United Healthcare Community Plan

UnitedHealthcare Community Plan
Medical Policy Update Bulletin: August 2025

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Medical Policy Updates

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Policy Title	**Effective Date**	**Summary of Changes**
Gender Dysphoria Treatment	Aug. 1, 2025	**Application** ***Maryland*** • Added language to indicate this Medical Policy does not apply to the state of Maryland; refer to the *Maryland Department of Health Gender-Affirming Treatment Services Under the Maryland Medicaid Program*
Hearing Aids and Devices Including Wearable, Bone-Anchored, and Semi-Implantable	Aug. 1, 2025	**Applicable Codes** • Updated list of applicable CPT codes to reflect quarterly edits; added 0951T, 0952T, 0953T, 0954T, and 0955T
Outpatient Surgical Procedures – Site of Service	Aug. 1, 2025	**Medical Records Documentation Used for Reviews** • Added language to indicate: ○ Benefit coverage for health services is determined by the federal, state, or contractual requirements, and applicable laws that may require coverage for a specific service ○ Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested; refer to the guidelines titled Medical Records Documentation Used for Reviews **Supporting Information** • Updated *References* section to reflect the most current information
Surgery of the Hip	Aug. 1, 2025	**Application** ***Nebraska*** and ***North Carolina*** • Added language to indicate this policy does not apply to the states of Nebraska and North Carolina; refer to the state-specific policy versions **Medical Records Documentation Used for Reviews** • Updated list of Medical Records Documentation Used for Reviews; replaced "complete diagnostic imaging *report(s) that are separate and distinct from the professional component of an evaluation and management office visit*" with "complete diagnostic *interpretation of* imaging *findings including, at a minimum: relevant clinical information, detailed report of imaging findings, impression, and specialty(ies) of the provider(s) who interpreted the images*"
Surgery of the Knee	Aug. 1, 2025	**Application** ***Nebraska*** and ***North Carolina*** • Added language to indicate this policy does not apply to the states of Nebraska and North Carolina; refer to the state-specific policy versions **Medical Records Documentation Used for Reviews** • Updated list of Medical Records Documentation Used for Reviews; replaced "complete diagnostic imaging *report(s) that are separate and distinct from the professional component of an evaluation and management office*

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Policy Title	Effective Date	Summary of Changes
Surgery of the Knee (continued)	Aug. 1, 2025	*visit*" with "complete diagnostic *interpretation of* imaging *findings including, at a minimum: relevant clinical information, detailed report of imaging findings, impression, and specialty(ies) of the provider(s) who interpreted the images*"

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Gastrointestinal Motility Disorders, Diagnosis and Treatment	Oct. 1, 2025	**Coverage Rationale** • Added language to indicate Esophageal Mucosal Integrity Testing by electrical impedance (e.g., MiVu™ Mucosal Integrity Testing System) for the diagnosis of gastroesophageal reflux disease (GERD), eosinophilic esophagitis (EoE), and nonacid reflux disease (non-GERD), or for the monitoring of treatment response in GERD and EoE are unproven and not medically necessary due to insufficient evidence of efficacy • Removed language indicating: ○ Rectal manometry, rectal sensation, tone, and compliance test, conventional defecography, and anorectal manometry are proven and medically necessary for evaluation of colorectal function ○ Colonic manometry for evaluating colon motility is unproven and not medically necessary due to insufficient evidence of efficacy ○ Ingestible vibrating capsule devices (e.g., the Vibrant® System) for the treatment of	**Gastric electrical stimulation (GES) 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.** Refer to the *U.S. Food and Drug Administration (FDA)* section of the policy for information regarding FDA labeling and Humanitarian Device Exemption (HDE) for GES. **The following procedures are unproven and not medically necessary due to insufficient evidence of efficacy:** • Magnetic Resonance Imaging (MRI) Defecography for evaluating Constipation and Anorectal or pelvic floor disorders. • Cutaneous, mucous, or serosal Electrogastrography, electroenterography, or body surface gastric mapping (e.g., Gastric Alimetry System, G-Tech Gut Tracker wireless patch system) for diagnosing intestinal or gastric disorders including Gastroparesis. • Esophageal Mucosal Integrity Testing by electrical impedance (e.g., MiVu™ Mucosal Integrity Testing System) for the diagnosis of gastroesophageal reflux disease (GERD), eosinophilic esophagitis (EoE), and nonacid reflux disease (non-GERD), or for the monitoring of treatment response in GERD and EoE.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**

Gastrointestinal Motility Disorders, Diagnosis and Treatment (continued)	Oct. 1, 2025	Constipation are unproven and not medically necessary due to insufficient evidence of efficacy
		Medical Records Documentation Used for Reviews
		• Added language to indicate:
		  ○ Benefit coverage for health services is determined by the federal, state, or contractual requirements, and applicable laws that may require coverage for a specific service
		  ○ Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested; refer to the guidelines titled Medical Records Documentation Used for Reviews
		Definitions
		• Added definition of "Esophageal Mucosal Integrity Testing"
		• Removed definition of:
		  ○ Anorectal Manometry
		  ○ Colonic Manometry
		  ○ Defecography
		Applicable Codes
		• Added CPT codes 43499 and 76498	

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Gastrointestinal Motility Disorders, Diagnosis and Treatment (continued)	Oct. 1, 2025	• Removed CPT/HCPCS codes 74270, 76496, 91117, 91120, 91122, A9286, A9900, A9999, and E1399 **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	

Gynecomastia Surgery (for Florida Only)	Sep. 1, 2025	**Coverage Rationale**
		• Replaced coverage guidelines with instruction to refer to the *Florida Medicaid Integumentary Services Coverage Policy* for medical necessity clinical coverage criteria
		Definitions
		• Removed definition of:
		  ○ Gynecomastia
		  ○ Functional or Physical Impairment
		Supporting Information
		• Updated *References* section to reflect the most current information
		• Removed *Description of Services* and *Clinical Evidence* sections
			For medical necessity clinical coverage criteria for gynecomastia surgery, refer to the Florida Medicaid Integumentary Services Coverage Policy.

Skin and Soft Tissue Substitutes	Oct. 1, 2025	**Coverage Rationale**
		• Revised list of skin and soft tissue substitutes that are unproven and not medically necessary for any indication; added:
		  ○ Abiomend Hydromembrane
		  ○ Abiomend Membrane
		  ○ Abiomend Xplus Hydromembrane
			EpiFix or Grafix® (GrafixPL, GrafixPRIME, and GrafixPL PRIME) (Non-Injectable)
			EpiFix or Grafix is proven and medically necessary for treating a diabetic foot ulcer when all of the following criteria are met:
			• Adequate circulation to the affected extremity as indicated by one or more of the following:
			  ○ Pedal pulses palpable or pulses confirmed with doppler examination
			  ○ Ankle-brachial index (ABI) between 0.7 and 1.2
			• Glycated hemoglobin test (HgA1c) < 12% (within the last 90 days)

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Skin and Soft Tissue Substitutes (continued)	Oct. 1, 2025	○ Abiomend Xplus Membrane ○ AmchoPlast FD ○ Amnio Burgeon Dual-Layer Membrane ○ Amnio Burgeon Membrane and Hydromembrane ○ Amnio Burgeon Xplus Membrane and Xplus Hydromembrane ○ AmnioCore SL ○ ChoriPly ○ CYGNUS Disk ○ Dual Layer Amnio Burgeon X-Membrane ○ EPIXPRESS ○ Foundation Dermal Regeneration Scaffold (DRS) Solo ○ Miro3D Fibers ○ MiroDry Wound Matrix ○ Myriad Matrix ○ Myriad Morcells ○ PalinGen Dual-Layer Membrane ○ Theracor P or Allacor P ○ XWRAP Dual ○ XWRAP Plus **Applicable Codes** • Added HCPCS codes A2030, A2031, A2032, A2033, A2034, A2035, Q4354, Q4355, Q4356, Q4357, Q4358, Q4359, Q4360, Q4361, Q4362, Q4364, Q4365, Q4366, and Q4367 • Removed HCPCS codes Q4231 **Supporting Information** • Updated *Clinical Evidence* and	• Ulcer has failed to demonstrate adequate healing with at least 4 weeks of standard wound care which includes **all** of the following: ○ Application of dressings to maintain a moist wound environment ○ Debridement of necrotic tissue if present ○ Offloading • No known contraindications which may include but are not limited to the following: ○ Active Charcot deformity or major structural abnormalities of the affected foot ○ Chronic infection to the ulcer site ○ Known or suspected malignancy of the current ulcer being treated ○ Ulcer being treated does not extend to tendon, muscle, capsule, or bone ***EpiFix and Grafix Application Limitations*** • EpiFix is limited to one application per week for up to 12 weeks. • Grafix is limited to one application per week for up to 12 weeks. **Due to insufficient evidence of efficacy, EpiFix and/or Grafix are unproven and not medically necessary for all other indications including but not limited to:** • EpiFix application more frequently than once a week or beyond 12 weeks • Grafix application more frequently than once a week or beyond 12 weeks **TransCyte™** **TransCyte is proven and medically necessary for treating surgically excised Full-Thickness Thermal Burn wounds and deep Partial-Thickness Thermal Burn wounds before autograft placement.** **TransCyte is unproven and not medically necessary for all other indications due to insufficient evidence of efficacy.** **Other Skin and Soft Tissue Substitutes** Other skin and soft tissue substitutes listed in the policy are unproven and not medically necessary for any indication due to insufficient evidence of

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Skin and Soft Tissue Substitutes (continued)	Oct. 1, 2025	*References* sections to reflect the most current information	efficacy. Refer to the policy for complete details.
Surgery of the Foot	Oct. 1, 2025	**Related Policies** • Added reference link to the Medical Policy titled *Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal Conditions and Soft Tissue Wounds* **Coverage Rationale** ***Hallux Rigidus (Correction With Implant)*** • Replaced language indicating "correction of the first metatarsophalangeal (MTP) joint with cheilectomy, debridement, and capsular release with implant is proven and medically necessary when all of the [listed] criteria are met" with "correction of the first metatarsophalangeal (MTP) joint with cheilectomy, debridement, and capsular release with implant *(Hemi-Implant or Total Implant Arthroplasty)* is proven and medically necessary when all of the [listed] criteria are met" **Definitions** • Added definition of: ○ Hemi-Implant Arthroplasty ○ Interposition Arthroplasty ○ Total Implant Arthroplasty **Supporting Information** • Updated *Clinical Evidence* and	**Surgery of the foot is proven and medically necessary in certain circumstances.** For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures: • Arthrodesis or Arthroplasty, Interphalangeal Joint, Second-Fifth Toes • Exostectomy, First Metatarsophalangeal (MTP) Joint (Bunionectomy) • Osteotomy, Distal Transpositional, First Metatarsal (MT) (Bunionectomy) • Osteotomy, Proximal, First Metatarsal (MT) (Bunionectomy) • Osteotomy, Proximal Phalanx, First Toe +/- Bunionectomy • Plantar Fascial Release Click here to view the InterQual® criteria. **Hallux Limitus or Rigidus (Correction Without Implant)** **Correction of the first metatarsophalangeal (MTP) joint with cheilectomy, debridement, and capsular release without implant is proven and medically necessary when all of the following criteria are met:** • Diagnosis of hallux limitus or hallux rigidus to include the following: ○ Radiographic imaging to confirm a mild to moderate pathology (e.g., a grading scale such as the Coughlin and Shurnas or Hattrup Johnson Classification may be used) • Persistent pain despite a reasonable trial of conservative treatment including one or more of the following: ○ Orthotics, shoe modification (e.g., high and wide toe box, rocker bottom sole), and/or shoe inserts ○ Medical therapy (NSAIDs, analgesics, or intra-articular injections) ○ Activity modification ○ Debridement of hyperkeratotic lesions if present **Correction of the first metatarsophalangeal (MTP) joint with cheilectomy, debridement, and capsular release without implant is unproven and not medically necessary for severe hallux rigidus (e.g., a**

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale

Surgery of the Foot (continued)	Oct. 1, 2025	*References* sections to reflect the most current information	**grading scale such as the Coughlin and Shurnas or Hattrup Johnson Classification may be used) due to insufficient evidence of efficacy.**
			
			Hallux Rigidus (Correction With Implant)
			Correction of the first metatarsophalangeal (MTP) joint with cheilectomy, debridement, and capsular release with implant (Hemi-Implant or Total Implant Arthroplasty) is proven and medically necessary when all of the following criteria are met:
			• Diagnosis of hallux rigidus to include the following:
			  ○ Radiographic imaging to confirm a moderate to severe pathology (e.g., a grading scale such as the Coughlin and Shurnas or Hattrup Johnson Classification may be used)
			• Persistent pain despite a reasonable trial of conservative treatment including one or more of the following:
			  ○ Orthotics, shoe modification (e.g., high and wide toe box, rocker bottom sole), and/or shoe inserts
			  ○ Medical therapy (NSAIDs, analgesics, or intra-articular injections)
			  ○ Activity modification
			  ○ Debridement of hyperkeratotic lesions if present
			
			Osteochondral Allograft or Autograft Transplantation
			Osteochondral allograft or autograft transplantation is unproven and not medically necessary for treating cartilage defects of the foot due to insufficient evidence of efficacy.

Umbilical Cord Blood Harvesting and Storage for Future Use	Oct. 1, 2025	**Coverage Rationale** • Replaced language indicating "collection and storage of umbilical cord blood is unproven and not medically necessary for *a person* who is currently healthy but desiring to provide the opportunity for a *hypothetical*, future transplantation due to insufficient evidence of efficacy" with "*prophylactic* collection and storage of umbilical cord blood is	**Due to insufficient evidence of efficacy, prophylactic collection and storage of umbilical cord blood is unproven and not medically necessary for an individual who is currently healthy but desiring to provide the opportunity for a future unspecified autologous or allogeneic stem cell transplantation.** For additional information and coverage of umbilical cord blood stem cell transplantation, refer to the Optum Clinical Guideline titled Hematopoietic Stem Cell Transplantation.

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Umbilical Cord Blood Harvesting and Storage for Future Use (continued)	Oct. 1, 2025	unproven and not medically necessary for *an individual* who is currently healthy but desiring to provide the opportunity for a future *unspecified autologous or allogeneic stem cell* transplantation due to insufficient evidence of efficacy" **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	

Retired

Policy Title	Effective Date	Summary of Changes
Core Decompression for Avascular Necrosis	Aug. 1, 2025	• Retired policy; core decompression for avascular necrosis no longer requires clinical review

Medical Benefit Drug Policy Updates

New

Policy Title	Effective Date	Coverage Rationale
Encelto™ (Revakinagene Taroretcel-Lwey)	Sep. 1, 2025	**Encelto is proven and medically necessary for one treatment per eye, per lifetime for the treatment of adults with idiopathic macular telangiectasia type 2 (MacTel) who meet all of the following:** • Patient is at least 18 years of age; **and** • Submission of medical records (e.g., chart notes) confirming diagnosis of non-proliferative macular telangiectasia type 2 (MacTel) in at least one eye; **and** • Patient will be monitored for signs and symptoms of retinal tears and/or retinal detachment (e.g., acute onset of flashing lights, floaters, and/or loss of visual acuity); **and** • Encelto is prescribed by an ophthalmologist; **and** • Dosing is in accordance with the United States Food and Drug Administration approved labeling; **and** • Authorization will be issued for no more than one treatment per eye per lifetime and for no longer than 60 days from approval

Updated

Policy Title	Effective Date	Summary of Changes
Niktimvo™ (Axatilimab-Csfr)	Aug. 1, 2025	**Application** ***Louisiana*** • Added instruction to refer to the state's Medicaid clinical policy ***Texas*** • Added language to indicate this Medical Benefit Drug Policy does not apply to the state of **Texas**; refer to the drug-specific criteria found within the *Texas Medicaid Provider Procedures Manual*
Oncology Medication Clinical Coverage	Aug. 1, 2025	**Application** ***Arizona*** • Added instruction to refer to the state's Medicaid clinical policy for preferred product criteria for bevacizumab, rituximab, and trastuzumab
Ophthalmologic Vascular Endothelial Growth Factor (VEGF) Inhibitors	Aug. 1, 2025	**Application** ***Arizona*** • Added language to indicate this Medical Benefit Drug Policy does not apply to the state of **Arizona**; refer to the state's Medicaid clinical policy
Oxlumo® (Lumasiran) and Rivfloza® (Nedosiran)	Aug. 1, 2025	**Application** ***Arizona*** • Added language to indicate this Medical Benefit Drug Policy does not apply to the state of **Arizona**; refer to the state's Medicaid clinical policy
Respiratory Interleukins (Cinqair®, Fasenra®, & Nucala®)	Aug. 1, 2025	**Application** ***Arizona*** • Added instruction to use the drug-specific criteria found within the state's Medicaid clinical policy, if available for the specific product, otherwise this medical benefit drug policy applies

Medical Benefit Drug Policy Updates

Updated

Policy Title	Effective Date	Summary of Changes
Rituximab (Riabni®, Rituxan®, Ruxience®, & Truxima®)	Aug. 1, 2025	**Application** ***Arizona*** • Added language to indicate this Medical Benefit Drug Policy does not apply to the state of **Arizona**; refer to the state's Medicaid clinical policy
RNA-Targeted Therapies (Amvuttra® and Onpattro®)	Aug. 1, 2025	**Application** ***Arizona*** • Added language to indicate this Medical Benefit Drug Policy does not apply to the state of **Arizona**; refer to the state's Medicaid clinical policy and use the drug-specific criteria, if available for the specific product, otherwise this medical benefit drug policy applies
Skyrizi® (Risankizumab-Rzaa)	Aug. 1, 2025	**Coverage Rationale** • Updated list of examples of targeted immunomodulators the patient must not be receiving in combination with Skyrizi: ***Crohn's Disease (CD)*** ○ Added: ▪ Entyvio (vedolizumab) ▪ Omvoh (mirikizumab-mrkz) ▪ Tremfya (guselkumab) ○ Removed: ▪ Xeljanz (tofacitinib) ○ Replaced: ▪ "*Humira* (adalimumab)" with "adalimumab" ▪ "*Stelara* (ustekinumb)" with "ustekinumab" ***Ulcerative Colitis (UC)*** ○ Added: ▪ Entyvio (vedolizumab) ▪ Tremfya (guselkumab) ▪ Zeposia (ozanimod) ○ Removed: ▪ Cimzia (certolizumab) ▪ Enbrel (etanercept) ▪ Olumiant (baricitinib) ▪ Orencia (abatacept) ○ Replaced: ▪ "*Stelara* (ustekinumab)" with "ustekinumab" ▪ "Xeljanz (tofacitinib)" with "Xeljanz/*Xeljanz XR* (tofacitinib)" • Updated list of examples of targeted immunomodulators with which the patient received previous treatment:

Medical Benefit Drug Policy Updates

Updated

Policy Title	Effective Date	Summary of Changes
Skyrizi® (Risankizumab-Rzaa) (continued)	Aug. 1, 2025	***Crohn's Disease (CD)*** ○ Added: ▪ Entyvio (vedolizumab) ▪ Omvoh (mirikizumab-mrkz) ▪ Rinvoq (upadacitinib) ▪ Tremfya (guselkumab) ○ Replaced: ▪ "*Stelara* (ustekinumb)" with "ustekinumab" ***Ulcerative Colitis (UC)*** ○ Added: ▪ Entyvio (vedolizumab) ▪ Omvoh (mirikizumab-mrkz) ▪ Tremfya (guselkumab) ▪ Zeposia (ozanimod) ○ Replaced: ▪ "*Stelara* (ustekinumab)" with "ustekinumab" ▪ "Xeljanz (tofacitinib)" with "Xeljanz/*Xeljanz XR* (tofacitinib)" **Supporting Information** • Updated *References* section to reflect the most current information
Spevigo® (Spesolimab-Sbzo)	Aug. 1, 2025	**Application** ***Arizona*** • Added language to indicate this Medical Benefit Drug Policy does not apply to the state of **Arizona**; refer to the state's Medicaid clinical policy
Testosterone Replacement or Supplementation Therapy	Aug. 1, 2025	**Application** ***Arizona*** • Added language to indicate this Medical Benefit Drug Policy does not apply to the state of **Arizona**; refer to the state's Medicaid clinical policy
Vyepti® (Eptinezumab-Jjmr)	Sep. 1, 2025	**Applicable Codes** • Added ICD-10 diagnosis codes G43.A0, G43.A1, G43.B0, G43.B1, G43.D0, and G43.D1 **Supporting Information** • Updated *Background*, *Clinical Evidence*, and *References* sections to reflect the most current information
White Blood Cell Colony Stimulating Factors	Aug. 1, 2025	**Application** ***Arizona*** • Added language to indicate this Medical Benefit Drug Policy does not apply to the state of **Arizona**; refer to the state's Medicaid clinical policy

Medical Benefit Drug Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Botulinum Toxins A and B	Sep. 1, 2025	**Coverage Rationale** • Added language to indicate: ○ Any U.S. Food and Drug Administration (FDA) approved and launched botulinum toxin product not listed by name in this policy will be considered non-preferred until reviewed by UnitedHealthcare ○ Botox (onabotulinumtoxinA) and Xeomin (incobotulinumtoxinA) are the preferred botulinum toxin products; coverage will be provided for Botox and Xeomin contingent on the coverage criteria in the *Diagnosis-Specific Criteria* section [of the policy] ○ Coverage for Dysport (abobotulinumtoxinA), Daxxify (daxibotulinumtoxinA-lanm), Myobloc (rimabotulinumtoxinB), or other non-preferred botulinum toxin products will be provided contingent on the criteria in the *Preferred Product* section [of the policy] and the coverage criteria in the *Diagnosis-Specific Criteria* section [of the policy] ○ In order to continue coverage, members already on for Dysport (abobotulinumtoxinA), Daxxify	This policy refers to the following botulinum toxin type A and B drug products: • Dysport® (abobotulinumtoxinA) • Daxxify® (daxibotulinumtoxinA-lanm) • Xeomin® (incobotulinumtoxinA) • Botox® (onabotulinumtoxinA) • Myobloc® (rimabotulinumtoxinB) Refer to the policy for complete details.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Botulinum Toxins A and B (continued)	Sep. 1, 2025	(daxibotulinumtoxinA-lanm), Myobloc (rimabotulinumtoxinB), or other non-preferred botulinum toxin products will be required to change therapy to Botox (onabotulinumtoxinA) or Xeomin (incobotulinumtoxinA) unless they meet the criteria in the *Preferred Product* section [of the policy] ○ Treatment with Dysport, Daxxify, Myobloc, or other non-preferred botulinum toxin products is medically necessary for the indications specified in the policy when one of the following criteria are met: ▪ Both of the following: – History of a trial of Botox or Xeomin resulting in minimal clinical response to therapy and residual disease activity – Physician attests that, in their clinical opinion, the clinical response would be expected to be superior with Dysport, Daxxify, Myobloc, or other non-preferred botulinum toxin products, than experienced with	

Medical Benefit Drug Policy Updates

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Botulinum Toxins A and B (continued)	Sep. 1, 2025	Botox or Xeomin ▪ Both of the following: – History of intolerance, contraindication, or adverse event to Botox or Xeomin – Physician attests that, in their clinical opinion, the same intolerance, contraindication, or serious adverse event would not be expected to occur with Dysport, Daxxify, Myobloc, or other non-preferred botulinum toxin products	
Denied Drug Codes – Pharmacy Benefit Drugs (for Arizona Only)	Sep. 1, 2025	**Coverage Rationale** • Revised list of specialty drugs that will be denied from paying on a medical professional and outpatient facility claim: ○ Added: ▪ Alhemo (HCPCS codes C9399, J3490, and J3590) ▪ Epysqli (HCPCS code Q5151) ▪ Hemgenix (HCPCS code J1411) ▪ Hympavzi (HCPCS code J7172) ▪ Qfitlia (HCPCS codes C9399, J3490, and J3590)	This Medical Benefit Drug Policy applies to the UnitedHealthcare Community Plan of Arizona. This policy applies to services reported using both the 1500 Health Insurance Claim Form (also known as CMS-1500) and the UB-04 form, their electronic equivalent, and their successor forms. This policy applies to all: • Network and non-network physicians and other qualified health care professionals, including, but not limited to, non-network authorized and percent of charge contract physicians and other qualified health care professionals • Network and non-network facilities including, but not limited to, non-network authorized and percent of charge contract facilities The Arizona Health Care Cost Containment System (AHCCCS) provides direction on how Managed Care Organizations should handle claims for specific medications that fall under their Catastrophic Reinsurance Program. AHCCCS requires that all biologic/high-cost specialty drugs included in this program must be reimbursed on a pharmacy claim form. As such, to be in

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Denied Drug Codes – Pharmacy Benefit Drugs (for Arizona Only) (continued)	Sep. 1, 2025	**Applicable Codes** • Added HCPCS codes J1411, J7172, and Q5151	compliance with these state requirements, the injectable medications identified in this policy will only be reimbursed under the outpatient pharmacy benefit for UnitedHealthcare Community Plan of Arizona members. Refer to the policy for a list of specialty drugs (as identified by their HCPCS code) that will be denied from paying on a medical professional and outpatient facility claim.
Denosumab	Sep. 1, 2025	**Coverage Rationale** • Revised list of applicable denosumab products; added: ○ Osenvelt® (denosumab-bmwo) ○ Stoboclo® (denosumab-bmwo) • Added language to indicate: ○ Stoboclo is proven and medically necessary for the treatment of the following indications when criteria listed in the policy are met: ▪ Glucocorticoid-induced osteoporosis in patients at high risk for fracture ▪ Patients at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer ▪ Patients at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer ▪ Postmenopausal patients with osteoporosis or to increase bone mass in	This policy refers to the following denosumab products: • Jubbonti® (denosumab-bbdz) • Osenvelt® (denosumab-bmwo) • Prolia® (denosumab) • Stoboclo® (denosumab-bmwo) • Wyost® (denosumab-bbdz) • Xgeva® (denosumab) Refer to the policy for complete details.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Denosumab (continued)	Sep. 1, 2025	patients with osteoporosis at high risk for fracture ○ Osenvelt is proven and medically necessary for the treatment of the following indications when criteria listed in the policy are met: ▪ Giant cell tumor of the bone ▪ Hypercalcemia of malignancy ▪ Men with castration-resistant prostate cancer who have bone metastases ▪ Multiple myeloma and with bone metastases from solid tumors ▪ Osteopenia/osteoporosis in patients with systemic mastocytosis with bone pain not responding to bisphosphonates ○ Denosumab-bmwo is unproven and not medically necessary for the following indications: ▪ Bone loss associated with hormone-ablation therapy (other than aromatase inhibitors) in breast/prostate cancer ▪ Cancer pain ▪ Central giant cell granuloma ▪ Combination therapy with	

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Denosumab (continued)	Sep. 1, 2025	intravenous bisphosphonates ▪ Hyper-parathyroidism ▪ Immobilization hypercalcemia ▪ Osteogenesis imperfecta ▪ Osteopenia **Applicable Codes** • Added HCPCS codes C9399, J3490, and J3590 • Updated list of applicable ICD-10 diagnosis codes for: ***Jubbonti, Prolia, and Stoboclo*** ○ Added M80.0B1A, M80.0B1D, M80.0B1G, M80.0B1K, M80.0B1P, M80.0B1S, M80.0B2A, M80.0B2D, M80.0B2G, M80.0B2K, M80.0B2P, M80.0B2S, M80.0B9A, M80.0B9D, M80.0B9G, M80.0B9K, M80.0B9P, M80.0B9S, M80.8B1A, M80.8B1D, M80.8B1G, M80.8B1K, M80.8B1P, M80.8B1S, M80.8B2A, M80.8B2D, M80.8B2G, M80.8B2K, M80.8B2P, M80.8B2S, M80.8B9A, M80.8B9D, M80.8B9G, M80.8B9K, M80.8B9P, and M80.8B9S ***Osenvelt, Wyost, and Xgeva*** ○ Added D48.110, D48.111, D48.112, D48.113, D48.114, D48.115, D48.116, D48.117,	

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Denosumab (continued)	Sep. 1, 2025	D48.118, D48.119, and D48.19 **Supporting Information** • Updated *Background*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	
Nplate® (Romiplostim)	Sep. 1, 2025	**Coverage Rationale** • Added language to indicate Nplate (romiplostim) is medically necessary for the treatment of myelodysplastic syndromes (MDS) when all of the following criteria are met: ***Initial Therapy*** ○ Diagnosis of lower risk myelodysplastic syndrome (IPSS-R very low, low, intermediate) ○ One of the following: ▪ Severe thrombocytopenia ▪ Refractory thrombocytopenia ○ One of the following: ▪ Disease progression after hypomethylating agent(s) (HMA) or immunosuppressive therapy (IST) ▪ No response to HMA or IST ▪ Relapse disease after HMA or IST ○ Initial authorization is for no more than 12 months ***Continuation of Therapy*** ○ Patient does not show	**Nplate (romiplostim) is proven and medically necessary for the treatment of chronic immune thrombocytopenic purpura (ITP) when all of the following criteria are met:** • For **initial therapy**, **all** of the following: ○ Diagnosis of chronic immune thrombocytopenic purpura (ITP); **and** ○ Documented baseline platelet count < 30 x 109/L; **and** ○ History of insufficient response, contraindication, or intolerance to **one** of the following: ▪ Corticosteroids; **or** ▪ Immunoglobulins; **or** ▪ Splenectomy **and** ○ Prescribed by or in consultation with a hematologist; **and** ○ Nplate is not being used to treat thrombocytopenia due to myelodysplastic syndrome (MDS) or any cause of thrombocytopenia other than ITP; **and** ○ Nplate is not being used to normalize platelet counts; **and** ○ Nplate is initiated and titrated according to U.S. Food and Drug Administration labeled dosing for ITP; **and** ○ Initial authorization is for no more than 12 months • For **continuation of therapy**, **all** of the following: ○ Patient has previously received Nplate subcutaneous injection; **and** ○ Documentation of positive clinical response to therapy as evidenced by an increase in platelet count to a level sufficient to avoid clinically important bleeding (platelet count ≥ 50 × 10^9/L as necessary to reduce the risk for bleeding); **and** ○ Nplate is not being used to treat thrombocytopenia due to myelodysplastic syndrome (MDS) or any cause of thrombocytopenia other than ITP; **and** ○ Nplate is not being used to normalize platelet counts; **and**

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Nplate® (Romiplostim) (continued)	Sep. 1, 2025	evidence of progressive disease while on Nplate therapy ○ Patient demonstrates clinically significant response to therapy as defined by one of the following: ▪ Increased platelet counts ▪ Decreased bleeding events ▪ Reduced need for platelet transfusion ○ Authorization is for no more than 12 months • Removed language indicating this policy refers to Nplate (romiplostim) subcutaneous injection only for the treatment of chronic immune thrombocytopenic purpura (ITP) in patients who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy **Applicable Codes** • Added ICD-10 diagnosis codes D46.9 and D46.Z **Supporting Information** • Updated *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	○ Nplate is dosed according to U.S. Food and Drug Administration labeled dosing for ITP; **and** ○ Authorization is for no more than 12 months **Nplate (romiplostim) is medically necessary for the treatment of Myelodysplastic Syndromes (MDS) when all of the following criteria are met:** • For **initial therapy**, **all** of the following: ○ Diagnosis of lower risk myelodysplastic syndrome (IPSS-R very low, low, intermediate); **and** ○ **One** of the following: ▪ Severe thrombocytopenia; **or** ▪ Refractory thrombocytopenia **and** ○ **One** of the following: ▪ Disease progression after hypomethylating agent(s) (HMA) or immunosuppressive therapy (IST); **or** ▪ No response to HMA or IST; **or** ▪ Relapse disease after HMA or IST **and** ○ Initial authorization is for no more than 12 months • For **continuation of therapy**, **all** of the following: ○ Patient does not show evidence of progressive disease while on Nplate therapy; **and** ○ Patient demonstrates clinically significant response to therapy as defined by **one** of the following: ▪ Increased platelet counts; **or** ▪ Decreased bleeding events; **or** ▪ Reduced need for platelet transfusion **and** ○ Authorization is for no more than 12 months
Ophthalmologic Vascular Endothelial Growth Factor (VEGF) Inhibitors	Sep. 1, 2025	**Coverage Rationale** • Added language to indicate Susvimo (ranibizumab) is proven and medically necessary for the treatment of diabetic retinopathy	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)

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Ophthalmologic Vascular Endothelial Growth Factor (VEGF) Inhibitors (continued)	Sep. 1, 2025	(DR) who have previously responded to ≥ 2 intravitreal injections of a VEGF inhibitor medication **Applicable Codes** • Updated list of applicable ICD-10 diagnosis codes for HCPCS code J2779; added E08.319, E08.3291, E08.3292, E08.3293, E08.3299, E08.3391, E08.3392, E08.3393, E08.3399, E08.3491, E08.3492, E08.3493, E08.3499, E08.3521, E08.3522, E08.3523, E08.3529, E08.3531, E08.3532, E08.3533, E08.3539, E08.3541, E08.3542, E08.3543, E08.3549, E08.3551, E08.3552, E08.3553, E08.3559, E08.3591, E08.3592, E08.3593, E08.3599, E09.3291, E09.3292, E09.3293, E09.3299, E09.3391, E09.3392, E09.3393, E09.3399, E09.3491, E09.3492, E09.3493, E09.3499, E09.3521, E09.3522, E09.3523, E09.3529, E09.3531, E09.3532, E09.3533, E09.3539, E09.3541, E09.3542, E09.3543, E09.3549, E09.3551, E09.3552, E09.3553, E09.3559, E09.3591, E09.3592, E09.3593, E09.3599, E10.3291, E10.3292, E10.3293, E10.3299, E10.3391, E10.3392, E10.3393, E10.3399, E10.3491, E10.3492, E10.3493, E10.3499, E10.3521, E10.3522, E10.3523, E10.3529, E10.3531, E10.3532, E10.3533, E10.3539, E10.3541, E10.3542, E10.3543,	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) • Susvimo™ (ranibizumab) • Vabysmo® (faricimab-svoa) **Note**: For requests that require medical necessity review, also refer to the *General Requirements* and *Diagnosis-Specific Requirements* sections below. **Coverage for Avastin®, Beovu®, Byooviz™, Cimerli®, Eylea®, Lucentis®, Pavblu™ 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 **Preferred Product** ***Neovascular (Wet) Age-Related Macular Degeneration (AMD)*** The preferred VEGF inhibitors for AMD are re-packaged Avastin (bevacizumab), followed by Eylea, Eylea HD, or Pavblu. **Coverage for Beovu, Byooviz, Cimerli, Eylea, Eylea HD, Lucentis, Pavblu, Susvimo, and Vabysmo will be provided contingent on the criteria in the *Preferred Product* and the *Diagnosis-Specific Requirements* sections.**

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Ophthalmologic Vascular Endothelial Growth Factor (VEGF) Inhibitors (continued)	Sep. 1, 2025	E10.3549, E10.3551, E10.3552, E10.3553, E10.3559, E10.3591, E10.3592, E10.3593, E10.3599, E11.3291, E11.3292, E11.3293, E11.3299, E11.3391, E11.3392, E11.3393, E11.3399, E11.3491, E11.3492, E11.3493, E11.3499, E11.3521, E11.3522, E11.3523, E11.3529, E11.3531, E11.3532, E11.3533, E11.3539, E11.3541, E11.3542, E11.3543, E11.3549, E11.3551, E11.3552, E11.3553, E11.3559, E11.3591, E11.3592, E11.3593, E11.3599, E13.3291, E13.3292, E13.3293, E13.3299, E13.3391, E13.3392, E13.3393, E13.3399, E13.3491, E13.3492, E13.3493, E13.3499, E13.3521, E13.3522, E13.3523, E13.3529, E13.3531, E13.3532, E13.3533, E13.3539, E13.3541, E13.3542, E13.3543, E13.3549, E13.3551, E13.3552, E13.3553, E13.3559, E13.3591, E13.3592, E13.3593, and E13.3599
		Supporting Information
		• Updated *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information
			Retinal Conditions Other Than Neovascular (Wet) Age-Related Macular Degeneration (AMD)
			Eylea, Eylea HD, and Pavblu are the preferred VEGF inhibitors for retinal conditions other than neovascular (wet) age-related macular degeneration. Coverage will be provided for Eylea, Eylea HD, and Pavblu contingent on the coverage criteria in the *Diagnosis-Specific Requirements* section.
			
			Coverage for Beovu, Byooviz, Cimerli, Lucentis, Susvimo, and Vabysmo will be provided contingent on the criteria in the *Preferred Product* and the *Diagnosis-Specific Requirements* sections.
			
			Preferred Product Criteria
			Treatment with Eylea, Eylea HD, or Pavblu are medically necessary for the treatment of neovascular (wet) age-related macular degeneration (AMD) when one of the following are met:
			• History of a trial of at least 3 doses, resulting in minimal clinical response to re-packaged Avastin (bevacizumab); **or**
			• History of intolerance, contraindication, or adverse event(s) to re-packaged Avastin (bevacizumab)
			
			Treatment with Beovu, Byooviz, Cimerli, Lucentis, Susvimo, or Vabysmo is medically necessary for the treatment of neovascular (wet) age-related macular degeneration (AMD) when one of the following are met:
			• **Both** of the following:
			  ○ Trial of at least 3 doses, resulting in minimal clinical response to re-packaged Avastin (bevacizumab); **and**
			  ○ History of use of Eylea, Eylea HD, or Pavblu, resulting in minimal clinical response to therapy
			or
			• History of contraindication, intolerance, or adverse event(s) to re-packaged Avastin (bevacizumab) **and** Eylea, Eylea HD, or Pavblu
			
			Treatment with Beovu, Byooviz, Cimerli, Lucentis, Susvimo, and Vabysmo is medically necessary for all retinal conditions other than neovascular (wet) age-related macular degeneration when one of the

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Ophthalmologic Vascular Endothelial Growth Factor (VEGF) Inhibitors (continued)	Sep. 1, 2025		**following are met:** • History of use of Eylea, Eylea HD, or Pavblu, resulting in minimal clinical response to therapy; **or** • History of contraindication, intolerance, or adverse event(s) to Eylea, Eylea HD, or Pavblu **Diagnosis-Specific Requirements** The information below indicates the list of proven and medically necessary indications. In absence of a product listed, and in addition to applicable criteria outlined within the drug policy, prescribing and dosing information from the package insert is the clinical information used to determine benefit coverage. **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:** • 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)

Medical Benefit Drug Policy Updates

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Ophthalmologic Vascular Endothelial Growth Factor (VEGF) Inhibitors (continued)	Sep. 1, 2025		• 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) • 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)

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Ophthalmologic Vascular Endothelial Growth Factor (VEGF) Inhibitors (continued)	Sep. 1, 2025		**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) **Susvimo (ranibizumab) is proven and medically necessary for the treatment of:** • Diabetic macular edema (DME) who have previously responded to ≥ 2 intravitreal injections of a VEGF inhibitor • Diabetic retinopathy (DR) who have previously responded to ≥ 2 intravitreal injections of a VEGF inhibitor medication • Neovascular age-related macular degeneration (nAMD) who have previously responded to ≥ 2 intravitreal injections of a VEGF inhibitor **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

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Ophthalmologic Vascular Endothelial Growth Factor (VEGF) Inhibitors (continued)	Sep. 1, 2025		their information page at: https://www.asrs.org/advocacy-practice/access-to-safe-compounded-agents for resources pertaining to access of safe compounded agents. Refer to the *U.S. Food and Drug Administration (FDA)* section of the policy for information related to contamination of compounded bevacizumab. In an effort to guard against contamination during the compounding process, the United States Veterans Health Administration (USVHA) requires that only USVHA pharmacies may dispense bevacizumab for intravitreal administration to Veterans Administration beneficiaries. The medication must 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.
Reblozyl® (Luspatercept-Aamt)	Sep. 1, 2025	**Coverage Rationale** • Added language to indicate UnitedHealthcare recognizes indications and uses of injectable oncology medications, including therapeutic radiopharmaceuticals, listed in the *NCCN Drugs and Biologics Compendium* with Categories of Evidence and Consensus of 1, 2A, and 2B as proven and medically necessary, and Categories of Evidence and Consensus of 3 as unproven and not medically necessary • Removed language indicating Reblozyl is proven and/or medically necessary for the treatment of symptomatic anemia in erythropoiesis stimulating agent-naïve (ESA-naïve) patients with myelodysplastic syndromes (MDS)	**Reblozyl is proven and medically necessary for the treatment of anemia in adult patients with beta thalassemia who meet all of the following criteria:** • **Initial Therapy** ○ Diagnosis of anemia due to beta thalassemia including beta^{+} thalassemia, beta^{0} thalassemia, and hemoglobin E/beta thalassemia; **and** ○ Patient is 18 years of age or older; **and** ○ Patient is transfusion dependent as evidenced by **both** of the following in the previous 24 weeks: ▪ Has required regular transfusion of at least six units of packed red blood cells (PRBC); **and** ▪ No transfusion free period greater than 35 days **and** ○ Prescribed by, or in consultation with, a hematologist, or other specialist with expertise in the diagnosis and management of beta thalassemia; **and** ○ Dosing is in accordance with the U.S. Food and Drug Administration (FDA) approved labeling; **and** ○ Initial authorization will be for no more than 12 months • **Continuation of Therapy** ○ Documentation of a positive clinical response to Reblozyl (e.g.,

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Reblozyl® (Luspatercept-Aamt) (continued)	Sep. 1, 2025	***Anemia in Adult Patients With Beta Thalassemia*** • Revised coverage criteria for: Initial Therapy ○ Replaced criterion requiring "diagnosis of beta thalassemia including beta+ thalassemia, beta0 thalassemia, and hemoglobin E/beta thalassemia" with "diagnosis of *anemia due to* beta thalassemia including beta+ thalassemia, beta0 thalassemia, and hemoglobin E/beta thalassemia" Continuation of Therapy ○ Added criterion requiring documentation of a positive clinical response to Reblozyl (e.g., reduction in transfusion burden, increase in hemoglobin from baseline) ○ Removed criterion requiring: ▪ Diagnosis of beta thalassemia including beta+ thalassemia, beta^0 thalassemia, and hemoglobin E/beta thalassemia ▪ Patient has experienced a reduction in transfusion requirements from pretreatment baseline of at least 2 units PRBC while receiving Reblozyl	reduction in transfusion burden, increase in hemoglobin from baseline); **and** ○ Prescribed by, or in consultation with, a hematologist, or other specialist with expertise in the diagnosis and management of beta thalassemia; **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 **Reblozyl is proven and medically necessary for the treatment of symptomatic anemia in patients with myelodysplastic syndromes who meet all of the following criteria:** • **Initial Therapy** ○ Diagnosis of symptomatic anemia due to myelodysplastic syndrome (MDS); **and** ○ Patient has lower risk disease as defined as International Prognostic Scoring System (IPSS-R): Very Low, Low, Intermediate; **and** ○ Patient does not have a confirmed mutation with deletion 5q [del(5q)]; **and** ○ **One** of the following: ▪ **Both** of the following: – Ring sideroblasts < 15% (or ring sideroblasts < 5% with an SF3B1 mutation); **and** – Serum erythropoietin ≤ 500 mU/mL **or** ▪ Ring sideroblasts ≥ 15% (or ring sideroblasts ≥ 5% with an SF3B1 mutation) **and** ○ Prescribed by, or in consultation with, a hematologist, oncologist, or other specialist with expertise in the diagnosis and management of myelodysplastic syndromes; **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 of Therapy** ○ Documentation of a positive clinical response to Reblozyl (e.g., reduction in transfusion burden, increase in hemoglobin from

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Reblozyl® (Luspatercept-Aamt) (continued)	Sep. 1, 2025	***Symptomatic Anemia in Patients With Myelodysplastic Syndromes*** • Revised language to indicate Reblozyl is proven and medically necessary for the treatment of symptomatic anemia in patients with myelodysplastic syndromes who meet all of the following criteria: Initial Therapy ○ Diagnosis of symptomatic anemia due to myelodysplastic syndrome (MDS) ○ Patient has lower risk disease as defined as International Prognostic Scoring System (IPSS-R): Very Low, Low, Intermediate ○ Patient does not have a confirmed mutation with deletion 5q [del(5q)] ○ One of the following: ▪ Both of the following: – Ring sideroblasts < 15% (or ring sideroblasts < 5% with an SF3B1 mutation) – Serum erythropoietin ≤ 500 mU/mL ▪ Ring sideroblasts ≥ 15% (or ring sideroblasts ≥ 5% with an SF3B1 mutation) ○ Prescribed by, or in consultation with, a	baseline); **and** ○ Prescribed by, or in consultation with, a hematologist, oncologist, or other specialist with expertise in the diagnosis and management of myelodysplastic syndromes; **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 **Reblozyl is proven and medically necessary for the treatment of anemia in patients with myelodysplastic syndrome/myeloproliferative neoplasm (MDS/MPN) who meet all of the following criteria:** • **Initial Therapy** ○ Diagnosis of anemia due to myelodysplastic syndrome/myeloproliferative neoplasm (MDS/MPN); **and** ○ Presence of a SF3B1 mutation; **and** ○ Thrombocytosis defined as platelet count ≥ 450 x 10^9/L; **and** ○ Prescribed by, or in consultation with, a hematologist, oncologist, or other specialist with expertise in the diagnosis and management of myelodysplastic syndromes; **and** ○ Dosing is in accordance with the FDA approved labeling; **and** ○ Initial authorization will be for no more than 12 months • **Continuation of Therapy** ○ Documentation of a positive clinical response to Reblozyl (e.g., reduction in transfusion burden, increase in hemoglobin from baseline); **and** ○ Reblozyl is prescribed by, or in consultation with, a hematologist, oncologist, or other specialist with expertise in the diagnosis and management of myelodysplastic syndromes; **and** ○ Dosing is in accordance with the FDA approved labeling; **and** ○ Reauthorization will be for no more than 12 months **Reblozyl is proven and medically necessary for the treatment of myelofibrosis-associated anemia who meet all of the following criteria:** • **Initial Therapy** ○ Diagnosis of myelofibrosis-associated anemia; **and** ○ **One** of the following: ▪ **Both** of the following:

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Reblozyl® (Luspatercept-Aamt) (continued)	Sep. 1, 2025	hematologist, oncologist, or other specialist with expertise in the diagnosis and management of myelodysplastic syndromes ○ Dosing is in accordance with the U.S. FDA approved labeling ○ Initial authorization will be for no more than 12 months Continuation of Therapy ○ Documentation of a positive clinical response to Reblozyl (e.g., reduction in transfusion burden, increase in hemoglobin from baseline) ○ Prescribed by, or in consultation with, a hematologist, oncologist, or other specialist with expertise in the diagnosis and management of myelodysplastic syndromes ○ Dosing is in accordance with the FDA approved labeling ○ Reauthorization will be for no more than 12 months ***Anemia in Patients With Myelodysplastic Syndrome/ Myeloproliferative Overlap Neoplasm (MDS/MPN)*** • Added language to indicate Reblozyl is proven and medically necessary for the treatment of anemia in patients with myelodysplastic syndrome/ myeloproliferative overlap	– Ongoing symptomatic splenomegaly and/or constitutional symptoms; **and** – Used in combination with Jakafi (ruxolitinib) **or** ▪ No splenomegaly or constitutional symptoms **or** ▪ **Both** of the following: – Splenomegaly and constitutional symptoms well controlled on current JAK inhibitor [e.g., Inrebic (fedratinib), Jakafi (ruxolitinib), Ojjaara (momelotinib),Vonjo (pacritinib)]; **and** – Used in combination with a JAK inhibitor [e.g., Inrebic (fedratinib), Jakafi (ruxolitinib), Ojjaara (momelotinib),Vonjo (pacritinib) **and** ○ Prescribed by, or in consultation with, a hematologist, oncologist, or other specialist with expertise in the diagnosis and management of myelofibrosis; **and** ○ Dosing is in accordance with the FDA approved labeling; **and** ○ Initial authorization will be for no more than 12 months • **Continuation of Therapy** ○ Documentation of a positive clinical response to Reblozyl (e.g., reduction in transfusion burden, increase in hemoglobin from baseline); **and** ○ Reblozyl is prescribed by, or in consultation with, a hematologist, oncologist, or other specialist with expertise in the diagnosis and management of myelofibrosis; **and** ○ Dosing is in accordance with the FDA approved labeling; **and** ○ Reauthorization will be for no more than 12 months **Reblozyl is not proven or medically necessary for the treatment of:** • Non-transfusion dependent beta thalassemia • Beta thalassemia in pediatric patients • Sickle beta thalassemia [hemoglobin S (HbS)/beta thalassemia] • Alpha thalassemia UnitedHealthcare recognizes indications and uses of injectable oncology medications, including therapeutic radiopharmaceuticals, listed in the NCCN

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Reblozyl® (Luspatercept-Aamt) (continued)	Sep. 1, 2025	neoplasm (MDS/MPN) who meet all of the following criteria: Initial Therapy ○ Diagnosis of anemia due to myelodysplastic syndrome/ myeloproliferative overlap neoplasm (MDS/MPN) ○ Presence of a SF3B1 mutation ○ Thrombocytosis defined as platelet count ≥ 450 x 109/L ○ Prescribed by, or in consultation with, a hematologist, oncologist, or other specialist with expertise in the diagnosis and management of MDS/MPN ○ Dosing is in accordance with the U.S. FDA approved labeling ○ Initial authorization will be for no more than 12 months Continuation of Therapy ○ Documentation of a positive clinical response to Reblozyl (e.g., reduction in transfusion burden, increase in hemoglobin from baseline) ○ Reblozyl is prescribed by, or in consultation with, a hematologist, oncologist, or other specialist with expertise in the diagnosis and management of MDS/MPN ○ Dosing is in accordance with the U.S. FDA approved labeling	Drugs and Biologics Compendium with Categories of Evidence and Consensus of 1, 2A, and 2B as proven and medically necessary, and Categories of Evidence and Consensus of 3 as unproven and not medically necessary.

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Reblozyl® (Luspatercept-Aamt) (continued)	Sep. 1, 2025	○ Reauthorization will be for no more than 12 months ***Myelofibrosis-Associated Anemia*** • Added language to indicate Reblozyl is proven and medically necessary for the treatment of myelofibrosis-associated anemia who meet all of the following criteria: Initial Therapy ○ Diagnosis of myelofibrosis-associated anemia ○ One of the following: ▪ Both of the following: – Ongoing symptomatic splenomegaly and/or constitutional symptoms – Used in combination with Jakafi (ruxolitinib) ▪ No splenomegaly or constitutional symptoms ▪ Both of the following: – Splenomegaly and constitutional symptoms well controlled on current JAK inhibitor [e.g., Inrebic (fedratinib), Jakafi (ruxolitinib), Ojjaara (momelotinib),Vonjo (pacritinib)] – Used in combination with a JAK inhibitor	

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Reblozyl® (Luspatercept-Aamt) (continued)	Sep. 1, 2025	[e.g., Inrebic (fedratinib), Jakafi (ruxolitinib), Ojjaara (momelotinib),Vonjo (pacritinib)] ○ Prescribed by, or in consultation with, a hematologist, oncologist, or other specialist with expertise in the diagnosis and management of myelofibrosis ○ Dosing is in accordance with the U.S. FDA approved labeling ○ Initial authorization will be for no more than 12 months Continuation of Therapy ○ Documentation of a positive clinical response to Reblozyl (e.g., reduction in transfusion burden, increase in hemoglobin from baseline) ○ Reblozyl is prescribed by, or in consultation with, a hematologist, oncologist, or other specialist with expertise in the diagnosis and management of myelofibrosis ○ Dosing is in accordance with the U.S. FDA approved labeling ○ Reauthorization will be for no more than 12 months **Supporting Information** • Updated *Clinical Evidence* section to reflect the most current information	

Medical Benefit Drug Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale

Respiratory Interleukins (Cinqair®, Fasenra®, & Nucala®)	Sep. 1, 2025	**Coverage Rationale**
		• Revised coverage criteria; replaced criterion requiring "the patient is not receiving any of [the listed therapies] in combination with Cinqair/Fasenra/Nucala" with "the patient is not receiving any of [the listed therapies] in combination with Cinqair/Fasenra/Nucala *for treatment of the same indication*"
		• Removed language indicating Nucala is unproven and not medically necessary for the treatment of chronic obstructive pulmonary disease (COPD)
		• Changed initial authorization duration from "***6*** months" to "***12*** months" for the treatment of:
		  ○ Chronic rhinosinusitis with nasal polyps (CRSwNP)
		  ○ Hypereosinophilic syndrome (HES)
		  ○ Severe asthma
		• Added language to indicate:
		  ○ Nucala, for provider administration, is proven for patients who meet the following criteria:
		  ▪ Diagnosis of chronic obstructive pulmonary disorder (COPD) defined by both of the following:
		  – Post-bronchodilator forced expiratory volume (FEV1)/forced vital
			This policy refers to the following drug products for administration by a healthcare professional:
			• Cinqair® (reslizumab) for intravenous (IV) route
			• Fasenra® (benralizumab) for subcutaneous (SC) route
			• Nucala® (mepolizumab) for subcutaneous (SC) route
			
			Fasenra® (benralizumab) and Nucala® (mepolizumab) for self-administered subcutaneous injection are obtained under the pharmacy benefit.
			
			Refer to the policy for complete details.

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Respiratory Interleukins (Cinqair®, Fasenra®, & Nucala®) (continued)	Sep. 1, 2025	capacity (FVC) ratio less than 0.7 – Post-bronchodilator FEV1 % predicted greater than or equal to 30% and less than or equal to 70% ▪ Patient has an eosinophilic phenotype defined by a baseline (pre-mepolizumab treatment) peripheral blood eosinophil level ≥ 300 cells/µL ▪ Patient has uncontrolled or inadequately controlled COPD demonstrated by both of the following: – One of the following: • Two or more COPD exacerbations in the previous year requiring treatment with systemic corticosteroids and/or antibiotics • One or more COPD exacerbation(s) that resulted in hospitalization or observation for over 24 hours in an emergency department or	

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Respiratory Interleukins (Cinqair®, Fasenra®, & Nucala®) (continued)	Sep. 1, 2025	urgent care facility in the past year – COPD exacerbation(s) occurred while receiving maintenance therapy with one of the following: • Triple therapy with a long-acting muscarinic antagonist (LAMA), long-acting beta agonist (LABA), and inhaled corticosteroid (ICS) (e.g., Breztri Aerosphere, Trelegy Ellipta) • Dual therapy with a LAMA and LABA (e.g., Anoro Ellipta, Bevespi Aerosphere, Stiolto Respimat) and a failure, contraindication, or intolerance to an ICS ▪ Symptoms of chronic productive cough for at	

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Respiratory Interleukins (Cinqair®, Fasenra®, & Nucala®) (continued)	Sep. 1, 2025	least 3 months in the past year ▪ Nucala will be used as add-on maintenance therapy in combination with one of the following: – Triple therapy with a long-acting muscarinic antagonist (LAMA), long-acting beta agonist (LABA), and inhaled corticosteroid (ICS) (e.g., Breztri Aerosphere, Trelegy Ellipta) – Dual therapy with a LAMA and LABA (e.g., Anoro Ellipta, Bevespi Aerosphere, Stiolto Respimat) and a failure, contraindication, or intolerance to an ICS ▪ One of the following: – Physician attestation that the patient or caregiver is not competent or is physically unable to administer the Nucala product FDA labeled for self-administration – Patient has documented history of severe hypersensitivity	

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Respiratory Interleukins (Cinqair®, Fasenra®, & Nucala®) (continued)	Sep. 1, 2025	reactions (e.g., anaphylaxis, angioedema, bronchospasm, or hypotension) to Nucala within the past 6 months and requires administration and direct monitoring by a healthcare professional – Patient is new to therapy with Nucala and requires initial dose to be directly monitored by a healthcare professional before continued self-administration (note: Authorization will be for 1 dose) ▪ Patient is not receiving Nucala in combination with any of the following for treatment of the same indication: – Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)] – Anti-IgE therapy [e.g., Xolair (omalizumab)] – Anti-interleukin 4 therapy [e.g.,	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Respiratory Interleukins (Cinqair®, Fasenra®, & Nucala®) (continued)	Sep. 1, 2025	Dupixent (dupilumab)] – Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)] ▪ Dosing is in accordance with the U.S. FDA approved labeling ▪ Prescribed by an allergist/immunologist/ pulmonologist ▪ Initial authorization will be for no more than 12 months ○ For patients currently on Nucala for the treatment of (COPD) authorization for continued use will be approved based on all of the following criteria: ▪ Documentation of positive clinical response to Nucala therapy ▪ Nucala is being used in combination with maintenance therapy [e.g., Advair/AirDuo (fluticasone/salmeterol), Bevespi Aerosphere (glycopyrrolate/ formoterol), Breo Ellipta (fluticasone furoate/vilanterol), Symbicort (budesonide/formoterol),	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Respiratory Interleukins (Cinqair®, Fasenra®, & Nucala®) (continued)	Sep. 1, 2025	Trelegy Ellipta (fluticasone furoate/umeclidinium/ vilanterol)] ▪ One of the following: – Physician attestation that the patient or caregiver is not competent or is physically unable to administer the Fasenra or Nucala product FDA labeled for self-administration – Patient has documented history of severe hypersensitivity reactions (e.g., anaphylaxis, angioedema, bronchospasm, or hypotension) to Fasenra or Nucala within the past 6 months and requires administration and direct monitoring by a healthcare professional ▪ Patient is not receiving Nucala in combination with any of the following for treatment of the same indication: – Anti-interleukin 5 therapy [e.g., Cinqair	

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Respiratory Interleukins (Cinqair®, Fasenra®, & Nucala®) (continued)	Sep. 1, 2025	(resilizumab), Fasenra (benralizumab)] – Anti-IgE therapy [e.g., Xolair (omalizumab)] – Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)] – Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)] ▪ Dosing is in accordance with the U.S. FDA approved labeling ▪ Reauthorization will be for no more than 12 months **Applicable Codes** • Added ICD-10 diagnosis codes J44.0, J44.1, and J44.9 **Supporting Information** • Updated *Background*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	
Rituximab (Riabni®, Rituxan®, Ruxience®, & Truxima®)	Sep. 1, 2025	**Coverage Rationale** ***Rheumatoid Arthritis*** • Updated list of examples of tumor necrosis factor (TNF) inhibitors with which the patient must have a history of failure, contraindication, or intolerance; added: ○ Cimzia (certolizumab)	This policy refers only to the following drug products, rituximab injections for intravenous infusion for non-oncology conditions: • Riabni® (rituximab-arrx) • Rituxan® (rituximab) • Rituxan Hycela® (rituximab and hyaluronidase human) • Ruxience® (rituximab-pvvr) • Truxima® (rituximab-abbs) • Any FDA-approved rituximab biosimilar product not listed here

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Rituximab (Riabni®, Rituxan®, Ruxience®, & Truxima®) (continued)	Sep. 1, 2025	○ Simponi (golimumab) • Updated list of examples of targeted immunomodulators the patient must not be receiving in combination with rituximab; added: ○ Olumiant (baricitinib) ○ Orencia (abatacept) ○ Rinvoq (upadacitinib) ***Neuromyelitis Optica*** • Updated list of examples of drug products the patient must not be receiving in combination with rituximab; added: ○ Kevzara (sarilumab) ○ Ultomiris (ravulizumab) ***Immunoglobulin G4-Related Disease (IgG4-RD)*** • Added language to indicate rituximab is proven for the treatment of IgG4-RD; rituximab is medically necessary for the treatment of IgG4-RD when all of the following criteria are met: ***Initial Therapy*** ○ Diagnosis of IgG4-RD ○ Confirmation of IgG4-RD by a positive assessment using the ACR/EULAR classification criteria, demonstrated by all of the following: ▪ Involvement of at least 1 or more organ(s) in a manner consistent with IgG4-RD	Refer to the policy for complete details.

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Rituximab (Riabni®, Rituxan®, Ruxience®, & Truxima®) (continued)	Sep. 1, 2025	▪ Exclusion criteria is negative and consistent with an IgG4-RD diagnosis (e.g., clinical findings, serologic results, radiology assessments, pathology interpretations) ▪ Inclusion criteria is positive and signifies a diagnosis of IgG4-RD (e.g., clinical findings, serologic results, radiology assessments, pathology interpretations) ○ Prescribed by, or in consultation with, a specialist with expertise in the treatment of IgG4-RD ○ Patient is not receiving rituximab in combination with a disease modifying therapy for the treatment of IgG4-related disease [e.g., Uplizna (inebilizumab-cdon)] ○ Initial authorization will be for no more than 12 months ***Continuation of Therapy*** ○ Documentation of positive clinical response ○ Prescribed by, or in consultation with, a specialist with expertise in the treatment of IgG4-RD ○ Patient is not receiving rituximab in combination with a disease modifying therapy	

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Rituximab (Riabni®, Rituxan®, Ruxience®, & Truxima®) (continued)	Sep. 1, 2025	for the treatment of IgG4-related disease [e.g., Uplizna (inebilizumab-cdon)] ○ Reauthorization will be for no more than 12 months **Applicable Codes** • Added ICD-10 diagnosis code D89.84 **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	
Uplizna® (Inebilizumab-Cdon)	Sep. 1, 2025	**Coverage Rationale** ***Neuromyelitis Optica Spectrum Disorder (NMOSD)*** • Revised coverage criteria; replaced criterion requiring "the patient is not receiving any of [the listed therapies] in combination with Uplizna" with "the patient is not receiving any of [the listed therapies] in combination with Uplizna *for treatment of the same indication*" ***Immunoglobulin G4-Related Disease (IgG4-RD)*** • Added language to indicate Uplizna (inebilizumab-cdon) is proven and medically necessary for the treatment of IgG4-RD when all the following criteria are met: Initial Therapy ○ Diagnosis of IgG4-RD ○ Confirmation of IgG4-RD by a positive assessment using	**Uplizna (inebilizumab-cdon) is proven and medically necessary for the treatment of neuromyelitis optica spectrum disorder (NMOSD) when all of the following criteria are met:** • For **initial therapy**, **all** of the following: ○ Diagnosis of neuromyelitis optica spectrum disorder (NMOSD) by a neurologist, confirming **all** of the following: ▪ Past medical history of **one** of the following: – Optic neuritis – Acute myelitis – Area postrema syndrome: episode of otherwise unexplained hiccups or nausea and vomiting – Acute brainstem syndrome – Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions – Symptomatic cerebral syndrome with NMOSD-typical brain lesions **and** ▪ Positive serologic test for anti-aquaporin-4 immunoglobulin G (AQP4-IgG)/NMO-IgG antibodies; **and** ▪ Diagnosis of multiple sclerosis or other diagnoses have been ruled out **and** ○ **One** of the following: ▪ History of failure of rituximab therapy; **or** ▪ **Both** of the following:

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Uplizna® (Inebilizumab-Cdon) (continued)	Sep. 1, 2025	the ACR/EULAR classification criteria, demonstrated by all of the following: ▪ Involvement of at least 1 or more organ(s) in a manner consistent with IgG4-RD ▪ Exclusion criteria is negative and consistent with an IgG4-RD diagnosis (e.g., clinical findings, serologic results, radiology assessments, pathology interpretations) ▪ Inclusion criteria is positive and signifies a diagnosis of IgG4-RD (e.g., clinical findings, serologic results, radiology assessments, pathology interpretations) ○ Both of the following: ▪ History of failure, contraindication, or intolerance to glucocorticoids ▪ One of the following: – History of failure of rituximab therapy – Both of the following: • History of intolerance or contraindication to rituximab • Physician attests	– History of intolerance or contraindication to rituximab; **and** – Physician attests that, in their clinical opinion, the same intolerance or severe adverse event would not be expected to occur with Uplizna **and** ○ **One** of the following: ▪ History of one or more relapses that required rescue therapy during the previous 12 months prior to initiating Uplizna ▪ History of two or more relapses that required rescue therapy during the previous 24 months, prior to initiating Uplizna **and** ○ Uplizna is initiated according to the U.S. Food and Drug Administration (FDA) labeled dosing for NMOSD; **and** ○ Prescribed by, or in consultation with, a neurologist; **and** ○ Patient is **not** receiving Uplizna in combination with **any** of the following for treatment of the same indication: ▪ Multiple sclerosis disease modifying therapies [e.g., dimethyl fumarate, fingolimod, Ocrevus (ocrelizumab), etc.] ▪ Complement inhibitors [e.g., eculizumab, PiaSky (crovalimab), Ultomiris (ravulizumab)] ▪ Anti-IL6 therapy (e.g., tocilizumab) ▪ Anti-CD20 therapy (e.g., rituximab) **and** ○ Initial authorization will be for no more than 12 months • For **continuation of therapy**, **all** of the following: ○ Documentation of positive clinical response; **and** ○ Uplizna is dosed according to the U.S. Food and Drug Administration (FDA) labeled dosing for NMOSD; **and** ○ Patient is **not** receiving Uplizna in combination with **any** of the following for treatment of the same indication: ▪ Multiple sclerosis disease modifying therapies [e.g., dimethyl fumarate, fingolimod, Ocrevus (ocrelizumab), etc.] ▪ Anti-IL6 therapy (e.g., tocilizumab) ▪ Complement inhibitors [e.g., eculizumab, PiaSky (crovalimab), Ultomiris (ravulizumab)] ▪ Anti-CD20 therapy (e.g., rituximab) **and**

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Uplizna® (Inebilizumab-Cdon) (continued)	Sep. 1, 2025	that, in their clinical opinion, the same intolerance or severe adverse event would not be expected to occur with Uplizna ○ Uplizna is initiated according to the U.S. FDA labeled dosing for IgG4-RD ○ Prescribed by, or in consultation with, a specialist with expertise in the treatment of IgG4-RD ○ Patient is not receiving Uplizna in combination with a disease modifying therapy for the treatment of IgG4-related disease (e.g., rituximab) ○ Initial authorization will be for no more than 12 months Continuation of Therapy ○ Documentation of positive clinical response ○ Uplizna is dosed according to the U.S. FDA labeled dosing for IgG4-RD ○ Prescribed by, or in consultation with, a specialist with expertise in the treatment of IgG4-RD ○ Patient is not receiving Uplizna in combination with a disease modifying therapy for the treatment of IgG4-related	○ Reauthorization will be for no more than 12 months **Uplizna (inebilizumab-cdon) is proven and medically necessary for the treatment of Immunoglobulin G4-related disease (IgG4-RD) when all the following criteria are met:** • For **initial therapy**, **all** of the following: ○ Diagnosis of Immunoglobulin G4-related disease (IgG4-RD); **and** ○ Confirmation of IgG4-RD by a positive assessment using the ACR/EULAR classification criteria, demonstrated by **all** of the following: ▪ Involvement of at least 1 or more organ(s) in a manner consistent with IgG4-RD; **and** ▪ Exclusion criteria is negative and consistent with an IgG4-RD diagnosis (e.g., clinical findings, serologic results, radiology assessments, pathology interpretations); **and** ▪ Inclusion criteria is positive and signifies a diagnosis of IgG4-RD (e.g., clinical findings, serologic results, radiology assessments, pathology interpretations) **and** ○ **Both** of the following: ▪ History of failure, contraindication, or intolerance to glucocorticoids; **and** ▪ **One** of the following: – History of failure of rituximab therapy; **or** – **Both** of the following: • History of intolerance or contraindication to rituximab; **and** • Physician attests that, in their clinical opinion, the same intolerance or severe adverse event would not be expected to occur with Uplizna **and** ○ Uplizna is initiated according to the U.S. FDA labeled dosing for IgG4-RD; **and** ○ Prescribed by, or in consultation with, a specialist with expertise in the treatment of IgG4-RD; **and** ○ Patient is **not** receiving Uplizna in combination with a disease modifying therapy for the treatment of IgG4-related disease (e.g.,

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Uplizna® (Inebilizumab-Cdon) (continued)	Sep. 1, 2025	disease (e.g., rituximab) ○ Reauthorization will be for no more than 12 months **Applicable Codes** • Added ICD-10 diagnosis code D89.84 **Supporting Information** • Updated *Background*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	rituximab); **and** ○ Initial authorization will be for no more than 12 months • For **continuation of therapy**, **all** of the following: ○ Documentation of positive clinical response; **and** ○ Uplizna is dosed according to the U.S. FDA labeled dosing for IgG4-RD; **and** ○ Prescribed by, or in consultation with, a specialist with expertise in the treatment of IgG4-RD; **and** ○ Patient is **not** receiving Uplizna in combination with a disease modifying therapy for the treatment of IgG4-related disease (e.g., rituximab); **and** ○ Reauthorization will be for no more than 12 months

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 Community Plan 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 Community Plan Medical Policies and Medical Benefit Drug Policies is available at **UHCprovider.com** > Policies and Protocols > Community Plan Policies > Medical & Drug Policies.