient must not be receiving in combination with Entyvio for treatment of the same indication:<br>– Added Zeposia (ozanimod)<br>– Removed:<br>• Simponi (golimumab)<br>• Tysabri (natalizumab)<br>• Xeljanz (tofacitinib)<br>– Replaced "Xeljanz (tofacitinib)" with "Xeljanz/*Xeljanz XR* (tofacitinib)"<br>Continuation of Therapy<br>○ Added **proven/medically necessary** criterion requiring the patient is not receiving Entyvio in combination with another systemic targeted immunomodulator [e.g., adalimumab, Omvoh (mirikizumab-mrkz), Rinvoq (upadacitinib), Simponi (golimumab), Skyrizi (risankizumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), ustekinumab, Zeposia (ozanimod)] for treatment of the same indication | |

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| **Policy Title** | **Effective Date** | **Summary of Changes** | **Coverage Rationale** |
| Entyvio® (Vedolizumab) (continued) | Aug. 1, 2026 | ***Immune Checkpoint Inhibitor-Related Toxicities***<br>Continuation of Therapy<br>○ Added criterion requiring:<br>▪ Documentation of positive clinical response<br>▪ Patient continues to experience checkpoint inhibitor-related toxicities<br>○ Removed criterion requiring:<br>▪ One of the following immunotherapy-related diagnosis:<br>– Moderate to severe esophagitis, gastritis, or duodenitis if no improvement on corticosteroids or budesonide<br>– Mild (G1) diarrhea or colitis if persistent or progressive symptoms and positive lactoferrin/ calprotectin<br>– Moderate (G2) or severe (G3-4) immunotherapy-related diarrhea or colitis<br>▪ Patient is receiving a checkpoint inhibitor [e.g., Keytruda (Pembrolizumab), Opdivo (Nivolumab)]<br>▪ One of the following: | |

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| **Policy Title** | **Effective Date** | **Summary of Changes** | **Coverage Rationale** |
| Entyvio® (Vedolizumab) (continued) | Aug. 1, 2026 | – History of failure, contraindication, or intolerance to infliximab<br>– Patient has immune-related hepatitis<br>***Gastrointestinal (GI) Acute Graft-Versus-Host Disease***<br>○ Removed criterion requiring one of the following:<br>▪ The patient is receiving Entyvio in combination with systemic corticosteroids<br>▪ The patient is intolerant to systemic corticosteroid therapy<br>**Supporting Information**<br>• Updated *Clinical Evidence* and *References* sections to reflect the most current information | |
| Maximum Dosage and Frequency | Aug. 1, 2026 | **Template Update**<br>• Transferred content to shared policy template that applies to both UnitedHealthcare Commercial and Individual Exchange benefit plans<br>• Added *Application* section to indicate this policy applies to:<br>○ UnitedHealthcare Commercial benefit plans<br>○ Individual Exchange benefit plans<br>**Coverage Rationale**<br>• Added language to indicate:<br>○ Biosimilars and their | 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.<br><br>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]. Biosimilars and their reference biologics that are considered therapeutically equivalent to each other by the UHC Pharmacy & |

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| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
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| Maximum Dosage and Frequency (continued) | Aug. 1, 2026 | reference biologics that are considered therapeutically equivalent to each other by the UHC Pharmacy & Therapeutics Committee will be considered therapeutically equivalent for purposes of applying maximum dosage and frequency limits<br>○ The allowed quantities and frequencies in the *Maximum Allowed Quantities and Frequencies by HCPCS Units* section of the policy are based upon the U.S. FDA-approved prescribing information for the applicable medications<br>▪ For indications covered by Oxford Health Plans without U.S. FDA-approved dosing, the frequencies are derived from available clinical evidence<br>▪ This list may not be inclusive of all medications listed and is subject to change<br>• Removed list of maximum allowed quantities for national drug code (NDC) billing<br>• Combined and reorganized lists of applicable drug products, maximum allowed quantities by HCPCS units, and maximum allowed frequencies | Therapeutics Committee will be considered therapeutically equivalent for purposes of applying maximum dosage and frequency limits. 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.<br><br>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.<br><br>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$^2$.<br><br>**Maximum Allowed Quantities and Frequencies by HCPCS Units**<br>The allowed quantities and frequencies in this section are based upon the FDA approved prescribing information for the applicable medications. For indications covered by Oxford Health Plans without FDA approved dosing, the frequencies are derived from available clinical evidence. This list may not be inclusive of all medications listed and is subject to change.<br><br>Refer to the policy for complete details. |

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| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
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| Maximum Dosage and Frequency (continued) | Aug. 1, 2026 | • Revised list of **Maximum Allowed Quantities and Frequencies by HCPCS Units**:<br>○ Added:<br>▪ Avtozma (tocilizumab-anoh)<br>▪ Jemperli (dostarlimab-gxly)<br>▪ Keytruda Qlex (pembrolizumab and berahyaluronidase alfa-pmph)<br>▪ Loqtorzi (toripalimab-tpzi)<br>▪ Opdivo Qvantig (nivolumab and hyaluronidase-nvhy)<br>▪ Opdualag (nivolumab and relatlimab-rmbw)<br>▪ Tecentriq Hybreza<br>▪ Tevimbra (tislelizumab-jsgr)<br>▪ Unloxcyt (cosibelimab-ipdl)<br>▪ Zynyz (retifanlimab-dlwr)<br>○ Revised maximum allowed quantities/frequencies for:<br>▪ Cimerli (ranibizumab-eqrn)<br>▪ Eylea<br>▪ Eylea HD<br>▪ Lucentis (ranibizumab)<br>▪ Pavblu (aflibercept-ayyh)<br>▪ Syfovre (pegcetacoplan)<br>▪ Vabysmo (faricimab-svoa)<br>**Applicable Codes**<br>• Added HCPCS codes J3263, J9024, J9272, J9275, J9277, | |

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| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| Maximum Dosage and Frequency (continued) | Aug. 1, 2026 | J9289, J9298, J9329, and J9345<br>• Removed list of applicable national drug codes (NDCs)<br>**Supporting Information**<br>• Updated *References* section to reflect the most current information | |
| Natalizumab (Tyruko® & Tysabri®) | Jul. 1, 2026 | **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 amended updates to be applied on **Jul. 1, 2026**.<br>**Coverage Rationale**<br>• Removed language indicating coverage criteria for Tyruko contained in this policy will be applicable immediately upon product launch<br>• Removed content/language pertaining to preferred products<br>~~***Preferred Product: Medical Necessity Plans***~~<br>• ~~Revised language to indicate:~~<br>○ ~~Tyruko is the preferred natalizumab product~~<br>○ ~~Coverage will be provided for Tyruko contingent on the coverage criteria in the Diagnosis-Specific Criteria section [of the policy]~~<br>○ ~~Coverage will be provided for Tysabri or other non-preferred natalizumab~~ | This policy refers to the following natalizumab products for injection:<br>• Tyruko (natalizumab-sztn)<br>• Tysabri (natalizumab)<br>• Any FDA-approved natalizumab biosimilar product not listed here*<br>*Any U.S. Food and Drug Administration approved and launched natalizumab biosimilar product not listed by name in this policy will be considered non-preferred until reviewed by UnitedHealthcare.<br>**Diagnosis-Specific Criteria**<br>"Natalizumab" will be used to refer to all natalizumab products.<br>**Natalizumab is proven for the treatment of:**<br>• **Relapsing forms of Multiple Sclerosis**<br>**Natalizumab is medically necessary for the treatment of relapsing forms of multiple sclerosis (MS) when all of the following are met:**<br>○ Initial Therapy<br>▪ Diagnosis of relapsing forms of multiple sclerosis (MS) (e.g., clinically isolated syndrome, relapsing-remitting disease, active secondary-progressive disease); **and**<br>▪ Patient is **not** receiving natalizumab in combination with **any** of the following (used as monotherapy):<br>– Disease modifying therapy (e.g., interferon beta preparations, glatiramer acetate, fingolimod, cladribine, siponimod, or teriflunomide)<br>– B cell targeted therapy (e.g., rituximab, belimumab, ofatumumab)<br>– Lymphocyte trafficking blockers (e.g., alemtuzumab, mitoxantrone) |

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| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
|---|---|---|---|
| Natalizumab (Tyruko® & Tysabri®) (continued) | Jul. 1, 2026 | ~~product contingent on the criteria in the Preferred Product Criteria section [of the policy] and the coverage criteria in the Diagnosis-Specific Criteria section [of the policy]~~<br>~~○ In order to continue coverage, members already on Tysabri or other non-preferred natalizumab product will be required to change therapy to Tyruko unless they meet the criteria in the *Preferred Product Criteria* section [of the policy]~~<br>~~Preferred Product Criteria~~<br>~~○ Treatment with Tysabri or other non-preferred natalizumab product is medically necessary for the indications specified in this policy when one of the following criteria are met:~~<br>~~▪ Both of the following:~~<br>~~– Documentation of a trial of Tyruko resulting in minimal clinical response to therapy and residual disease activity~~<br>~~– Provider attests that in their clinical opinion, the clinical response would be expected to be superior with Tysabri~~ | **and**<br>▪ Natalizumab is dosed according to the U.S. FDA labeled dosing; **and**<br>▪ Initial authorization is for no more than 12 months<br>○ Continuation of Therapy<br>▪ Patient has previously received treatment with natalizumab; **and**<br>▪ Documentation of positive clinical response to natalizumab therapy; **and**<br>▪ Patient is **not** receiving natalizumab in combination with **any** of the following (used as monotherapy):<br>– Disease modifying therapy (e.g., interferon beta preparations, glatiramer acetate, fingolimod, cladribine, siponimod, or teriflunomide)<br>– B cell targeted therapy (e.g., rituximab, belimumab, ofatumumab)<br>– Lymphocyte trafficking blockers (e.g., alemtuzumab, mitoxantrone)<br>**and**<br>▪ Natalizumab is dosed according to the U.S. FDA labeled dosing; **and**<br>▪ Authorization is for no more than 12 months<br>• **Crohn's Disease**<br>**Natalizumab is medically necessary for inducing and maintaining clinical response and remission in patients with moderate to severe Crohn's disease (CD) when all of the following are met:**<br>○ Initial Therapy<br>▪ Diagnosis of moderately to severely active Crohn's disease; **and**<br>▪ History of inadequate response or intolerance to conventional Crohn's disease therapies and inhibitors of TNF-α. Conventional Crohn's disease therapies may include aminosalicylates (such as mesalamine and sulfasalazine), corticosteroids, immunomodulators (such as azathioprine, 6-mercaptopurine, and methotrexate) and TNF-inhibitors [e.g., infliximab, adalimumab, certolizumab pegol (Cimzia®)]; **and**<br>▪ Patient is not receiving concomitant treatment with immunosuppressants (e.g., 6-MP, azathioprine, cyclosporine, or methotrexate) **or** TNF-inhibitors [e.g., Enbrel (etanercept), |

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| **Policy Title** | **Effective Date** | **Summary of Changes** | **Coverage Rationale** |
| Natalizumab (Tyruko® & Tysabri®) (continued) | Jul. 1, 2026 | ~~or other natalizumab biosimilar product, than experienced with Tyruko~~<br>~~▪ Both of the following:~~<br>~~– Documentation of intolerance, contraindication, or adverse event to Tyruko~~<br>~~– Provider attests that in their clinical opinion, the same intolerance, contraindication, or adverse event would not be expected to occur with Tysabri or other natalizumab biosimilar product~~<br>~~***Diagnosis-Specific Criteria***~~<br>• ~~Revised coverage criteria for continuation of therapy:~~<br>~~○ Added criterion requiring one of the following:~~<br>~~▪ The patient is currently on Tyruko~~<br>~~▪ The patient is currently on Tysabri, but the provider is requesting a switch to Tyruko~~<br>~~▪ The patient is currently on Tysabri and meets the criteria in the *Preferred Product Criteria* section [of the policy]~~ | infliximab, adalimumab, or certolizumab pegol (Cimzia)]; **and**<br>▪ Natalizumab is dosed according to the U.S. FDA labeled dosing; **and**<br>▪ Initial authorization is for no more than 12 months<br>○ Continuation of Therapy<br>▪ Patient has previously received treatment with natalizumab; **and**<br>▪ Documentation of positive clinical response to natalizumab therapy; **and**<br>▪ Patient is not receiving concomitant treatment with immunosuppressants (e.g., 6-MP, azathioprine, cyclosporine, or methotrexate) or TNF-inhibitors [e.g., Enbrel (etanercept), adalimumab, certolizumab pegol (Cimzia), or infliximab]; **and**<br>▪ Natalizumab is dosed according to the U.S. FDA labeled dosing; **and**<br>▪ Authorization is for no more than 12 months<br><br>**Natalizumab is unproven for the treatment of other conditions or diseases, including types of MS other than relapsing forms.** Statistically robust randomized controlled trials are needed to address the issue of whether natalizumab has sufficient superiority in clinical efficacy compared to other available treatments to justify the substantial inherent clinical risk in its use. |

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| **Policy Title** | **Effective Date** | **Summary of Changes** | **Coverage Rationale** |
| Natalizumab (Tyruko® & Tysabri®) (continued) | Jul. 1, 2026 | ~~o Removed criterion requiring the patient has previously received treatment with natalizumab~~<br>**Supporting Information**<br>• Updated *FDA*, *CMS*, and *References* sections to reflect the most current information | |
| Provider Administered Drugs – Site of Care | Jul. 1, 2026 | **Coverage Rationale**<br>• Revised list of medications that require administration by a healthcare provider; added Avtozma® (tocilizumab-anoh)<br>**Documentation Requirements**<br>• Revised list of specialty medications with associated documentation requirements; added Avtozma® (tocilizumab-anoh)<br>**Applicable Codes**<br>• Added HCPCS code Q5156 | 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:<br>• 19 Off Campus-Outpatient Hospital; and<br>• 22 On Campus-Outpatient Hospital<br><br>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.<br><br>**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:**<br>• 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:<br>o History of cardiopulmonary conditions that cause an increased risk of severe adverse reactions during or immediately following infusion; **or**<br>o 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**<br>o Risk of becoming medically unstable due to concomitant use of medications or other drug-drug or drug-disease interaction(s) |

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| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
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| Provider Administered Drugs – Site of Care (continued) | Jul. 1, 2026 | | **or**<br>• Treatment at an alternative Site of Care presents a health risk due to a clinically significant physical or cognitive impairment; **or**<br>• Severe patent vascular access issues (for intravenous infusions only) that require specialized equipment only available in an outpatient hospital setting (e.g., ultrasound guidance); **or**<br>• 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**<br>• 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**<br>• **For IVIG or SCIG only**: Individual has immunoglobulin A (IgA) deficiency with anti-IgA antibodies; **or**<br>• **All** of the following:<br>  ○ Homecare or home infusion provider has deemed that the individual or home environment is not suitable for home infusion therapy; **and**<br>  ○ The prescriber is unable to administer in the office setting; **and**<br>  ○ There are no ambulatory infusion suite options available for this member<br><br>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.<br><br>**Note**: If more than one of the above criteria are met, then the greatest of the applicable approval time periods will be allowed. |
| Sodium Hyaluronate | Jul. 1, 2026 | **Coverage Rationale**<br>• Added language to indicate Hymovis One is typically excluded from coverage; coverage reviews may be in place if required by law or the benefit plan | **Gel-One, GenVisc 850, Hyalgan, Hymovis, Hymovis One, Monovisc, Orthovisc, Supartz, Synojoynt, Synvisc or Synvisc-One, Triluron, TriVisc, and Visco-3 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 |

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| Policy Title | Effective Date | Summary of Changes | Coverage Rationale |
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| Sodium Hyaluronate (continued) | Jul. 1, 2026 | • Revised list of U.S. FDA-approved sodium hyaluronate products and their respective FDA labeled dosage per treatment course per joint; added Hymovis One (1 injection)<br>**Documentation Requirements**<br>• Revised list of non-preferred products; added Hymovis One<br>**Supporting Information**<br>• Updated *FDA*, *CMS*, and *References* sections to reflect the most current information | preferred alternatives.<br><br>**Note**: For requests that require medical necessity review also refer to the *Diagnosis-Specific Criteria* section below (for Medicare reviews, refer to the *CMS* section of the policy).<br><br>Coverage for Durolane, Euflexxa, and Gelsyn-3 is contingent on criteria in the *Diagnosis-Specific Criteria* section. Prior authorization is not required.<br><br>**Diagnosis-Specific Criteria**<br>***Initial Authorization (Sodium Hyaluronate Naïve Patients)***<br>**Intra-articular injections of sodium hyaluronate are proven and medically necessary when all of the following are met:**<br>• Diagnosis of knee osteoarthritis; **and**<br>• The member has not responded adequately to conservative therapy which may include physical therapy or pharmacotherapy [e.g., non-steroidal anti-inflammatory drugs (NSAIDs), acetaminophen, and/or topical capsaicin cream] or injection of intra-articular steroids and such therapy has not resulted in functional improvement after at least 3 months, or the member is unable to tolerate conservative therapy because of adverse side effects; **and**<br>• The member reports pain which interferes with functional activities (e.g., ambulation, prolonged standing); **and**<br>• The pain is attributed to degenerative joint disease/primary osteoarthritis of the knee; **and**<br>• There are no contraindications to the injections (e.g., active joint infection, bleeding disorder); **and**<br>• Dosing is in accordance with the U.S. FDA approved labeling as shown in the table in the policy; **and**<br>• Initial authorization is for a single treatment course once per joint for 6 months (see table in the policy)<br><br>***Reauthorization/Continuation***<br>**Repeated courses of intra-articular hyaluronan injections may be considered when all of the following are met:** |

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| **Policy Title** | **Effective Date** | **Summary of Changes** | **Coverage Rationale** |
| Sodium Hyaluronate (continued) | Jul. 1, 2026 | | • Diagnosis of knee osteoarthritis; **and**<br>• Documentation of positive clinical response to therapy (e.g., significant pain relief was achieved with the prior course of injections); **and**<br>• Pain has recurred; **and**<br>• At least 6 months have passed since the prior course of treatment for the respective joint; **and**<br>• Dosing is in accordance with the U.S. FDA approved labeling as shown in the table in the policy; **and**<br>• Continuing authorization is for a single treatment course once per joint for 6 months (see table in the policy)<br><br>**Intra-articular injections of sodium hyaluronate are unproven and not medically necessary for treating any other indication due to insufficient evidence of efficacy including, but not limited to the following:**<br>• Hip osteoarthritis<br>• Temporomandibular joint osteoarthritis<br>• Temporomandibular joint disc displacement<br><br>**Hyaluronic acid gel preparations to improve the skin's appearance, contour and/or reduce depressions due to acne, scars, injury, or wrinkles are considered cosmetic and are not covered.** |
| Tocilizumab Injection for Intravenous Infusion | Jul. 1, 2026 | **Title Change**<br>• Previously titled *Tocilizumab (Actemra®, Tofidence™, & Tyenne®) Injection for Intravenous Infusion*<br>**Coverage Rationale**<br>• Revised list of applicable drug products; added Avtozma® (tocilizumab-anoh)<br>• Added language to indicate Avtozma (tocilizumab-anoh) for self-administered subcutaneous injection are obtained under the pharmacy benefit, unless otherwise specified in the member's benefit plan documents | Refer to the Medical Benefit Drug Policy titled Oncology Medication Clinical Coverage for updated information based upon the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium® (NCCN Compendium®) for oncology indications.<br><br>This policy refers only to **Actemra® (tocilizumab), Avtozma® (tocilizumab-anoh), Tofidence® (tocilizumab-bavi), and Tyenne® (tocilizumab-aazg) injection for intravenous infusion**. Actemra (tocilizumab), Avtozma (tocilizumab-anoh), and Tyenne (tocilizumab-aazg) for self-administered subcutaneous injection are obtained under the pharmacy benefit, unless otherwise specified in the member's benefit plan documents. Exception: For members enrolled in UnitedHealthcare of California plans with a delegated provider group conducting the prior authorization review, the available self-administered tocilizumab products may be obtained under the medical benefit. |

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| **Policy Title** | **Effective Date** | **Summary of Changes** | **Coverage Rationale** |
| Tocilizumab Injection for Intravenous Infusion (continued) | Jul. 1, 2026 | ***Preferred Product***<br>• Added language to indicate:<br>  ○ Avtozma (tocilizumab-anoh) is a preferred tocilizumab product; coverage will be provided for Avtozma contingent on the coverage criteria in the *Diagnosis-Specific Criteria* section [of the policy]<br>  ○ Coverage for Tyenne (tocilizumab-aazg) will be provided contingent on the criteria in the *Preferred Product Criteria* section [of the policy] and the coverage criteria in the *Diagnosis-Specific Criteria* section [of the policy]<br>  ○ Treatment with Tyenne is medically necessary for the indications specified in this policy when one of the [listed] criteria are met<br>• Removed language indicating Tyenne (tocilizumab-aazg) is a preferred tocilizumab product; coverage will be provided for Tyenne contingent on the coverage criteria in the *Diagnosis-Specific Criteria* section [of the policy]<br>• Replaced language indicating "in order to continue coverage, members already on Tofidence (tocilizumab-bavi) or other non-preferred tocilizumab product will | *Any U.S. Food and Drug Administration approved and launched tocilizumab biosimilar product not listed by name in this policy will be considered non-preferred until reviewed by UnitedHealthcare.<br><br>Refer to the policy for complete details. |

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| **Policy Title** | **Effective Date** | **Summary of Changes** | **Coverage Rationale** |
| Tocilizumab Injection for Intravenous Infusion (continued) | Jul. 1, 2026 | be required to change therapy to Actemra or *Tyenne* unless they meet the criteria in the *Preferred Product Criteria* section [of the policy]" with "in order to continue coverage, members already on Tofidence (tocilizumab-bavi), *Tyenne (tocilizumab-aazg)*, or other non-preferred tocilizumab product will be required to change therapy to Actemra or *Avtozma* unless they meet the criteria in the *Preferred Product Criteria* section [of the policy]"<br>• Revised preferred product criteria:<br>○ Removed criterion requiring the patient has not had a loss of a favorable response after established maintenance therapy with Actemra or Tyenne or other tocilizumab biosimilar product<br>○ Replaced criterion requiring:<br>▪ "Documentation of a trial of at least 14 weeks of Actemra or *Tyenne* resulting in minimal clinical response to therapy and residual disease activity" with "documentation of a trial of at least 14 weeks of Actemra or *Avtozma* resulting in minimal clinical response to therapy and residual disease activity" | |

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| **Policy Title** | **Effective Date** | **Summary of Changes** | **Coverage Rationale** |
| Tocilizumab Injection for Intravenous Infusion (continued) | Jul. 1, 2026 | ▪ "The physician attests that in their clinical opinion, the clinical response would be expected to be superior with Tofidence or other tocilizumab biosimilar product, than experienced with Actemra or *Tyenne*" with "the physician attests that in their clinical opinion, the clinical response would be expected to be superior with Tofidence, *Tyenne*, or other tocilizumab biosimilar product, than experienced with Actemra or *Avtozma*"<br>▪ "Documentation of intolerance, contraindication, or adverse event to Actemra or *Tyenne*" with "documentation of intolerance, contraindication, or adverse event to Actemra or *Avtozma*"<br>▪ "The physician attests that in their clinical opinion, the same intolerance, contraindication, or adverse event would not be expected to occur with | |

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| **Policy Title** | **Effective Date** | **Summary of Changes** | **Coverage Rationale** |
| Tocilizumab Injection for Intravenous Infusion (continued) | Jul. 1, 2026 | Tofidence or other tocilizumab biosimilar product" with "the physician attests that in their clinical opinion, the same intolerance, contraindication, or adverse event would not be expected to occur with Tofidence, *Tyenne*, or other tocilizumab biosimilar product"<br>***Giant Cell Arteritis***<br>• Revised coverage criteria; replaced "the patient is not receiving tocilizumab in combination with *a* systemic targeted immunomodulator *[e.g., Kevzara (sarilumab), Orencia (abatacept), Rinvoq (upadacitinib)]* for treatment of the same indication" with "the patient is not receiving tocilizumab in combination with *another* systemic targeted immunomodulator for treatment of the same indication"<br>**Applicable Codes**<br>• Added HCPCS code Q5156<br>**Supporting Information**<br>• Updated *CMS* and *References* sections to reflect the most current information | |

# General Information

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

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

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

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

## Policy Update Classifications

### *New*

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

### *Updated*

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

### *Revised*

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

### *Replaced*

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

### *Retired*

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

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