United Healthcare Community Plan

UnitedHealthcare Community Plan of Tennessee
Medical Policy Update Bulletin: October 2021

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Annual ICD-10 Diagnosis Code and Quarterly CPT® and HCPCS Code Updates

Effective Oct. 1, 2021, the following Medical Policies, Medical Benefit Drug Policies, and Coverage Determination Guidelines have been updated to reflect the annual ICD-10 diagnosis code and quarterly CPT/HCPCS code additions, revisions, and deletions. Refer to the following sources for information on the code updates:

- American Medical Association. Current Procedural Terminology: CPT®
- Centers for Medicare & Medicaid Services (CMS) International Classification of Diseases, Tenth Revision (ICD-10) Clinical Modification (CM) (Diagnosis) Codes
- Centers for Medicare & Medicaid Services (CMS) International Classification of Diseases, Tenth Revision (ICD-10) Procedure Coding System (PCS) Codes
- Centers for Medicare & Medicaid Services. Healthcare Common Procedure Coding System: HCPCS Level II

Policy Title	Policy Type	Summary of Changes
Actemra® (Tocilizumab) Injection for Intravenous Infusion	Medical Benefit Drug Policy	• Added ICD-10 diagnosis codes T80.82XA, T80.82XD, T80.82XS, and Z92.850
Airway Clearance Devices (for Tennessee Only)	Medical Policy	• Revised description for ICD-10 diagnosis code G71.20
Amondys 45™ (Casimersen)	Medical Benefit Drug Policy	• Removed HCPCS code C9075 • Replaced HCPCS codes J3490 and J3590 with J1426
Breast Reconstruction Post Mastectomy and Poland Syndrome (for Tennessee Only)	Coverage Determination Guideline	• Added ICD-10 diagnosis code C84.7A
Cell-Free Fetal DNA Testing (for Tennessee Only)	Medical Policy	• Removed CPT code 0168U
Chromosome Microarray Testing (Non-Oncology Conditions) (for Tennessee Only)	Medical Policy	• Added ICD-10 diagnosis codes F78.A1 and F78.A9 • Removed ICD-10 diagnosis code F78
Cimzia® (Certolizumab Pegol)	Medical Benefit Drug Policy	• Added ICD-10 diagnosis codes M45.A0, M45.A1, M45.A2, M45.A3, M45.A4, M45.A5, M45.A6, M45.A7, M45.A8, and M45.AB
Denosumab (Prolia® & Xgeva®)	Medical Benefit Drug Policy	• Added ICD-10 diagnosis code C79.63
Evkeeza™ (Evinacumab-Dgnb)	Medical Benefit Drug Policy	• Removed HCPCS code C9079 • Replaced HCPCS codes J3490 and J3590 with J1305
Long-Acting Injectable Antiretroviral Agents for HIV	Medical Benefit Drug Policy	• Removed HCPCS code C9077 • Replaced HCPCS code J3490 with J0741
Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions (for Tennessee Only)	Medical Policy	• Added CPT code 0262U
Obstructive Sleep Apnea Treatment (for Tennessee Only)	Medical Policy	• Added HCPCS code K1027

Take Note

Policy Title	Policy Type	Summary of Changes
Occipital Neuralgia and Headache Treatment (for Tennessee Only)	Medical Policy	• Added HCPCS code K1023
Omnibus Codes (for Tennessee Only)	Medical Policy	Instrument-Based Ocular Photo Screening • Added ICD-10 diagnosis codes F78.A1 and F78.A9 • Removed ICD-10 diagnosis code F78
Oral and Enteral Nutrition (for Tennessee Only)	Coverage Determination Guideline	Metabolic and Specialized Foods • Added HCPCS code S9432
Prosthetic Devices, Specialized, Microprocessor or Myoelectric Limbs (for Tennessee Only)	Coverage Determination Guideline	• Added HCPCS code K1022
Rituximab (Riabni™, Rituxan®, Ruxience®, & Truxima®)	Medical Benefit Drug Policy	• Added ICD-10 diagnosis codes M31.10, M31.11, and M31.19 • Removed ICD-10 diagnosis code M31.1
Skin and Soft Tissue Substitutes (for Tennessee Only)	Medical Policy	• Added HCPCS codes Q4251, Q4252, and Q4253 • Removed HCPCS codes Q4228 and Q4236
Transcutaneous Electrical Nerve/Joint Stimulators (for Tennessee Only)	Coverage Determination Guideline	• Added HCPCS code K1023 • Added ICD-10 diagnosis codes M54.50, M54.51, and M54.59 • Removed ICD-10 diagnosis code M54.5
Whole Exome and Whole Genome Sequencing (for Tennessee Only)	Medical Policy	• Added CPT code 0265U

Medical Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale

Articular Cartilage Defect Repairs (for Tennessee Only)	Nov. 1, 2021	**Template Update**
		• Replaced content sub-heading titled "Professional Societies" with "Clinical Practice Guidelines" in *Clinical Evidence* section
		• Removed *CMS* section
		Related Policies
		• Added reference link to the Medical Policy titled *Surgery of the Knee (for Tennessee Only)*
		Coverage Rationale
		• Revised language to indicate:
		  ○ Autologous chondrocyte transplantation (ACT) is proven and medically necessary for treating individuals with a symptomatic full-thickness articular cartilage defect
		  ○ ACT is unproven and not medically necessary for treating individuals with the following indications due to insufficient evidence of efficacy:
		  ▪ Treatment of joints other than the knee
		  ▪ Growth plates have not closed
		  ▪ History of partial-thickness defects
		  ▪ Osteochondritis dissecans (OCD)
			Autologous chondrocyte transplantation (ACT) is proven and medically necessary for treating individuals with a symptomatic full-thickness articular cartilage defect.
			
			ACT is unproven and not medically necessary for treating individuals with the following indications due to insufficient evidence of efficacy:
			• Treatment of joints other than the knee
			• Growth plates have not closed
			• History of partial-thickness defects
			• Osteochondritis dissecans (OCD)
			• Malignancy in the bone, cartilage, fat or muscle of the treated limb
			• Active infection in the affected knee
			• Instability of the knee
			• History of total meniscectomy
			• Repeat ACT
			• Active inflammatory degenerative, rheumatoid or osteoarthritis
			• As initial or first line of surgical therapy
			
			Osteochondral Autograft and Allograft transplantation is proven and medically necessary for treating individuals with cartilage defects of the knee.
			
			Microfracture repair to treat full and partial thickness chondral defects of the knee is proven and medically necessary.
			
			Focal articular cartilage repair is unproven and not medically necessary for treating individuals with any of the following due to insufficient evidence of efficacy:
			• Osteochondral Autograft and Allograft transplantation for all other indications than those listed above
			• Use of minced articular cartilage repair (whether synthetic, allograft or autograft) for treating osteochondral defects of the knee

Medical Policy Updates

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Articular Cartilage Defect Repairs (for Tennessee Only) (continued)	Nov. 1, 2021	▪ Malignancy in the bone, cartilage, fat or muscle of the treated limb ▪ Active infection in the affected knee ▪ Instability of the knee ▪ History of total meniscectomy ▪ Repeat ACT ▪ Active inflammatory degenerative, rheumatoid or osteoarthritis ▪ As initial or first line of surgical therapy ○ Osteochondral Autograft and Allograft transplantation is proven and medically necessary for treating individuals with cartilage defects of the knee ○ Microfracture repair to treat full and partial thickness chondral defects of the knee is proven and medically necessary ○ Focal articular cartilage repair is unproven and not medically necessary for treating individuals with any of the following due to insufficient evidence of efficacy: ▪ Osteochondral Autograft and Allograft transplantation for all other	● Use of cryopreserved viable Osteochondral Allograft products (e.g., Cartiform) ● Microfracture repair of the knee with any of the following indications: ○ Misalignment of the knee ○ Osteoarthritis ○ Systemic immune-mediated disease, disease-induced arthritis, or cartilage disease ○ Unwilling or unable to participate in post-operative physical rehabilitation program For medical necessity clinical coverage criteria for ACT and microfracture repair, refer to the InterQual® Client Defined 2021, CP: Procedures, Articular Cartilage Defect Repairs (Custom) - UHG. For medical necessity clinical coverage criteria for Osteochondral Autograft and Allograft transplantation, refer to the InterQual® 2021, CP: Procedures: ● Arthroscopy or Arthroscopically Assisted Surgery, Knee ● Arthroscopy or Arthroscopically Assisted Surgery, Knee (Pediatric) ● Arthrotomy, Knee

Medical Policy Updates

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Articular Cartilage Defect Repairs (for Tennessee Only) (continued)	Nov. 1, 2021	indications than those listed above ▪ Use of minced articular cartilage repair (whether synthetic, allograft or autograft) for treating osteochondral defects of the knee ▪ Use of cryopreserved viable Osteochondral Allograft products (e.g., Cartiform) ▪ Microfracture repair of the knee with any of the following indications: – Misalignment of the knee – Osteoarthritis – Systemic immune-mediated disease, disease-induced arthritis, or cartilage disease – Unwilling or unable to participate in post-operative physical rehabilitation program ○ For medical necessity clinical coverage criteria for ACT and microfracture repair, refer to the InterQual® Client Defined 2021, CP: Procedures, Articular Cartilage Defect	

Medical Policy Updates

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Articular Cartilage Defect Repairs (for Tennessee Only) (continued)	Nov. 1, 2021	Repairs (Custom) - UHG ○ For medical necessity clinical coverage criteria for Osteochondral Autograft and Allograft transplantation, refer to the InterQual® 2021, CP: Procedures: ▪ Arthroscopy or Arthroscopically Assisted Surgery, Knee ▪ Arthroscopy or Arthroscopically Assisted Surgery, Knee (Pediatric) ▪ Arthrotomy, Knee	
Deep Brain and Cortical Stimulation (for Tennessee Only)	Nov. 1, 2021	Application ● Added language to indicate this Medical Policy applies to CoverKids Coverage Rationale ● Removed language indicating: ○ Responsive cortical stimulation (e.g., NeuroPace® RNS® System) is proven and medically necessary for treating Partial Onset Seizures when used according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings and precautions ○ Responsive cortical stimulation is unproven and not medically necessary for treating conditions	Deep brain stimulation and cortical stimulation is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® 2021, Apr. 2021 Release, CP: Procedures, Stereotactic Introduction, Subcortical or Cortical Electrodes. The following are unproven and not medically necessary due to insufficient evidence of efficacy: ● Deep brain stimulation for treating obsessive-compulsive disorder (OCD) ● Directional deep brain stimulation that enables specific steering of current towards targeted lesions for treating any condition including but not limited to: ○ Dystonia ○ Parkinson's disease ○ Tremor

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Deep Brain and Cortical Stimulation (for Tennessee Only) (continued)	Nov. 1, 2021	in individuals who do not meet the [listed] criteria due to insufficient evidence of efficacy *Proven and Medically Necessary* ● Revised language to indicate deep brain stimulation is proven and medically necessary in certain circumstances; for medical necessity clinical coverage criteria, refer to the InterQual® 2021, Apr. 2021 Release, CP: Procedures, Stereotactic Introduction, Subcortical or Cortical Electrodes *Unproven and Not Medically Necessary* ● Revised list of unproven and not medically necessary indications to include: ○ Deep brain stimulation for treating obsessive-compulsive disorder (OCD) ○ Directional deep brain stimulation that enables specific steering of current towards targeted lesions for treating any condition including but not limited to: ▪ Dystonia ▪ Parkinson's disease ▪ Tremor Supporting Information ● Removed *Definitions* and *CMS* sections	

Medical Policy Updates

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Deep Brain and Cortical Stimulation (for Tennessee Only) (continued)	Nov. 1, 2021	• Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	
Implanted Electrical Stimulator for Spinal Cord (for Tennessee Only)	Nov. 1, 2021	Coverage Rationale • Added list of proven and medically necessary indications: ○ Complex regional pain syndrome (CRPS) ○ Failed back surgery syndrome • Added language to indicate implanted electrical stimulators for spinal cord are unproven and not medically necessary for treating the following indications: ○ Diabetic neuropathy ○ Refractory angina pectoris	Implanted electrical stimulators for spinal cord, including high-frequency dorsal column stimulators (also known as BurstDR spinal cord stimulators), are proven and medically necessary for treating the following indications: • Complex regional pain syndrome (CRPS) • Failed back surgery syndrome For medical necessity clinical coverage criteria, refer to the InterQual® 2021, Apr. 2021 Release, CP: Procedures, Spinal Cord Stimulator (SCS) Insertion. Implanted electrical stimulators for spinal cord are unproven and not medically necessary for treating the following indications: • Diabetic Neuropathy • Refractory angina pectoris Note: • Coverage of a replacement battery/generator for a previously implanted electrical stimulator is appropriate when the individual's existing battery/generator is malfunctioning, cannot be repaired, and is no longer under warranty. • For dorsal root ganglion (DRG) stimulation, refer to the Medical Policy titled *Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation (for Tennessee Only).*

Medical Benefit Drug Policy Updates

New		
Policy Title	**Effective Date**	**Coverage Rationale**
Ryplazim® (Plasminogen, Human-Tvmh)	Nov. 1, 2021	Ryplazim® (plasminogen, human-tvmh) is proven and medically necessary for the treatment of plasminogen deficiency type 1 (hypoplasminogenemia) when the following criteria are met: ● For initial therapy, all of the following: ○ Diagnosis of hypoplasminogenemia as measured by plasminogen activity level ≤ 45% of laboratory standard; and ○ Presence of clinical signs and symptoms of the disease (e.g., ligneous conjunctivitis, gingivitis, tonsillitis, abnormal wound healing, etc.); 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. ● For continuation therapy, all of the following: ○ Patient has previously received treatment with Ryplazim® therapy; and ○ Patient has experienced a positive clinical response to Ryplazim® therapy (e.g., improved (reduction) in lesion number/size, improvement in wound-healing, etc.); 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. Ryplazim® is unproven and not medically necessary for the treatment of idiopathic pulmonary fibrosis.
Saphnelo™ (Anifrolumab-Fnia)	Nov. 1, 2021	Saphnelo™ (anifrolumab-fnia) is proven and medically necessary for the treatment of moderate to severe systemic lupus erythematosus (SLE) when all of the following criteria are met: ● For initial therapy, all of the following: ○ Diagnosis of moderate to severe systemic lupus erythematosus, without severe active central nervous system lupus or severe active lupus nephritis; and ○ Laboratory testing has documented the presence of autoantibodies [e.g., ANA, Anti-dsDNA, Anti-Sm, Anti-Ro/SSA, Anti-La/SSB]; and ○ Currently receiving at least one standard of care treatment for active systemic lupus erythematosus (e.g., antimalarials, corticosteroids, or immunosuppressants) that is not a biologic; and ○ Patient is not receiving Saphnelo™ in combination with a biologic agent or Benlysta; and ○ Saphnelo™ is dosed according to US Food and Drug Administration labeled dosing for SLE; and ○ Initial authorization is for no more than 6 months. ● For continuation of therapy, all of the following: ○ Patient has previously received Saphnelo™ injection for intravenous infusion; and ○ Documentation of positive clinical response; and ○ Patient is without severe active central nervous system lupus or severe active lupus nephritis; and

Medical Benefit Drug Policy Updates

New

Policy Title	Effective Date	Coverage Rationale
Saphnelo™ (Anifrolumab-Fnia) (continued)	Nov. 1, 2021	○ Currently receiving at least one standard of care treatment for active systemic lupus erythematosus (e.g., antimalarials, corticosteroids, or immunosuppressants) that is not a biologic; and ○ Patient is not receiving Saphnelo™ in combination with a biologic agent or Benlysta; and ○ Saphnelo™ is dosed according to US Food and Drug Administration labeled dosing for SLE; and ○ Authorization is for no more than 12 months. Saphnelo™ is unproven and not medically necessary for: • Severe active lupus nephritis • Severe active central nervous system (CNS) lupus • Use in combination with other biologics

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Antiemetics for Oncology	Nov. 1, 2021	**Coverage Rationale** *Medical Necessity Plans* • Changed product status for Aloxi injection from "non-preferred" to "preferred" *Preferred Product Criteria* • Added language to clarify the criterion requiring: ○ History of a trial of adequate dose and duration *to one of the* preferred NK1 RA or 5HT3 RA products, resulting in minimal clinical response ○ History of intolerance, contraindication, or adverse event to *one of the* preferred NK1 RA or 5HT3 RA products **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the	This policy refers to the following products used as antiemetics for oncology use: • Akynzeo® (palonosetron/fosnetupitant) injection • Akynzeo® (palonosetron/netupitant) capsule • Aloxi® (palonosetron) injection • Cinvanti™ (aprepitant) injectable emulsion • Emend® (fosaprepitant) injection, capsule • Sustol® (granisetron extended release) injection • Kytril® (granisetron) injection, tablets • Varubi® (rolapitant) tablet • Zofran® (ondansetron) injection, tablets **Neurokinin 1 Receptor Antagonist (NK1 RA)** Preferred Product (s): Emend injection; Emend capsule Non-Preferred Product (s): Cinvanti injectable emulsion; Varubi tablet

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Antiemetics for Oncology (continued)	Nov. 1, 2021	most current information	

5-Hydroxytryptamine Receptor Antagonist (5HT3 RA)

Preferred Product (s)	Non-Preferred Product (s)
Kytril injection	Aloxi injection
Kytril tablet	Sustol injection
Zofran injection	
Zofran tablet	

NK1 RA/5HT3 RA Combination

Preferred Product (s)	Non-Preferred Product (s)
	Akynzeo injection
	Akynzeo capsule

Coverage for antiemetics will be provided contingent on the coverage criteria in the *Diagnosis-Specific Criteria* section.

Preferred Product

Coverage for Cinvanti and Varubi will be provided contingent on the criteria in this section and the coverage criteria in the *Diagnosis-Specific Criteria* section.

Coverage of Aloxi and Sustol will be provided contingent on the criteria in this section and the coverage criteria in the *Diagnosis-Specific Criteria* section.

NK1 RA/5HT3 RA Combination (Akynzeo): Coverage of Akynzeo will be provided contingent on the criteria in this section and the coverage criteria in the *Diagnosis-Specific Criteria* section.

Preferred Product Criteria

Treatment with non-preferred NK1 RA, 5HT3 RA, or NK1 RA/5HT3 RA combination product is medically necessary for the indications specified in the policy when one of the following is met:

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Antiemetics for Oncology (continued)	Nov. 1, 2021		• Both of the following: ○ History of a trial of adequate dose and duration to one of the preferred NK1 RA or 5HT3 RA products, resulting in minimal clinical response; and ○ Physician attests that, in their clinical opinion, the clinical response would be expected to be superior with non-preferred NK1 RA, 5HT3 RA, or NK1 RA/5HT3 RA combination product than experienced with preferred NK1 RA or 5HT3 RA product or • Both of the following: ○ History of intolerance, contraindication, or adverse event to one of the preferred NK1 RA or 5HT3 RA products; and ○ Physician attests that, in their clinical opinion, the same intolerance, contraindication, or adverse event would not be expected to occur with non-preferred NK1 RA, 5HT3 RA, or NK1 RA/5HT3 RA combination products **Diagnosis-Specific Criteria** For the coverage criteria below, in absence of specified drug products, the term "antiemetics" will be used in this policy where the coverage criteria apply to all products listed above. Antiemetics are proven and medically necessary for the following indications: • NK1 RA (Emend, Cinvanti, Varubi) may be indicated when one of following are present: ○ Both of the following: ▪ Prevention of chemotherapy-induced nausea and vomiting due to High Emetic Risk parenteral anticancer agents; and ▪ In combination with a 5HT3 RA or ○ All of the following: ▪ Prevention of chemotherapy-induced nausea and vomiting due to

Medical Benefit Drug Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Antiemetics for Oncology (continued)	Nov. 1, 2021		Moderate Emetic Risk parenteral anticancer agents; and ▪ In combination with a 5HT3 RA; and ▪ One of the risk factors for anticancer-agent induced nausea/vomiting: – Younger age (< 55 years) – Female sex – Previous history of chemotherapy induced nausea or vomiting – Little or no previous alcohol use – History of motion sickness or morning sickness during pregnancy – High anxiety • 5HT3 RA (Aloxi, Kytril, Sustol, Zofran) may be indicated when one of the following are present: ○ Both of the following: ▪ Prevention of chemotherapy-induced nausea and vomiting due to High Emetic Risk parenteral anticancer agents[12]; and ▪ In combination with a NK1 RA or ○ Prevention of chemotherapy-induced nausea and vomiting due to Moderate Emetic Risk parenteral anticancer agents; or ○ All of the following: ▪ Prevention of chemotherapy-induced nausea and vomiting due to Moderate Emetic Risk parenteral anticancer agents; and ▪ In combination with a NK1 RA; and ▪ One of the risk factors for anticancer-agent induced nausea/vomiting: – Younger age (< 55 years) – Female sex – Previous history of chemotherapy induced nausea or vomiting – Little or no previous alcohol use – History of motion sickness or morning sickness during pregnancy

Medical Benefit Drug Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Antiemetics for Oncology (continued)	Nov. 1, 2021		– High anxiety or ▪ Treatment of breakthrough nausea and/or vomiting due to anticancer agent(s) • NK1 RA/5HT3 RA combination product (Akynzeo) may be indicated when one of the following are present: ○ Prevention of chemotherapy-induced nausea and vomiting due to High Emetic Risk parenteral anticancer agents; or ○ Both of the following: ▪ Prevention of chemotherapy-induced nausea and vomiting due to Moderate Emetic Risk parenteral anticancer agents; and ▪ One of the risk factors for anticancer-agent induced nausea/vomiting: – Younger age (< 55 years) – Female sex – Previous history of chemotherapy induced nausea or vomiting – Little or no previous alcohol use – History of motion sickness or morning sickness during pregnancy – High anxiety
Botulinum Toxins A and B	Nov. 1, 2021	Coverage Rationale • Revised language to indicate: ○ Dysport (abobotulinumtoxinA) is medically necessary for the treatment of certain conditions outlined within the InterQual® criteria; for medical necessity clinical coverage criteria, refer to the current release of the InterQual® guideline, CP: Specialty Rx Non-Oncology, AbobotulinumtoxinA (Dysport)	This policy refers to the following Botulinum toxin type A and B drug products: • Dysport® (abobotulinumtoxinA) • Xeomin® (incobotulinumtoxinA) • Botox® (onabotulinumtoxinA) • Myobloc® (rimabotulinumtoxinB) The following drug products are medically necessary for the treatment of certain conditions outlined within the InterQual® criteria; for medical necessity clinical coverage criteria, refer to the current release of the InterQual® guideline: • Dysport (abobotulinumtoxinA): CP: Specialty Rx Non-Oncology, AbobotulinumtoxinA (Dysport)

Medical Benefit Drug Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Botulinum Toxins A and B (continued)	Nov. 1, 2021	○ Xeomin (incobotulinumtoxinA) is medically necessary for the treatment of certain conditions outlined within the InterQual® criteria; for medical necessity clinical coverage criteria, refer to the current release of the InterQual® guideline, CP: Specialty Rx Non-Oncology, IncobotulinumtoxinA (Xeomin) ○ Botox (onabotulinumtoxinA) is medically necessary for the treatment of certain conditions outlined within the InterQual® criteria; for medical necessity clinical coverage criteria, refer to the current release of the InterQual® guideline, CP: Specialty Rx Non-Oncology, OnabotulinumtoxinA (Botox) ○ Myobloc (rimabotulinumtoxinB) is medically necessary for the treatment of certain conditions outlined within the InterQual® criteria; for medical necessity clinical coverage criteria, refer to the current release of the InterQual® guideline, CP: Specialty Rx Non-Oncology, RimabotulinumtoxinB (Myobloc)	• Xeomin (incobotulinumtoxinA): CP: Specialty Rx Non-Oncology, IncobotulinumtoxinA (Xeomin) • Botox (onabotulinumtoxinA): CP: Specialty Rx Non-Oncology, OnabotulinumtoxinA (Botox) • Myobloc (rimabotulinumtoxinB): CP: Specialty Rx Non-Oncology, RimabotulinumtoxinB (Myobloc) Click here to view the InterQual® criteria.

Medical Benefit Drug Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Botulinum Toxins A and B (continued)	Nov. 1, 2021	Supporting Information • Removed *Background*, *Clinical Evidence*, *FDA*, and *References* sections	
Denosumab (Prolia® & Xgeva®)	Nov. 1, 2021	Coverage Rationale • Revised language pertaining to Prolia to indicate Prolia is proven and medically necessary for the treatment of certain conditions outlined within the InterQual® criteria; for medical necessity clinical coverage criteria, refer to the current release of the InterQual® guideline, CP: Specialty Rx Non-Oncology, Denosumab (Prolia) Applicable Codes • Removed lists of applicable ICD-10 diagnosis codes, maximum allowed quantities by HCPCS units, and maximum allowed quantities by national drug code (NDC) units for Prolia Supporting Information • Updated *Clinical Evidence* and *FDA* sections to reflect the most current information	This policy refers to the following denosumab products: • Prolia • Xgeva Refer to the policy for complete details.
Entyvio® (Vedolizumab)	Nov. 1, 2021	Coverage Rationale • Replaced language indicating "Entyvio (vedolizumab) is proven and medically necessary for the treatment of *[the conditions listed in the policy]*" with "Entyvio	Entyvio (vedolizumab) is proven and medically necessary for the treatment of certain conditions outlined within the InterQual® criteria. For medical necessity clinical coverage criteria, refer to the current release of the InterQual® guideline, CP: Specialty Rx Non-Oncology, Vedolizumab (Entyvio). Click here to view the InterQual® criteria.

Medical Benefit Drug Policy Updates

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Entyvio® (Vedolizumab) (continued)	Nov. 1, 2021	(vedolizumab) is proven and medically necessary for the treatment of *certain conditions outlined within the InterQual® criteria*" • Replaced medical necessity clinical coverage criteria with instruction to refer to the current release of the InterQual® guideline, CP: Specialty Rx Non-Oncology, Vedolizumab (Entyvio) for applicable details **Applicable Codes** • Removed lists of applicable ICD-10 diagnosis codes, maximum allowed quantities by HCPCS units, and maximum allowed quantities by national drug code (NDC) units **Supporting Information** • Removed *Background*, *Clinical Evidence*, *FDA*, and *References* sections	
Intravenous Iron Replacement Therapy (Feraheme®, Injectafer®, & Monoferric®)	Nov. 1, 2021	**Template Update** • Replaced reference to "MCG™ Care Guidelines" with "InterQual® criteria" in *Instructions for Use* **Coverage Rationale** • Replaced language indicating "Feraheme (ferumoxytol), Injectafer (ferric carboxymaltose), and Monoferric (ferric derisomaltose) are proven and medically necessary for the treatment of *[the conditions listed in the policy]*" with	This policy refers to the following intravenous iron replacements: • Feraheme® (ferumoxytol) • Injectafer® (ferric carboxymaltose) • Monoferric® (ferric derisomaltose) The following intravenous iron replacements are not subject to the coverage criteria in this section: • Ferrlecit (sodium ferric gluconate complex) • Infed® (iron dextran) • Venofer® (iron sucrose)

Medical Benefit Drug Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Intravenous Iron Replacement Therapy (Feraheme®, Injectafer®, & Monoferric®) (continued)	Nov. 1, 2021	"Feraheme (ferumoxytol), Injectafer (ferric carboxymaltose), and Monoferric (ferric derisomaltose) are proven and medically necessary for the treatment of *certain conditions outlined within the InterQual® criteria*" • Replaced medical necessity clinical coverage criteria with instruction to refer to the current release of the following InterQual® guidelines for applicable details: ○ CP: Specialty Rx Non-Oncology, Ferumoxytol (Feraheme) ○ CP: Specialty Rx Non-Oncology, Ferric carboxymaltose (Injectafer) ○ CP: Specialty Rx Non-Oncology, Ferric derisomaltose (Monoferric) • Added language to indicate Feraheme, Injectafer and Monoferric will also be subject to the following Step Therapy (both of the following): ○ Submission of laboratory values demonstrating treatment failure after at least 3 weeks of therapy, to at least two of the following intravenous iron therapies each (note: laboratory values	Feraheme (ferumoxytol), Injectafer (ferric carboxymaltose), and Monoferric (ferric derisomaltose) are proven and medically necessary for the treatment of certain conditions outlined within the InterQual® criteria. For medical necessity clinical coverage criteria refer to the current InterQual® guideline: • Feraheme®: CP: Specialty Rx Non-Oncology, Ferumoxytol (Feraheme) • Injectafer®: CP: Specialty Rx Non-Oncology, Ferric carboxymaltose (Injectafer) • Monoferric®: CP: Specialty Rx Non-Oncology, Ferric derisomaltose (Monoferric) Click here to view the InterQual® criteria. **Step Therapy** Feraheme, Injectafer, and Monoferric will also be subject to the following Step Therapy: Both of the following: • Submission of laboratory values demonstrating treatment failure after at least 3 weeks of therapy, to at least two of the following intravenous iron therapies each (Note: Laboratory values should be obtained within 1 to 3 weeks following the last dose of intravenous iron in a treatment course): ○ Infed® (iron dextran) ○ Ferrlecit (sodium ferric gluconate complex) ○ Venofer® (iron sucrose) and • Physician attests that in their clinical opinion, the clinical response would be expected to be superior with Feraheme, Injectafer, or Monoferric than experienced with the other products

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Intravenous Iron Replacement Therapy (Feraheme®, Injectafer®, & Monoferric®) (continued)	Nov. 1, 2021	should be obtained within 1 to 3 weeks following the last dose of intravenous iron in a treatment course) ▪ Infed® (iron dextran) ▪ Ferrlecit (sodium ferric gluconate complex) ▪ Venofer® (iron sucrose) ○ Physician attests that in their clinical opinion, the clinical response would be expected to be superior with Feraheme, Injectafer, or Monoferric than experienced with the other products **Applicable Codes** • Removed list of applicable ICD-10 diagnosis codes **Supporting Information** • Removed *Definitions*, *Background*, *Clinical Evidence*, *FDA*, *CMS*, and *References* sections	
Medical Therapies for Enzyme Deficiencies	Nov. 1, 2021	**Coverage Rationale** • Revised list of applicable medical therapies for enzyme deficiency products; added Nexviazyme™ (avalglucosidase alfa-ngpt) • Added language to indicate Nexviazyme (avalglucosidase alfa-ngpt) proven for the treatment of late-onset Pompe disease; Nexviazyme is medically necessary	This policy refers to the following medical therapies for enzyme deficiency products: • Aldurazyme® (laronidase) • Elaprase® (idursulfase) • Fabrazyme® (agalsidase beta) • Kanuma® (sebelipase alfa) • Lumizyme® (alglucosidase alfa) • Mepsevii™ (vestronidase alfa-vjbk) • Naglazyme® (galsulfase) • Nexviazyme™ (avalglucosidase alfa-ngpt) • Nulibry™ (fosdenopterin)

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Medical Therapies for Enzyme Deficiencies (continued)	Nov. 1, 2021	when the following additional criteria are met: ○ For initial therapy, all of the following: ▪ Diagnosis of late-onset Pompe disease as confirmed by one the following: – Absence or deficiency (< 40% of the lab specific normal mean) acid alpha-glucosidase deficiency (GAA) activity in lymphocytes, fibroblasts or muscle – Molecular genetic testing for deletion or mutations in the GAA gene ▪ Presence of clinical signs and symptoms of the disease (e.g., cardiac hypertrophy, respiratory distress, skeletal muscle weakness, etc.) ▪ Dosing is in accordance with the US FDA approved labeling ▪ Initial authorization will be for no more than 12 months ○ For continuation of therapy, all	● Revcovi™ (elapegademase-lvlr) ● Vimizim® (elosulfase alfa) Refer to the policy for complete details.

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Medical Therapies for Enzyme Deficiencies (continued)	Nov. 1, 2021	of the following: ▪ Patient has previously received treatment with avalglucosidase alfa-ngpt therapy ▪ Patient has experienced a positive clinical response to avalglucosidase alfa-ngpt therapy (e.g., improved respiratory/cardiac function, improved endurance, etc.) ▪ Dosing is in accordance with the United States Food and Drug Administration approved labeling ▪ Reauthorization will be for no more than 12 months **Applicable Codes** *Nexviazyme* • Added HCPCS codes C9399, J3490, and J3590 • Added ICD-10 diagnosis code E74.02 **Supporting Information** • Updated *Background*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	

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Ocrevus® (Ocrelizumab)	Nov. 1, 2021	**Template Update** • Replaced reference to "MCG™ Care Guidelines" with "InterQual® criteria" in *Instructions for Use* **Application** • Removed language indicating this Medical Benefit Drug Policy does not apply to the state of Kentucky **Coverage Rationale** • Revised language to indicate Ocrevus (ocrelizumab) is proven and medically necessary for the treatment of certain conditions outlined within the InterQual® criteria; for medical necessity clinical coverage criteria, refer to the current release of the InterQual® guideline, CP: Specialty Rx Non-Oncology, Ocrelizumab (Ocrevus) **Applicable Codes** • Removed ICD-10 diagnosis code G35 **Supporting Information** • Removed *Background*, *Clinical Evidence*, *FDA*, *CMS*, and *References* sections	Ocrevus (ocrelizumab) is proven and medically necessary for the treatment of certain conditions outlined within the InterQual® criteria. For medical necessity clinical coverage criteria, refer to the current release of the InterQual® guideline, CP: Specialty Rx Non-Oncology, Ocrelizumab (Ocrevus). Click here to view the InterQual® criteria.
Oncology Medication Clinical Coverage	Nov. 1, 2021	**Coverage Rationale** • Revised preferred product criteria; replaced criterion requiring "history of intolerance or contraindication to the UnitedHealthcare's preferred oncology *product*" with "history of	**Description** This policy provides parameters for coverage of injectable oncology medications (including, but not limited to, octreotide acetate, leuprolide acetate, leucovorin, and levoleucovorin), including therapeutic radiopharmaceuticals, covered under the medical benefit based upon the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium® (NCCN Compendium®). The

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Oncology Medication Clinical Coverage (continued)	Nov. 1, 2021	intolerance or contraindication to *one of* the UnitedHealthcare's preferred oncology *products*" • Revised list of UnitedHealthcare Preferred Oncology Products: ○ Removed Firmagon, Trelstar, Vantas, and Zoladex ○ Replaced "Lupron Depot (J9217)" with "Lupron *Depot 7.5 mg* (J9217)" • Revised list of UnitedHealthcare Non-Preferred Oncology Products; replaced "Lupron Depot (J1950)" with "Lupron Depot *3.75 mg* (J1950)"	Compendium lists the appropriate drugs and biologics for specific cancers using US Food and Drug Administration (FDA)-approved disease indications and specific NCCN panel recommendations. Each recommendation is supported by a level of evidence category. Coverage of White Blood Cell Colony Stimulating Factors and Erythropoiesis-Stimulating Agents are addressed in separate policies. This policy does not provide coverage criteria for Chimeric Antigen Receptor (CAR)-T Cell products. Coverage determinations are based on the member's benefits and the OptumHealth Transplant Solutions criteria for covered transplants in the Clinical Guideline titled Chimeric Antigen Receptor T-cell Therapy. **Coverage Rationale** The Oncology Products table below lists the UnitedHealthcare preferred oncology products and respective non-preferred products. Coverage will be provided for the UnitedHealthcare preferred oncology product contingent on the coverage criteria in the Diagnosis-Specific Criteria section. Coverage for any respective non-preferred oncology product will be provided contingent on the criteria in the Preferred Product Criteria and the Diagnosis-Specific Criteria sections. ***Preferred Product Criteria*** Treatment with the respective non-preferred product specified in the Oncology Products table below is medically necessary for oncology indications when both of the following are met: • History of intolerance or contraindication to one of UnitedHealthcare's preferred oncology products; and • Physician attests that, in their clinical opinion, the same intolerance, contraindication, or adverse event would not be expected to occur with the respective non-preferred product Oncology Products Below are UnitedHealthcare preferred oncology products with therapeutically

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Oncology Medication Clinical Coverage (continued)	Nov. 1, 2021		equivalent and/or biosimilar* non-preferred products as determined by the UnitedHealthcare P&T Committee:

Preferred Oncology Product	Non-Preferred Oncology Product
Mvasi (bevacizumab-awwb)	Avastin (bevacizumab) Zirabev (bevacizumab-bvzr)
Kanjinti (trastuzumab-anns)	Herceptin (trastuzumab) Herceptin Hylecta (trastuzumab and hyaluronidase-oysk) Herzuma (trastuzumab-pkrb) Ogivri (trastuzumab-dkst) Ontruzant (trastuzumab-dttb) Trazimera (trastuzumab-qyyp)
Gemcitabine	Infugem (gemcitabine in sodium chloride injection)
Leucovorin	Levoleucovorin
Ruxience (rituximab-pvvr) Truxima (rituximab-abbs)	Riabni (rituximab-arrx) Rituxan (rituximab) Rituxan Hycela (rituximab/hyaluronidase human, recombinant)
Eligard, Lupron Depot 7.5mg (J9217)	Lupron Depot 3.75mg (J1950)

*Biosimilar means that the biological product is FDA-approved based on data demonstrating that it is highly similar to an already FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product.

Diagnosis-Specific Criteria

Injectable Oncology Medications

UnitedHealthcare recognizes indications and uses of injectable oncology

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Oncology Medication Clinical Coverage (continued)	Nov. 1, 2021		medications, including therapeutic radiopharmaceuticals, in the NCCN Drugs and Biologics Compendium with Categories of Evidence and Consensus of 1, 2A, and 2B as proven and Categories of Evidence and Consensus of 3 as unproven and not medically necessary. (However, see Benefit Considerations.) UnitedHealthcare will cover all chemotherapy agents for individuals under the age of 19 years for oncology indications. The majority of pediatric patients receive treatments on national pediatric protocols that are quite similar in concept to the NCCN patient care guidelines. Refer to *Preferred Product Criteria* for the UnitedHealthcare preferred oncology products that have therapeutically equivalent and/or biosimilar products available.
Orencia® (Abatacept) Injection for Intravenous Infusion	Nov. 1, 202	Coverage Rationale • Replaced language indicating "Orencia is proven and medically necessary for the treatment of *[the conditions listed in the policy]*" with "Orencia is proven and medically necessary for the treatment of *certain conditions outlined within the InterQual® criteria*" • Replaced medical necessity clinical coverage criteria with instruction to refer to the current release of the InterQual® guideline, CP: Specialty Rx Non-Oncology, Abatacept (Orencia) for applicable details • Added language to indicate in addition [to the InterQual® criteria], Orencia for provider administration will require all of the following:	This policy refers to Orencia (abatacept) injection for intravenous infusion. Orencia (abatacept) for self-administered subcutaneous injection is obtained under the pharmacy benefit. Orencia is proven and medically necessary for the treatment of certain conditions outlined within the InterQual® criteria. For medical necessity clinical coverage criteria, refer to the current release of the InterQual® guideline, CP: Specialty Rx Non-Oncology, Abatacept (Orencia). Click here to view the InterQual® criteria.

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Orencia® (Abatacept) Injection for Intravenous Infusion (continued)	Nov. 1, 20211	○ Prescriber attestation that the patient or caregiver is not able to be trained or is physically unable to administer Orencia FDA labeled for self-administration, and ○ Prescriber must submit explanation **Applicable Codes** ● Removed list of applicable ICD-10 diagnosis codes **Supporting Information** ● Removed *Background*, *Clinical Evidence*, *FDA*, and *References* sections	
Respiratory Interleukins (Cinqair®, Fasenra®, & Nucala®)	Nov. 1, 2021	**Coverage Rationale** ● Revised language to indicate: ○ Cinqair® is proven and medically necessary for the treatment of certain conditions outlined within the InterQual® criteria; for medical necessity clinical coverage criteria, refer to the current release of the InterQual® guideline, CP: Specialty Rx Non-Oncology, Reslizumab (Cinqair) ▪ Cinqair when used for Severe Asthma will also be subject to the following Step Therapy (one of the following):	This policy provides information about the use of certain specialty pharmacy medications administered by either the subcutaneous (SC) or intravenous (IV) route. Fasenra and Nucala for self-administration are obtained under the pharmacy benefit. This policy refers to the following drug products: ● Cinqair® (reslizumab) ● Fasenra® (benralizumab) ● Nucala® (mepolizumab) Cinqair®† is proven and medically necessary for the treatment of certain conditions outlined within the InterQual® criteria. For medical necessity clinical coverage criteria, refer to the current release of the InterQual® guideline, CP: Specialty Rx Non-Oncology, Reslizumab (Cinqair). Click here to view the InterQual® criteria.

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Respiratory Interleukins (Cinqair®, Fasenra®, & Nucala®) (continued)	Nov. 1, 2021	– History of failure to a 4 month trial of Fasenra or Nucala – Contraindication or intolerance to Fasenra or Nucala ○ Fasenra® is proven and medically necessary for the treatment of certain conditions outlined within the InterQual® criteria; for medical necessity clinical coverage criteria, refer to the current release of the InterQual® guideline, CP: Specialty Rx Non-Oncology, Benralizumab (Fasenra) ○ Nucala® is proven and medically necessary for the treatment of certain conditions outlined within the InterQual® criteria; for medical necessity clinical coverage criteria, refer to the current release of the InterQual® guideline, CP: Specialty Rx Non-Oncology, Mepolizumab (Nucala) ○ In addition, Fasenra and Nucala for provider administration will require one of the following: ▪ Physician attestation that the patient or caregiver is not competent or is	†Cinqair when used for Severe Asthma will also be subject to the following Step Therapy: One of the following: • History of failure to a 4 month trial of Fasenra or Nucala; or • Contraindication or intolerance to Fasenra or Nucala Fasenra®* and Nucala®* are proven and medically necessary for the treatment of certain conditions outlined within the InterQual® criteria. For medical necessity clinical coverage criteria, refer to the current release of the InterQual® guideline: • Fasenra: CP: Specialty Rx Non-Oncology, Benralizumab (Fasenra) • Nucala: CP: Specialty Rx Non-Oncology, Mepolizumab (Nucala) Click here to view the InterQual® criteria. *In addition, Fasenra and Nucala for provider administration will require 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; or • Patient has experienced 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; or • Patient is new to therapy with Fasenra or Nucala and requires initial dose to be directly monitored by a healthcare professional before continued self-administration (Note: Authorization will be for 1 dose); or • Patient is ≤ 11 years of age (for asthma and Hypereosinophilic Syndrome (HES) only)

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Respiratory Interleukins (Cinqair®, Fasenra®, & Nucala®) (continued)	Nov. 1, 2021	physically unable to administer the Fasenra or Nucala product FDA labeled for self-administration; or ▪ Patient has experienced 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; or ▪ Patient is new to therapy with Fasenra or Nucala and requires initial dose to be directly monitored by a healthcare professional before continued self-administration (Note: Authorization will be for 1 dose); or ▪ Patient is ≤11 years of age (for asthma and Hypereosinophilic Syndrome (HES) only) Applicable Codes • Removed list of applicable ICD-10 diagnosis codes	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Respiratory Interleukins (Cinqair®, Fasenra®, & Nucala®) (continued)	Nov. 1, 2021	Supporting Information ● Removed *Background*, *Clinical Evidence*, *FDA*, and *References* sections	
Sodium Hyaluronate	Nov. 1, 2021	Coverage Rationale ● Revised language to indicate: ○ The preferred sodium hyaluronate products are Durolane, Euflexxa, and Gelsyn-3 ○ Coverage for Durolane, Euflexxa, and Gelsyn-3, intra-articular injections of sodium hyaluronate, are proven and medically necessary for the treatment of certain conditions outlined within the InterQual® criteria; For medical necessity clinical coverage criteria, refer to the current release of the InterQual® guideline, CP: Specialty Rx Non-Oncology: ▪ Durolane (sodium hyaluronate) ▪ Euflexxa (1% sodium hyaluronate) ▪ GelSyn-3 (sodium hyaluronate) ○ Coverage for intra-articular injections of sodium hyaluronate products GenVisc 850, Hyalgan, Supartz, Visco-3, Hymovis, Orthovisc, Synvisc or	The preferred sodium hyaluronate products are Durolane, Euflexxa, and Gelsyn-3. Coverage for Durolane, Euflexxa, and Gelsyn-3, intra-articular injections of sodium hyaluronate, are proven and medically necessary for the treatment of certain conditions outlined within the InterQual® criteria. For medical necessity clinical coverage criteria refer to the current relase of the InterQual® guideline: ● Durolane: CP: Specialty Rx Non-Oncology, Durolane (sodium hyaluronate) ● Euflexxa: CP: Specialty Rx Non-Oncology, Euflexxa (1% sodium hyaluronate) ● Gelsyn-3: CP: Specialty Rx Non-Oncology, GelSyn-3 (sodium hyaluronate) Click here to view the InterQual® criteria. Coverage for intra-articular injections of sodium hyaluronate: GenVisc 850, Hyalgan, Supartz, Visco-3, Hymovis, Orthovisc, Synvisc or Synvisc-One, Gel-One, Monovisc, Triluron, TriVisc, and Synojoynt, are proven and medically necessary for the treatment of certain conditions outlined within the InterQual® criteria and are contingent upon the Preferred Product Criteria. In order to continue coverage, members already on these products will be required to change therapy to Durolane, Euflexxa, or Gelsyn-3, unless they meet the Preferred Product Criteria below. **Preferred Product Criteria** Treatment with GenVisc 850, Hyalgan, Supartz, Visco-3, Hymovis, Orthovisc, Synvisc or Synvisc-One, Gel-One, Monovisc, Triluron, TriVisc, or Synojoynt is medically necessary for the indications outlined in the InterQual® criteria when one of the criteria below are met:

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Sodium Hyaluronate (continued)	Nov. 1, 2021	Synvisc-One, Gel-One, Monovisc, Triluron, TriVisc, and Synojoynt are proven and medically necessary for the treatment of certain conditions outlined within the InterQual® criteria and are contingent upon the Preferred Product Criteria [in this policy] ○ In order to continue coverage, members already on these products will be required to change therapy to Durolane, Euflexxa, or Gelsyn-3, unless they meet the Preferred Product Criteria [in the policy] ○ Treatment with GenVisc 850, Hyalgan, Supartz, Visco-3, Hymovis, Orthovisc, Synvisc or Synvisc-One, Gel-One, Monovisc, Triluron, TriVisc, or Synojoynt is medically necessary for the indications outlined in the InterQual® criteria when one of the criteria below are met: ▪ Both of the following: – History of a trial of adequate dose and duration of Durolane, Euflexxa, and Gelsyn-3, resulting in minimal clinical response; and	• Both of the following: ○ History of a trial of adequate dose and duration of Durolane, Euflexxa, and Gelsyn-3, resulting in minimal clinical response; and ○ Physician attests that, in their clinical opinion, the clinical response would be expected to be superior than experienced with Durolane, Euflexxa, and Gelsyn-3 or • Both of the following: ○ History of failure, contraindication, or intolerance to Durolane, Euflexxa, and Gelsyn-3; and ○ Physician attests that, in their clinical opinion, the same failure, contraindication, or intolerance would not be expected to occur with GenVisc 850, Hyalgan, Supartz, Visco-3, Hymovis, Orthovisc, Synvisc or Synvisc-One, Gel-One, Monovisc, Triluron, TriVisc, or Synojoynt For medical necessity clinical coverage criteria, refer to the current relase of the InterQual® guideline: • GenVisc 850: CP: Specialty Rx Non-Oncology, GenVisc 850 (sodium hyaluronate) • Hyalgan: CP: Specialty Rx Non-Oncology, Hyalgan (sodium hyaluronate) • Supartz: CP: Specialty Rx Non-Oncology, Supartz (sodium hyaluronate) • Visco-3: CP: Specialty Rx Non-Oncology, Visco-3 (sodium hyaluronate) • Hymovis: CP: Specialty Rx Non-Oncology, Hymovis (high molecular weight viscoelastic hyaluronan) • Orthovisc: CP: Specialty Rx Non-Oncology, Orthovisc (high-molecular-weight hyaluronan) • Synvisc / Synvisc-One: CP: Specialty Rx Non-Oncology, Synvisc (Hylan G-F 20) • Gel-One: CP: Specialty Rx Non-Oncology, Gel-One (cross-linked hyaluronate) • Monovisc: CP: Specialty Rx Non-Oncology, Monovisc (high-molecular-weight hyaluronan) • Triluron: CP: Specialty Rx Non-Oncology, Triluron (sodium hyaluronate)

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Sodium Hyaluronate (continued)	Nov. 1, 2021	– Physician attests that, in their clinical opinion, the clinical response would be expected to be superior than experienced with Durolane, Euflexxa, and Gelsyn-3 or ▪ Both of the following: – History of failure, contraindication, or intolerance to Durolane, Euflexxa, and Gelsyn-3; and – Physician attests that, in their clinical opinion, the same failure, contraindication, or intolerance would not be expected to occur with GenVisc 850, Hyalgan, Supartz, Visco-3, Hymovis, Orthovisc, Synvisc or Synvisc-One, Gel-One, Monovisc, Triluron, TriVisc, or Synojoynt ○ For medical necessity clinical coverage criteria, refer to the current release of the InterQual® guideline, CP:	• TriVisc: CP: Specialty Rx Non-Oncology, TriVisc (sodium hyaluronate) • Synojoynt: CP: Specialty Rx Non-Oncology, Synojoynt (1% sodium hyaluronate) Click here to view the InterQual® criteria.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Sodium Hyaluronate (continued)	Nov. 1, 2021	Specialty Rx Non-Oncology ▪ GenVisc 850 (sodium hyaluronate) ▪ Hyalgan (sodium hyaluronate) ▪ Supartz (sodium hyaluronate) ▪ Visco-3 (sodium hyaluronate) ▪ Hymovis (high molecular weight viscoelastic hyaluronan) ▪ Orthovisc (high-molecular-weight hyaluronan) ▪ Synvisc (Hylan G-F 20) for Synvisc/Synvisc-One ▪ Gel-One (cross-linked hyaluronate) ▪ Monovisc (high-molecular-weight hyaluronan) ▪ Triluron (sodium hyaluronate) ▪ TriVisc (sodium hyaluronate) ▪ Synojoynt (1% sodium hyaluronate) **Applicable Codes** • Removed list of applicable ICD-10 diagnosis codes **Supporting Information** • Removed *Background*, *Clinical Evidence*, *FDA*, and *References* sections	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Synagis® (Palivizumab)	Nov. 1, 2021	Coverage Rationale *Additional Information* • Replaced language indicating "season onset is defined as the first of 2 consecutive weeks during which the mean percentage of specimens testing positive for RSV antigen is ≥ 10% and RSV 'season' offset is defined as the last of 2 consecutive weeks during which the mean percentage of positive specimens is ≥ 10" with "season onset is defined as the first of 2 consecutive weeks during which the mean percentage of specimens testing positive for RSV antigen is ≥ 10% *or the mean percentage of specimens testing positive for RSV by PCR is ≥ 3%, whichever occurs first*; RSV 'season' offset is defined as the last week during which the mean percentage of positive specimens *by antigen* is ≥ 10%, *or the mean percentage of positive specimens by PCR is ≥ 3%, whichever occurs last*" Supporting Information • Updated *References* section to reflect the most current information	Synagis (palivizumab) is proven and medically necessary to prevent serious respiratory syncytial virus disease (RSV) in high risk infants and young children when all of the following are met: • Administered during RSV season as defined by Centers for Disease and Prevention (CDC) surveillance reports (http://www.cdc.gov/surveillance/nrevss/rsv/index.html) or state or local health departments to confirm the start of the respiratory syncytial virus (RSV) "season;" and • Monthly dose of Synagis does not exceed 15 mg/kg per dose; and • Monthly dose of Synagis does not exceed 5 doses per single RSV "season" ◦ Infants in a neonatal intensive care unit who qualify for prophylaxis may receive the first dose 48 to 72 hours before discharge to home or promptly after discharge. If the first dose is administered in the hospital, this dose will be considered the first dose of the maximum 5 dose series for the season. And any subsequent doses received in the hospital setting are also considered as part of the maximum 5 dose series. For infants born during the RSV "season," fewer than 5 monthly doses may be needed and • One of the following clinical situations: ◦ Prematurity ▪ Infants born before 29 weeks, 0 day's gestation who are < 12 months of age at the start of RSV "season" ◦ Chronic Lung Disease (CLD) ▪ Age 0 to < 12 months: – Prophylaxis may be considered during the RSV "season" during the first year of life for preterm infants who develop chronic lung disease (CLD) of prematurity defined as gestational age < 32 weeks, 0 days and a requirement for > 21% oxygen for at least the first 28 days after birth ▪ Age ≥ 12 to < 24 months: – Synagis is proven for use in pre-term infants born at < 32 weeks, 0 day's gestation who are ≥ 12 to < 24 months of age

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Synagis® (Palivizumab) (continued)	Nov. 1, 2021		who required at least 28 days of oxygen after birth and who continue to require supplemental oxygen, diuretics, or chronic systemic corticosteroid therapy within 6 months of the start of the second RSV "season" ○ Congenital Heart Disease (CHD) ▪ Age 0 to < 12 months: – Infants and children with hemodynamically significant CHD who are born within 12 months of onset of RSV "season" and who will most likely benefit from immunoprophylaxis include: • Infants and children with acyanotic heart disease that are receiving medication to control congestive heart failure and will require cardiac surgical procedures • Infants and children with moderate to severe pulmonary hypertension • Documentation that decisions regarding Synagis prophylaxis for infants with cyanotic heart defects in the first year of life were made in consultation with a pediatric cardiologist ▪ Age < 24 months: – A postoperative dose for children who still require prophylaxis and who have undergone surgical procedures should be administered Synagis prophylaxis after cardiac bypass or at the conclusion of extracorporeal membrane oxygenation • Children who undergo cardiac transplantation during the RSV "season" may be considered for Synagis prophylaxis ○ Congenital abnormalities of the airway or neuromuscular disease ▪ Age 0 to < 12 months: – Infants and children with neuromuscular disease or congenital anomaly that impairs the ability to clear secretions from the lower airway because of ineffective cough may be considered for prophylaxis during the first year of life ○ Immunocompromised children < 24 months of age ▪ Synagis may be administered when used for prophylaxis in children

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Synagis® (Palivizumab) (continued)	Nov. 1, 2021		who are receiving cancer chemotherapy or are severely immunocompromised although the efficacy of prophylaxis in this population is unknown (e.g., children who are receiving chemotherapy or undergo hematopoietic stem cell transplantation or solid organ transplantation) ○ Cystic fibrosis (CF) with other qualifying indications ▪ Age 0 to < 12 months: – Infants and children with cystic fibrosis with clinical evidence of CLD and/or nutritional compromise in the first year of life may be considered for prophylaxis • Failure to thrive defined as weight for length less than the 10th percentile on a pediatric growth chart ▪ Age ≥ 12 to < 24 months: – Continued use of Synagis prophylaxis in the second year may be considered for infants and children with manifestations of severe lung disease including: • Previous hospitalization for pulmonary exacerbation in the first year of life • Abnormalities on chest radiography or chest computed tomography that persists when stable • Weight for length less than the 10th percentile on a pediatric growth chart Synagis is unproven for the following situations: • Infants with chronic lung disease (CLD) who do not continue to require medical support in the second year of life • Infants and children with hemodynamically insignificant heart disease (e.g., secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus) • Infants with cardiac lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure • Infants with cardiomyopathy sufficiently mild that they do not require pharmacotherapy

Medical Benefit Drug Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale

Synagis® (Palivizumab) (continued)	Nov. 1, 2021		• Children in the second year of life unless otherwise indicated as proven above
			• Routine use of prophylaxis in children with Down syndrome [unless qualifying heart disease, CLD, airway clearance issues (the inability to clear secretions from the upper airway because of ineffective cough), or prematurity (< 29 weeks, 0 day's gestation) is present]
			• Routine use of prophylaxis in children with cystic fibrosis (unless indications noted in proven indications above are present)
			• Administration of monthly Synagis prophylaxis after an infant or child has experienced a breakthrough RSV hospitalization during the current season if child had met criteria for palivizumab
			• Prophylaxis for primary asthma prevention or to reduce subsequent episodes of wheezing in infants and children.
			• Synagis prophylaxis for prevention of nosocomial disease
			• When Synagis prophylaxis is administered in any of the following scenarios:
			  ○ Outside of the RSV "season"
			  ○ In doses greater than needed to provide protection in the RSV "season"
			  ○ In excess of 5 doses per single RSV "season"
			  ○ To persons other than those at defined high risk, as specified above
			• Treatment of symptomatic RSV disease
			
			Additional Information
			In most of North America, peak RSV activity typically occurs between November and March, usually beginning in November or December, peaking in January or February, and ending by the end of March or sometime in April. Communities in the southern United States, particularly some communities in the state of Florida, tend to experience the earliest onset of RSV. Data from the Centers for Disease Control and Prevention (CDC) have identified variations in the onset and offset of the RSV "season" in the state of Florida that could affect the timing of Synagis administration.
			• Despite varied onsets, the RSV "season" is of the same duration (5 months) in the different regions of Florida.

Medical Benefit Drug Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Synagis® (Palivizumab) (continued)	Nov. 1, 2021		• On the basis of the epidemiology of RSV in Alaska, particularly in remote regions where the burden of RSV disease is significantly greater than the general US population, the selection of Alaska Native infants eligible for prophylaxis may differ from the remainder of the United States. Clinicians may wish to use RSV surveillance data generated by the state of Alaska to assist in determining onset and end of the RSV season for qualifying infants. • Limited information is available concerning the burden of RSV disease among Native American populations. However, special consideration may be prudent for Navajo and White Mountain Apache infants in the first year of life. For analysis of National Respiratory and Enteric Virus Surveillance System (NREVSS) reports in the CDC Morbidity and Mortality Weekly Report, season onset is defined as the first of 2 consecutive weeks during which the mean percentage of specimens testing positive for RSV antigen is ≥10% or the mean percentage of specimens testing positive for RSV by PCR is ≥ 3%, whichever occurs first. RSV "season" offset is defined as the last week during which the mean percentage of positive specimens by antigen is ≥10%, or the mean percentage of positive specimens by PCR is ≥ 3%, whichever occurs last. Use of specimens to determine the start of the RSV "season" requires that the number of specimens tested be statistically significant.
Xolair® (Omalizumab)	Nov. 1, 2021	Coverage Rationale • Replaced language indicating "Xolair (omalizumab) for provider administration is proven and medically necessary for the treatment of *[the conditions listed in the policy]*" with "Xolair (omalizumab) for provider administration is proven and medically necessary for the treatment of *certain conditions outlined within the InterQual® criteria*"	This policy refers to Xolair (omalizumab) subcutaneous injection for administration by a healthcare professional.* Xolair (omalizumab) for self-administered subcutaneous injection is obtained under the pharmacy benefit. Xolair (omalizumab) for provider administration is proven and medically necessary for the treatment of certain conditions outlined within the InterQual® criteria. For medical necessity clinical coverage criteria, refer to the current release of the InterQual® guideline, CP: Specialty Rx Non-Oncology, Omalizumab (Xolair). Click here to view the InterQual® criteria.

Medical Benefit Drug Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Xolair® (Omalizumab) (continued)	Nov. 1, 2021	• Replaced medical necessity clinical coverage criteria with instruction to refer to the current release of the InterQual® guideline, CP: Specialty Rx Non-Oncology, Omalizumab (Xolair) for applicable details **Applicable Codes** • Removed lists of applicable ICD-10 diagnosis codes, maximum allowed quantities by HCPCS units, and maximum allowed quantities by national drug code (NDC) units **Supporting Information** • Removed *Background*, *Clinical Evidence*, *FDA*, and *References* sections	*In addition, Xolair for provider administration will require documentation required to support one of the following: • Physician attestation that the patient or caregiver are not competent or are physically unable to administer the Xolair product FDA labeled for self-administration; or • Patient has experienced severe hypersensitivity reactions (e.g., anaphylaxis, angioedema, bronchopasm, or hypotention) to Xolair within the past 6 months and requests administration and direct monitoring by a healthcare professional; or • Patient is new to therapy with Xolair and requires initial doses to be directly monitored by a healthcare professional before continued self-administration. Note: Authorization will be for 3 doses.

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 UnitedHealthcare Community Plan of Tennessee Medical Policy, Medical Benefit Drug Policy, Coverage Determination Guideline, and Utilization Review Guideline updates. 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 of Tennessee Medical Policies, Medical Benefit Drug Policies, Coverage Determination Guidelines, and Utilization Review Guidelines is available at UHCprovider.com/Tennessee > Medicaid (Community Plan) > Current Policies and Clinical Guidelines > UnitedHealthcare Community Plan of Tennessee Medical & Drug Policies and Coverage Determination Guidelines.