United Healthcare Oxford

UnitedHealthcare Oxford
Policy Update Bulletin: October 2021

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

The following Clinical, Administrative, and Reimbursement Policies 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	Clinical Policy	• Added ICD-10 diagnosis codes T80.82XA, T80.82XD, T80.82XS, and Z92.850
Airway Clearance Devices	Clinical Policy	• Revised description for ICD-10 diagnosis code G71.20
Ambulance	Reimbursement Policy	Ambulance Bundled Codes • Removed HCPCS codes J0693, J7303, J9315, Q4228, and Q4236
Amondys 45™ (Casimersen)	Clinical Policy	• Removed HCPCS code C9075 • Replaced HCPCS codes J3490 and J3590 with J1426
Autism	Administrative Policy	• Added ICD-10 diagnosis codes F78.A1 and F78.A9 • Removed ICD-10 diagnosis code F78
Behavioral Health Services	Administrative Policy	Connecticut (CT) - Parity Exclusions • Added ICD-10 diagnosis codes F78.A1 and F78.A9 • Removed ICD-10 diagnosis code F78 New York (NY) Small - Parity for Biologically Based Mental Illness • Added ICD-10 diagnosis code F32.A
Breast Reconstruction Post Mastectomy and Poland Syndrome	Clinical Policy	• Added ICD-10 diagnosis code C84.7A
Cell-Free Fetal DNA Testing	Clinical Policy	• Removed CPT code 0168U
Chromosome Microarray Testing (Non-Oncology Conditions)	Clinical Policy	• Added ICD-10 diagnosis codes F78.A1 and F78.A9 • Removed ICD-10 diagnosis code F78
Cimzia® (Certolizumab Pegol)	Clinical 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®)	Clinical Policy	• Added ICD-10 diagnosis code C79.63

Take Note

Policy Title	Policy Type	Summary of Changes
Drug Coverage Guidelines	Clinical Policy	• Added HCPCS codes C9081, J0741, J1305, J1426, J7294, J7295, and Q2054 • Removed HCPCS codes C9075, C9076, C9077, C9079, and J7303
Evkeeza™ (Evinacumab-Dgnb)	Clinical Policy	• Removed HCPCS code C9079 • Replaced HCPCS codes J3490 and J3590 with J1305
Formula and Specialized Food	Administrative Policy	• Added HCPCS code S9432
From - To Date Policy	Reimbursement Policy	• Removed HCPCS codes J0693, J7303, and J9315
Long-Acting Injectable Antiretroviral Agents for HIV	Clinical Policy	• Removed HCPCS code C9077 • Replaced HCPCS code J3490 with J0741
Maximum Frequency Per Day (CES)	Reimbursement Policy	Maximum Frequency Per Day Codes and Codes Restricting Modifiers LT and RT • Removed HCPCS codes J0693, Q4228, and Q4236 MAI2 Indicator Codes • Removed CPT codes 0139U and 0168U
Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions	Clinical Policy	• Added CPT code 0262U
Obstructive and Central Sleep Apnea Treatment	Clinical Policy	• Added HCPCS code K1027
Occipital Nerve Injections and Ablation (Including Occipital Neuralgia and Headache)	Clinical Policy	• Added HCPCS code K1023
Omnibus Codes	Clinical Policy	Instrument-Based Ocular Photo Screening • Added ICD-10 diagnosis codes F78.A1 and F78.A9 • Removed ICD-10 diagnosis code F78
Otoacoustic Emissions Testing	Clinical Policy	• Added ICD-10 diagnosis codes F78.A1 and F78.A9 • Removed ICD-10 diagnosis code F78
Outpatient Hospital Maximum Frequency Per Day (CES)	Reimbursement Policy	Maximum Frequency Per Day Code List • Removed HCPCS code J9315 MAI2 Indicator Codes • Removed CPT codes 0139U and 0168U

Take Note

Policy Title	Policy Type	Summary of Changes
Prior Authorization Exemptions for Outpatient Services	Administrative Policy	Pathology and Laboratory • Added CPT codes 0018M, 0256U, 0257U, 0258U, 0259U, 0260U, 0261U, 0263U, 0264U, 0266U, 0267U, 0268U, 0269U, 0270U, 0271U, 0272U, 0273U, 0274U, 0275U, 0276U, 0277U, 0278U, 0279U, 0280U, 0281U, 0282U, 0283U, and 0284U • Removed CPT code 0139U
Prosthetic Devices, Wigs, Specialized, Microprocessor or Myoelectric Limbs	Clinical Policy	• Added HCPCS code K1022
Provider Administered Drugs – Site of Care	Clinical Policy	• Added HCPCS codes J0741, J1305, and J1426 • Removed HCPCS code C9075
Rituximab (Riabni™, Rituxan®, Ruxience®, & Truxima®)	Clinical 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	Clinical Policy	• Added HCPCS codes Q4251, Q4252, and Q4253 • Removed HCPCS codes Q4228 and Q4236
Supply Policy	Reimbursement Policy	Supply Facility J-Code Denial Codes • Removed HCPCS codes J7303 and J9315
Transcutaneous Electrical Nerve/Joint Stimulators	Clinical Policy	• 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	Clinical Policy	• Added CPT code 0265U

Clinical Policy Updates

New		
Policy Title	**Effective Date**	**Coverage Rationale**
Ryplazim® (Plasminogen, Human-Tvmh)	Oct. 1, 2021	Ryplazim (plasminogen, human-tvmh) has been added to the Review at Launch program. Some members may not be eligible for coverage of this medication at this time. Refer to the Clinical policy titled Review at Launch for New to Market Medications for additional details. 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)	Oct. 1, 2021	Saphnelo™ (anifrolumab-fnia) has been added to the Review at Launch program. Some members may not be eligible for coverage of this medication at this time. Refer to the Clinical Policy titled Review at Launch for New to Market Medications for additional details. 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

Clinical Policy Updates

New

Policy Title	Effective Date	Coverage Rationale
Saphnelo™ (Anifrolumab-Fnia) (continued)	Oct. 1, 2021	○ 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 ○ 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

Updated

Policy Title	Effective Date	Summary of Changes
Computer-Assisted Surgical Navigation for Musculoskeletal Procedures	Oct. 1, 2021	**Definitions** • Added definition of: ○ Appendicular Skeleton System ○ Musculoskeletal System **Supporting Information** • Updated *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information
Epidural Steroid Injections for Spinal Pain	Nov. 1, 2021	**Documentation Requirements** • Added list of *Required Clinical Information*
Facet Joint Injections for Spinal Pain	Nov. 1, 2021	**Documentation Requirements** • Added list of *Required Clinical Information*
Gender Dysphoria Treatment	Oct. 1, 2021	**Supporting Information** • Updated *Description of Services*, *Clinical Evidence* and *References* sections to reflect the most current information

Clinical Policy Updates

Updated

Policy Title	Effective Date	Summary of Changes
Glaucoma Surgical Treatments	Nov. 1, 2021	Documentation Requirements • Added list of *Required Clinical Information*
Implanted Spinal Drug Delivery Systems	Nov. 1, 2021	Documentation Requirements Added list of *Required Clinical Information*
Obstructive Sleep Apnea Treatment	Nov. 1, 2021	Documentation Requirements • Updated list of *Required Clinical Information* for Oral Appliance Therapy (OAT) for OSA
Outpatient Physical and Occupational Therapy	Oct. 1, 2021	Coverage Rationale *In-Network Subsequent Physical and Occupational Therapy* • Replaced language indicating "an initial *evaluation report* must be submitted to OptumHealth Care Solutions within ten calendar days of the initial visit or prior to the second visit, whichever occurs first" with "an initial *patient summary form* must be submitted to OptumHealth Care Solutions within ten calendar days of the initial visit or prior to the second visit, whichever occurs first"
Prostate Surgeries and Interventions	Nov. 1, 2021	Documentation Requirements • Added list of *Required Clinical Information*
Total Artificial Heart and Ventricular Assist Devices	Nov. 1, 2021	Coverage Rationale • Updated coverage criteria; replaced criterion requiring "members have sufficient space in the chest cavity to accommodate the device (generally, this includes *patients* who have a body surface area ≥ 1.7m^2)" with "members have sufficient space in the chest cavity to accommodate the device (generally, this includes *individuals* who have a body surface area ≥ 1.7m^2 *for the 70cc device and a body surface area of ≤ 1.85m^2 for the 50cc device*)" Supporting Information • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Antiemetics for Oncology	Nov. 1, 2021	Related Policies • Removed reference link to the Clinical Policy titled *Review at Launch for New to Market Medications* Coverage Rationale *Medical Necessity Plans*	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

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Antiemetics for Oncology (continued)	Nov. 1, 2021	• 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 Prior Authorization Requirements • Removed language pertaining to dates of service prior to Aug. 1, 2021 Applicable Codes • Added ICD-10 diagnosis code Z51.11 • Removed ICD-10 diagnosis code V58.11 Supporting Information • Updated *Clinical Evidence* and *References* sections to reflect the most current information	• Sustol® (granisetron extended release) injection • Kytril® (granisetron) injection, tablets • Varubi® (rolapitant) tablet • Zofran® (ondansetron) injection, tablets Inclusion of oral antiemetics in this policy and application of the preferred product criteria to them is limited to when these are administered prior to the chemotherapy infusion and not when they are self-administered by the patient outside of the infusion. **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**

Preferred Product(s)	Non-Preferred Product(s)
Neurokinin 1 Receptor Antagonist (NK1 RA)	
Emend injection	Cinvanti injectable emulsion
Emend capsules	Varubi tablets
5-Hydroxytryptamine Receptor Antagonist (5HT3 RA)	
Aloxi Injection	
Kytril injection	
Kytril tablets	Sustol injection
Zofran injection	
Zofran tablets	
NK1 RA/5HT3 RA combination	
	Akynzeo injection
	Akynzeo capsule

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

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Antiemetics for Oncology (continued)	Nov. 1, 2021		**policy when one of the following is met:** • 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[10]; and ▪ In combination with a 5HT3 RA or ○ All of the following:

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Antiemetics for Oncology (continued)	Nov. 1, 2021		▪ Prevention of chemotherapy-induced nausea and vomiting due to 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[11]; or ○ All of the following: ▪ Prevention of chemotherapy-induced nausea and vomiting due to Moderate Emetic Risk parenteral anticancer agents[11]; 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

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Antiemetics for Oncology (continued)	Nov. 1, 2021		– History of motion sickness or morning sickness during pregnancy – High anxiety or ○ Treatment of breakthrough nausea and/or vomiting due to anticancer agent(s) • NK1 RA/5HT3 RA combination (Akynzeo) may be indicated when one of the following are present: ○ All 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 or ▪ Prevention of chemotherapy-induced nausea and vomiting due to High Emetic Risk parenteral anticancer agents
Beds and Mattresses	Nov. 1, 2021	Coverage Rationale • Added language to indicate: ○ Pressure reducing support surfaces (group 2) (HCPCS code E0193) are proven and medically necessary in certain circumstances; for medical necessity clinical coverage criteria, refer to InterQual®	**Indications for Coverage** Hospital beds and accessories are proven and Medically Necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® 2021, Apr. 2021 Release, Medicare: Durable Medical Equipment, Hospital Beds and Accessories. • Pressure Reducing Support Surfaces (Group 2) (E0193) are proven and Medically Necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to InterQual® 2021, May 2021 Release,

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Beds and Mattresses (continued)	Nov. 1, 2021	2021, May 2021 Release, Medicare: Durable Medical Equipment, Pressure Reducing Support Surfaces (Group 2) ○ Pressure reducing support surfaces (group 3) (HCPCS code E0194) are proven and medically necessary in certain circumstances; for medical necessity clinical coverage criteria, refer to InterQual® 2021, May 2021 Release, Medicare: Durable Medical Equipment, Pressure Reducing Support Surfaces (Group 3) ○ Pediatric cribs (HCPCS code E0300) are proven and medically necessary in certain circumstances; for medical necessity clinical coverage criteria, refer to InterQual® 2021, Apr. 2021 Release, CP: Durable Medical Equipment, Hospital Beds and Cribs Applicable Codes • Removed HCPCS codes E0270 and E0462	Medicare:Durable Medical Equipment Pressure Reducing Support Surfaces (Group 2) • Pressure Reducing Support Surfaces (Group 3) (E0194) are proven and Medically Necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to InterQual® 2021, May 2021 Release, Medicare:Durable Medical Equipment Pressure Reducing Support Surfaces (Group 3) • Pediatric cribs (E0300) are proven and Medically Necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to InterQual® 2021, Apr. 2021 Release, CP:Durable Medical Equipment Hospital Beds and Cribs Click here to view the InterQual® criteria. ***Safety Enclosure with Beds*** Safety enclosure with beds (e.g., pediatric enclosed bed, adult bed, safety enclosure) are covered as DME for individuals that have a risk for safety in bed when all of the following criteria are met: • Use of equipment is required due to a diagnosis related to cognitive impairment (e.g., traumatic brain injury, cerebral palsy, seizure disorder) or a severe behavioral disorder • There is a safety risk that includes but is not limited to any of the following: ○ Claustrophobia ○ High risk of falls due to a clinical conditions ○ Uncontrolled movements ○ Violent or self-destructive behaviors such as uncontrolled head banging • Less restrictive alternatives methods such as the following have been tried and have not been successful or are contraindicated: ○ A mattress on the floor ○ Protective helmet ○ Side rails ○ Weighted blankets The physician documentation must include:

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Beds and Mattresses (continued)	Nov. 1, 2021		• A signed physicians order for the enclosed bed • Behavioral Management Program, if applicable • Evaluation for contraindications to use of the equipment • Member assessment for physical, environmental, and behavioral factors • Name and model of protective or enclosure bed with a valid HCPCS code • Physician directed written monitoring plan • The medical, neurologic, or behavioral diagnosis ***Repair and Replacement*** Refer to the Administrative Policy titled Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/Replacements. **Coverage Limitations and Exclusions** The following services are excluded from coverage: • Personal care, comfort, or convenience items • Mattresses • Motorized beds • Retail beds/furniture When more than one piece of DME can meet the member's functional needs, benefits are available only for the item that meets the minimum specifications for member needs. Examples include but are not limited to, standard bed vs Semi-Electric Bed vs fully electric or flotation system. This limitation is intended to exclude coverage for deluxe or additional components of a DME item which are not necessary to meet the member's minimal specifications to treat an Injury or Sickness. Note: Examples of mattresses that are excluded from coverage include but are not limited to retail mattresses such as tempurpedic™ and Posturepedic™.

Clinical Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Deep Brain and Cortical Stimulation	Nov. 1, 2021	Coverage Rationale *Deep Brain Stimulation* • Revised language to indicate deep brain stimulation is proven and medically necessary for treating the following indications: ○ Dystonia ○ Essential tremor ○ Parkinson's disease ○ Refractory epilepsy • Removed language indicating directional deep brain stimulation that enables specific steering of current towards targeted lesions is unproven and not medically necessary for treating any condition including but not limited to dystonia, Parkinson's disease, or tremor • Replaced language indicating "*conventional* deep brain stimulation is unproven and not medically necessary for treating obsessive-compulsive disorder (OCD) and for all other indications not listed [in the policy as proven and medically necessary]" with "deep brain stimulation is unproven and not medically necessary for treating obsessive-compulsive disorder (OCD) and for all other indications not listed [in the policy	Deep brain stimulation is proven and medically necessary for treating the following indications: • Dystonia • Essential Tremor • Parkinson's disease • Refractory Epilepsy Responsive cortical stimulation is proven and medically necessary for treating partial or focal seizure disorder. For medical necessity clinical coverage criteria, refer to the InterQual® 2021, Apr. 2021 Release, CP: Procedures, Stereotactic Introduction, Subcortical or Cortical Electrodes. Click here to view the InterQual® criteria. The following are unproven and not medically necessary due to insufficient evidence of efficacy: • Deep brain stimulation and cortical stimulation for treating obsessive-compulsive disorder (OCD) and for all other indications not listed above. • Responsive cortical stimulation for treating all other indications not listed above.

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Deep Brain and Cortical Stimulation (continued)	Nov. 1, 2021	as proven and medically necessary]" Supporting Information • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	
Drug Coverage Criteria: New and Therapeutic Equivalent Medications	Nov. 1, 2021	Coverage Rationale • Revised list of medications requiring prior authorization through the pharmacy benefit manager (PBM): ○ Added Chlorpromazine Concentrate (generic Thorazine), Loreev XR, and Myrbetriq granules ○ Removed Annovera, Fotivda, Klisyri, Nevirapine Extended-Release, Pantoprazole (Camber Products), Tolterodine (generic Detrol), Truseltiq, Xolair (omalizumab) (prefilled syringe), Zegalogue, and ZTLido ○ Replaced: ▪ "Kapvay" with "Kapvay (brand only)" ▪ "Sanctura (brand and generic)" with "Sanctura (brand)" ○ Revised formulary alternative(s) for Aciphex Sprinkle, Acticlate, Prilosec	Refer to the policy for complete details.

Clinical Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Drug Coverage Criteria: New and Therapeutic Equivalent Medications (continued)	Nov. 1, 2021	Suspension, Proctocort (brand only), Protonix (brand only), and Protonix Granules for Suspension	

Revised				
Policy Title	**Effective Date**	**Drug/Medication**	**Status**	**Summary of Changes**
Drug Coverage Guidelines	Oct. 1, 2021	Amondys 45™ (Casimersen)	Updated	• Updated list of applicable HCPCS codes to reflect quarterly edits; replaced C9075, J3490, and J3590 with J1426
		Annovera (Segesterone Acetate and Ethinyl Estradiol Vaginal System)	Updated	• Updated list of applicable HCPCS codes to reflect quarterly edits; replaced J3490 with J7294
		Cabenuva (Cabotegravir; Rilpivirine)	Revised	• Revised prior authorization guidelines to indicate: ○ Prior authorization is required through Oxford's Medical Management ○ The administration of Cabenuva in a hospital outpatient facility (including any ambulatory infusion suite associated with the hospital) requires prior authorization with review by a Medical Director or their designee ○ Refer to *Prior Authorization Guidelines: Provider Administered Drugs – Site of Care* for complete details • Removed reference link to *Prior Authorization Guidelines: Review at Launch for New to Market Medications* • Updated list of applicable HCPCS codes to reflect quarterly edits; replaced C9077 and J3490 with J0741
		[CAR-T (Chimeric Antigen Receptor) Cell Therapy]	Updated	• Updated list of applicable HCPCS codes to reflect quarterly edits: ○ Added C9081 and Q2054 ○ Removed C9076

Clinical Policy Updates

Revised				
Policy Title	**Effective Date**	**Drug/Medication**	**Status**	**Summary of Changes**
Drug Coverage Guidelines (continued)	Oct. 1, 2021	Evkeeza (Evinacumab-Dgnb)	Revised	• Revised prior authorization guidelines to indicate: ○ Prior authorization is required through Oxford's Medical Management ○ The administration of Evkeeza in a hospital outpatient facility (including any ambulatory infusion suite associated with the hospital) requires prior authorization with review by a Medical Director or their designee ○ Refer to *Prior Authorization Guidelines: Provider Administered Drugs – Site of Care* for complete details • Removed reference link to *Prior Authorization Guidelines: Review at Launch for New to Market Medications* • Updated list of applicable HCPCS codes to reflect quarterly edits: ○ Added J1305 ○ Removed J3490 and C9079
		EluRyng (Etonogestrel/Ethinyl Estradiol)	New	• Added language to indicate: ○ Coverage is provided under the pharmacy benefit ○ Prior Authorization is not required ○ Coverage is limited to Members with coverage for contraceptives through their prescription drug plan ▪ If the Member does not have contraceptive coverage through their prescription drug plan, then EluRyng is not covered ▪ Members should refer to their Certificate of Coverage or Prescription Drug Rider language for coverage guidelines • Added benefit guidelines; refer to *Benefit Guidelines: Contraceptives* for complete details
		Nuvaring (Etonogestrel/Ethinyl Estradiol)	Updated	• Updated list of applicable HCPCS codes to reflect quarterly edits; replaced J7303 with J7295
		Ryplazim (Plasminogen, Human-Tvmh)	New	• Added language to indicate coverage is provided under the medical benefit ○ Prior authorization is not required however it is strongly recommended ○ While no penalty will be imposed for failure to request a pre-service review, if one is not requested, a medical necessity review will be conducted post-service to determine coverage ○ It is the referring physician's responsibility to provide medical documentation to demonstrate clinical necessity for the medication

Clinical Policy Updates

Revised				
Policy Title	**Effective Date**	**Drug/Medication**	**Status**	**Summary of Changes**
Drug Coverage Guidelines (continued)	Oct. 1, 2021	Ryplazim (Plasminogen, Human-Tvmh) (continued)	New	○ Beginning Jan. 1, 2022, prior authorization will be required • Added prior authorization guidelines; refer to the following policies for complete details: ○ *Prior Authorization Guidelines: Ryplazim* ○ *Prior Authorization Guidelines: Review at Launch for New to Market Medications*
		Saphnelo (Anifrolumab-Fnia)	New	• Added language to indicate coverage is provided under the medical benefit ○ Prior authorization is not required however it is strongly recommended ○ While no penalty will be imposed for failure to request a pre-service review, if one is not requested, a medical necessity review will be conducted post-service to determine coverage ○ It is the referring physician's responsibility to provide medical documentation to demonstrate clinical necessity for the medication ○ Beginning Jan. 1, 2022, prior authorization will be required • Added prior authorization guidelines; refer to the following policies for complete details: ○ *Prior Authorization Guidelines: Saphnelo* ○ *Prior Authorization Guidelines: Review at Launch for New to Market Medications*
Drug Coverage Guidelines	Nov. 1, 2021	Alecensa (Alectinib)	Revised	• Revised prior authorization/notification guidelines; refer *to Prior Authorization/Notification Guidelines: Alecensa* for complete details
		Annovera (Segesterone Acetate and Ethinyl Estradiol Vaginal System)	Revised	• Revised coverage guidelines to indicate prior authorization is not required • Removed therapeutic equivalent guidelines and corresponding reference link to the policy titled Therapeutic Equivalent Guidelines: Drug Coverage Criteria - New and Therapeutic Equivalent Medications
		Banzel (Brand Only) (Rufinamide)	New	• Added language to indicate prior authorization is required through the Pharmacy Benefit Manager (PBM) • Added prior authorization/medical necessity guidelines; refer *to Prior Authorization/Medical Necessity Guidelines: Multisource Brand/Modified Release Anticonvulsants* for complete details
		Banzel (Generic) (Rufinamide)	Updated	• Updated medication/drug name; added "(Generic)"

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Policy Title	**Effective Date**	**Drug/Medication**	**Status**	**Summary of Changes**
Drug Coverage Guidelines (continued)	Nov. 1, 2021	Cetrotide (Cetrorelix Acetate)	Updated	• Updated prior authorization/medical necessity guidelines; refer *to Prior Authorization/Medical Necessity Guidelines: Cetrotide* for complete details
		Chlorpromazine Concentrate (Generic Thorazine)	New	• Added language to indicate prior authorization is required through the Pharmacy Benefit Manager (PBM) • Added therapeutic equivalent guidelines; refer to *Therapeutic Equivalent Guidelines: Drug Coverage Criteria - New and Therapeutic Equivalent Medications* for complete details
		Epclusa (Sofosbuvir/ Velpatasfir)	Updated	• Updated prior authorization/medical necessity guidelines; refer *to Prior Authorization/Medical Necessity Guidelines: Epclusa* for complete details
		Flowtuss (Hydrocodone/ Guaifenesin)	Revised	• Removed prior authorization/medical necessary guidelines and corresponding reference link to the policy titled *Prior Authorization/Medical Necessity Guidelines: Opioid Containing Cough Medicines*
		Fotivda (Tivozanib)	Revised	• Removed therapeutic equivalent guidelines and corresponding reference link to the policy titled Therapeutic Equivalent Guidelines: Drug Coverage Criteria - New and Therapeutic Equivalent Medications
		Hycofenix (Hydrocodone/ Pseudoephedrine/ Guaifenesin)	Revised	• Removed prior authorization/medical necessary guidelines and corresponding reference link to the policy titled *Prior Authorization/Medical Necessity Guidelines: Opioid Containing Cough Medicines*
		Hydrocodone Bitartrate/ Chlorpheniramine	New	• Added language to indicate prior authorization is required through the Pharmacy Benefit Manager (PBM) • Added prior authorization/medical necessity guidelines; refer *to Prior Authorization/Medical Necessity Guidelines: Opioid Containing Cough Medicines* for complete details
		Hydrocodone Bitartrate/Guaifenesin	New	• Added language to indicate prior authorization is required through the Pharmacy Benefit Manager (PBM) • Added prior authorization/medical necessity guidelines; refer *to Prior Authorization/Medical Necessity Guidelines: Opioid Containing Cough Medicines* for complete details

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Policy Title	**Effective Date**	**Drug/Medication**	**Status**	**Summary of Changes**
Drug Coverage Guidelines (continued)	Nov. 1, 2021	Hydrocodone Polistirex/ Chlorpheniramine Polistirex	New	• Added language to indicate prior authorization is required through the Pharmacy Benefit Manager (PBM) • Added prior authorization/medical necessity guidelines; refer *to Prior Authorization/Medical Necessity Guidelines: Opioid Containing Cough Medicines* for complete details
		Kalydeco (Ivacaftor)	Revised	• Revised prior authorization/medical necessity guidelines; refer *to Prior Authorization/Medical Necessity Guidelines: Kalydeco* for complete details
		Kapvay (Brand Only) (Clonidine Hydrochloride)	Updated	• Updated medication/drug name; added "(Brand Only)"
		Klisyri (Tirbanibuli)	Revised	• Removed prior authorization/medical necessary guidelines and corresponding reference link to the policy titled *Prior Authorization/Medical Necessity Guidelines: Opioid Containing Cough Medicines*
		Koselugo (Selumetinib)	Revised	• Revised prior authorization/notification guidelines; refer *to Prior Authorization/Notification Guidelines: Koselugo* for complete details
		Levemir (Insulin Detemir)	Updated	• Changed policy type classification for *Prior Authorization/Non-Formulary Guidelines: Levemir*; no change to coverage guidelines
		Lidocaine Patch (Lidoderm) (Generic)	Revised	• Revised prior authorization/notification guidelines; refer *to Prior Authorization/Notification Guidelines: Lidocaine Patch* for complete details
		Lidoderm (Lidocaine) (Brand)	Revised	• Revised prior authorization/notification guidelines; refer *to Prior Authorization/Notification Guidelines: Lidocaine Patch* for complete details
		Loreev XR (Lorazepam)	New	• Added language to indicate prior authorization is required through the Pharmacy Benefit Manager (PBM) • Added therapeutic equivalent guidelines; refer to *Therapeutic Equivalent Guidelines: Drug Coverage Criteria - New and Therapeutic Equivalent Medications* for complete details
		Mavyret (Glecaprevir and Pibrentasvir)	Updated	• Updated prior authorization/medical necessity guidelines; refer *to Prior Authorization/Medical Necessity Guidelines: Mavyret* for complete details
		Mektovi (Binimetinib)	Updated	• Updated prior authorization/notification guidelines; refer *to Prior Authorization/Notification Guidelines: Mektovi* for complete details

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Policy Title	**Effective Date**	**Drug/Medication**	**Status**	**Summary of Changes**
Drug Coverage Guidelines (continued)	Nov. 1, 2021	Myfembree (Relugolix and Estradiol Hemihydrate/ Norethindrone)	Revised	• Added prior authorization/medical necessity guidelines; refer *to Prior Authorization/Medical Necessity Guidelines: Myfembree* for complete details • Updated medication/drug name; added "Estradiol Hemihydrate/Norethindrone"
		Myrbetriq Granules (Mirabegron for Oral Suspension)	New	• Added language to indicate prior authorization is required through the Pharmacy Benefit Manager (PBM) • Added therapeutic equivalent guidelines; refer to *Therapeutic Equivalent Guidelines: Drug Coverage Criteria - New and Therapeutic Equivalent Medications* for complete details
		Nevirapine Extended Release (Nevirapine)	Revised	• Revised coverage guidelines to indicate prior authorization is not required • Removed therapeutic equivalent guidelines and corresponding reference link to the policy titled Therapeutic Equivalent Guidelines: Drug Coverage Criteria - New and Therapeutic Equivalent Medications
		Nexviazyme (Avalglucosidase Alfa-Ngpt)	New	• Added language to indicate coverage is provided under the medical benefit ○ Prior authorization is not required however it is strongly recommended ○ While no penalty will be imposed for failure to request a pre-service review, if one is not requested, a medical necessity review will be conducted post-service to determine coverage ○ It is the referring physician's responsibility to provide medical documentation to demonstrate clinical necessity for the medication ○ Beginning Jan. 1, 2022, prior authorization will be required • Added prior authorization guidelines; refer to the following policies for complete details: ○ *Prior Authorization Guidelines:* Medical Therapies for Enzyme Deficiencies ○ *Prior Authorization Guidelines:* Review at Launch for New to Market Medications
		Oriahnn (Elagolix/Estradiol/ Norethindrone Acetate)	Updated	• Updated prior authorization/medical necessity guidelines; refer *to Prior Authorization/Medical Necessity Guidelines: Oriahnn* for complete details
		Orladeyo (Berotralstat)	Revised	• Revised prior authorization/medical necessity guidelines; refer *to Prior Authorization/Medical Necessity Guidelines: Orladeyo* for complete details

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Policy Title	**Effective Date**	**Drug/Medication**	**Status**	**Summary of Changes**
Drug Coverage Guidelines (continued)	Nov. 1, 2021	Pantoprazole	Revised	• Revised coverage guidelines to indicate prior authorization is not required • Removed therapeutic equivalent guidelines and corresponding reference link to the policy titled *Therapeutic Equivalent Guidelines: Drug Coverage Criteria - New and Therapeutic Equivalent Medications* • Updated medication/drug name; removed "(Camber Products)"
		Sanctura (Trospium) (Brand) and Sanctura XR (Trospium Chloride) (Brand and Generic)	Updated	• Updated medication/drug name; removed "Generic" from Sanctura (Trospium)
		Sensipar (Cinacalcet)	Updated	• Updated prior authorization/medical necessity guidelines; refer *to Prior Authorization/Medical Necessity Guidelines: Sensipar* for complete details
		Solosec (Secnidazole)	Revised	• Revised step therapy guidelines; refer *to Step Therapy Guidelines: Solosec* for complete details
		Striant (Testosterone)	Revised	• Revised coverage guidelines to indicate prior authorization is not required • Removed prior authorization/medical necessity guidelines and corresponding reference link to the policy titled *Prior Authorization/Medical Necessity Guidelines: Striant*
		Stromectol (Ivermectin)	New	• Added language to indicate prior authorization is required through the Pharmacy Benefit Manager (PBM) • Added prior authorization/notification guidelines; refer *to Prior Authorization/Notification Guidelines: Stromectol* for complete details
		Symdeko (Tezacaftor/ Ivacaftor)	Revised	• Revised prior authorization/medical necessity guidelines; refer *to Prior Authorization/Medical Necessity Guidelines: Symdeko* for complete details
		Tadalafil 2.5 mg and 5 mg (Generic Cialis)	Revised	• Revised coverage guidelines to indicate prior authorization is not required • Removed step therapy guidelines and corresponding reference link to the policy titled *Step Therapy Guidelines: BPH Cialis*
		Tolterodine (Generic Detrol)	Revised	• Revised coverage guidelines to indicate prior authorization is not required • Removed therapeutic equivalent guidelines and corresponding reference link to the policy titled Therapeutic Equivalent Guidelines: Drug Coverage Criteria - New and Therapeutic Equivalent Medications

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Policy Title	Effective Date	Drug/Medication	Status	Summary of Changes
Drug Coverage Guidelines (continued)	Nov. 1, 2021	Truseltiq (Infigratinib)	Revised	• Removed therapeutic equivalent guidelines and corresponding reference link to the policy titled Therapeutic Equivalent Guidelines: Drug Coverage Criteria - New and Therapeutic Equivalent Medications
		Tussionex	Revised	• Revised coverage guidelines to indicate prior authorization is not required • Removed prior authorization/medical necessity guidelines and corresponding reference link to the policy titled *Prior Authorization/Medical Necessity Guidelines: Opioid Containing Cough Medicines*
		Xolair (Omalizumab) (Prefilled Syringe)	Revised	• Removed therapeutic equivalent guidelines and corresponding reference link to the policy titled Therapeutic Equivalent Guidelines: Drug Coverage Criteria - New and Therapeutic Equivalent Medications
		Zegalogue (Dasiglucagon)	Revised	• Revised coverage guidelines to indicate prior authorization is not required • Removed therapeutic equivalent guidelines and corresponding reference link to the policy titled Therapeutic Equivalent Guidelines: Drug Coverage Criteria - New and Therapeutic Equivalent Medications
		Ztlido (Lidocaine)	Revised	• Revised prior authorization/notification guidelines; refer *to Prior Authorization/Notification Guidelines: Lidocaine Patch* for complete details • Removed therapeutic equivalent guidelines and corresponding reference link to the policy titled Therapeutic Equivalent Guidelines: Drug Coverage Criteria - New and Therapeutic Equivalent Medications

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Electric Tumor Treatment Field Therapy	Nov. 1, 2021	Coverage Rationale • Revised coverage criteria for subsequent approval(s) for continuation of electric tumor treatment fields (TTF); added criterion requiring the individual with newly diagnosed glioblastoma (GBM) continues to receive Temozolomide as the only cancer drug or the device is used as the only treatment for an individual with recurrent GBM	The following is proven and medically necessary for treating newly diagnosed histologically-confirmed Supratentorial glioblastoma (GBM): • The use of U.S. Food and Drug Administration (FDA) approved devices to generate electric tumor treatment fields (TTF) when used according to FDA labeled indications, contraindications, warnings and precautions, and when all of the following criteria are met: ○ Treatment with radiation therapy has been completed; and ○ Individual is receiving Temozolomide as the only cancer drug; and ○ Individual has a Karnofsky Performance Status (KPS) score of ≥ 60 or Eastern Cooperative Oncology Group (ECOG) Performance Status ≤ 2; and

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Electric Tumor Treatment Field Therapy (continued)	Nov. 1, 2021	**Documentation Requirements** • Updated list of *Required Clinical Information* **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information	○ Individual has been counselled that the device must be worn at least 18 hours daily The following is proven and medically necessary for treating radiologically confirmed recurrence of GBM in the Supratentorial region of the brain: • The use of FDA approved devices to generate electric TTF after initial chemotherapy when used according to FDA labeled indications, contraindications, warnings and precautions and when all of the following criteria are met: ○ The device is used as the only treatment; and ○ Individual has a KPS score of ≥ 60 or ECOG Performance Status ≤ 2; and ○ Individual has been counselled that the device must be worn at least 18 hours daily When all of the above criteria are met for either newly diagnosed or recurrent GBM, an initial 3 months of electric TTF therapy will be approved. Subsequent approval(s) for continuation of electric TTF is based on: • Magnetic resonance imaging (MRI) scan has been performed ≤ 2months prior to request and documents no evidence of disease progression; and • Individual with newly diagnosed glioblastoma continues to receive Temozolomide as the only cancer drug or the device is used as the only treatment for an individual with recurrent GBM; and • KPS score of ≥ 60 or ECOG Performance Status ≤ 2; and • Documentation that the individual has been using the device at least 18 hours daily. Due to insufficient evidence of efficacy, the use of devices to generate electric TTF is unproven, and not medically necessary when the criteria above are not met and for all other indications including but not limited to the following: • Treatment of tumors other than GBM

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Electric Tumor Treatment Field Therapy (continued)	Nov. 1, 2021		• Use of electric TTF therapy with concurrent medical therapy (e.g., bevacizumab or chemotherapy) for treatment of recurrent GBM Computer software used for therapeutic radiology clinical treatment planning in conjunction with electric TFF therapy is unproven and not medically necessary due to insufficient evidence of efficacy.
Follicle Stimulating Hormone (FSH) Gonadotropins	Nov. 1, 2021	Coverage Rationale *Controlled Ovarian Stimulation* • Revised coverage criteria: ○ Replaced criterion requiring "gonadotropins are used *alone or* in conjunction with intrauterine insemination (IUI)" with "gonadotropins are used in conjunction with intrauterine insemination (IUI)" ○ Removed criterion requiring the treatment is for individuals ≥ 40 years of age in conjunction with ART • Revised list of unproven and not medically necessary indications; replaced "beyond 4 cycles for individuals age < 38, 2 cycles for individuals age 38-39, individuals > 40 years of age *without ART*" with "beyond 4 cycles for individuals age < 38, 2 cycles for individuals age 38-39, individuals > 40 years of age"	Oxford has engaged Optum to perform reviews of requests for prior authorization of infertility related services (assisted reproductive technologies). Oxford continues to be responsible for decisions to limit or deny coverage and for appeals. All prior authorization requests are handled by Optum. To obtain prior authorization for a procedure related to the treatment of infertility, call Optum at 877-512-9340. This policy addresses the following gonadotropins: • Gonal-f/Gonal-f RFF (follitropin alfa) • Follistim AQ (follitropin beta) All follicle stimulating hormone (FSH) gonadotropins currently available on the U.S. market are considered to be therapeutically equivalent. The clinically appropriate dosing for FSH agents is 450 IU per day or less for an assisted reproductive technology (ART) cycle when administered alone. The total dose of gonadotropin should not exceed 450 IU per day when used in any mixed stimulation protocol of FSH and human menopausal gonadotropin (hMG) (e.g., FSH 300 IU/day with hMG 150 IU/day), for not more than 14 days of treatment. Exceeding this daily dose and duration of treatment has not been proven to be efficacious in terms of pregnancy outcome. The clinically appropriate dosing for FSH agents is 150 IU/day or less when used for ovulation induction, or controlled ovarian stimulation, for not more than 14 days of treatment. Exceeding this daily dose and duration of treatment has not been proven to be efficacious in terms of pregnancy outcome.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Follicle Stimulating Hormone (FSH) Gonadotropins (continued)	Nov. 1, 2021		The following information pertains to the medical necessity review: **General Requirements (applicable to all medical necessity requests)** For initial and continuation of therapy with FSH agents, all of the following must be met for consideration of treatment: • Prognosis for conception must be ≥ 5%; and • Adequate ovarian reserve as indicated but not limited to at least one the following markers (one or more of the following within the previous 6 months): ○ FSH level < 15 mIU/ml if > 35 years of age; or ○ FSH level < 20 mIU/ml if ≤ 35 years of age; or ○ AMH level > 0.3 ng/ml; or ○ Antral follicle count > 6 and • Evidence of adequate ovarian response to stimulation if there has been previously monitored, medicated-stimulated infertility treatment within the previous 6 months. Examples of adequate ovarian response are: ○ One follicle ≥ 15 mm diameter for IUI ○ Minimum of 1 follicle ≥ 15 mm diameter for ART **Diagnosis-Specific Requirements** Infertility treatment with Follistim AQ is medically necessary for the indications for FSH gonadotropins specified in this policy. Infertility treatment with Gonal-f and Gonal-f RFF is medically necessary for the indications for FSH gonadotropins specified in this policy when there is a history of failure, contraindication, or intolerance to Follistim AQ. The information below indicates additional requirements for those indications having specific medical necessity criteria in the list of proven indications. FSH gonadotropins are proven and medically necessary for:

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

Follicle Stimulating Hormone (FSH) Gonadotropins (continued)	Nov. 1, 2021		***Ovulation Induction***
			Gonadotropins are proven and medically necessary for the treatment of ovulatory dysfunction when all of the following criteria are met:
			• Failure to ovulate with both Clomid (clomiphene citrate) and Femara (letrozole)*; and
			• One of the following:
			  ○ Anovulation; or
			  ○ Oligo-ovulation; or
			  ○ Both of the following:
			  ▪ Amenorrhea; and
			  ▪ Other specific causative factors (e.g., thyroid disease, hyperprolactinemia) have been excluded or treated
			and
			• One of the following:
			  ○ For assisted reproductive technologies (ART), dose does not exceed 450 IU/day, for no more than 14 days per cycle; or
			  ○ For ovulation induction, dose does not exceed 225 IU/day, for no more than 14 days per cycle.
			
			* PCOS, anovulatory or oligo-ovulatory patients who fail to ovulate with clomiphene after dosage adjustment up to 150 mg per day should attempt ovulation induction with letrozole before proceeding to gonadotropins. Patients diagnosed with hypothalamic amenorrhea (failure to withdraw to progesterone) who demonstrate hypoestrogenemia may move directly to gonadotropins.
			
			Gonadotropins are unproven and not medically necessary for the treatment of ovulatory dysfunction in the following situations:
			• Beyond the 6th gonadotropin induced ovulatory cycle
			• When there are ≥ 4 follicles which are ≥15 mm in diameter from a previously gonadotropin-induced ovulation, despite a dosage adjustment (e.g., doses of gonadotropin down to 37.5 IU per day)
			• When used alone for individuals with unexplained infertility

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Follicle Stimulating Hormone (FSH) Gonadotropins (continued)	Nov. 1, 2021		• When there is a failure to respond to ovulation stimulation, (e.g., doses of gonadotropins up to 225 IU per day and no follicles ≥ 15 mm in diameter) • In lieu of clomiphene or letrozole to correct a thin endometrial lining • An estradiol level < 100 pg/ml/follicle ≥ 15 mm in diameter • Doses that exceed 450 IU/day for ART or 225 IU/day for ovulation induction, respectively • Duration of therapy that exceeds 14 days per cycle; a longer than 14-day stimulation may be considered in the setting of hypothalamic amenorrhea ***Controlled Ovarian Stimulation*** Gonadotropins are proven and medically necessary for the treatment of controlled ovarian stimulation when all of the following criteria are met: • Used in conjunction with intrauterine insemination (IUI); and • One of the following: ○ Treatment in individuals with diminished ovarian reserve that have not responded to clomiphene or letrozole; or ○ Initial treatment for individuals with diminished ovarian reserve; or ○ In the setting of unilateral proximal tubal disease in conjunction with IUI when there is no evidence of tubal compromise on the patent side when at least 2 cycles of oral agents (clomiphene or letrozole) have failed to yield a dominant follicle on the side with a patent fallopian tube and • One of the following: ○ For assisted reproductive technologies (ART), dose does not exceed 450 IU/day, for no more than 14 days per cycle; or ○ For controlled ovulation stimulation, dose does not exceed 150 IU/day, for no more than 14 days per cycle. Gonadotropins are unproven and not medically necessary for the treatment of controlled ovarian stimulation in the following situations: • Treatment in individuals with unexplained infertility, endometriosis, bilateral tubal factor infertility, recurrent pregnancy loss or male factor infertility • In lieu of clomiphene or letrozole to correct a thin endometrial lining

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Follicle Stimulating Hormone (FSH) Gonadotropins (continued)	Nov. 1, 2021		• When there is a failure to respond to ovarian stimulation, (e.g., doses of gonadotropins up to 150 IU per day and no follicles ≥ 15 mm in diameter) • An estradiol level < 100 pg/ml/follicle ≥ 15 mm in diameter) • When there are ≥ 4 follicles which are ≥ 15 mm in diameter from a previously gonadotropin-induced ovulation, despite a dosage adjustment • Following ART cycles that fail to result in conception due to poor ovarian response or poor-quality oocytes or embryos • Doses that exceed 450 IU/day for ART or 150 IU/day for controlled ovulation stimulation, respectively • Duration of therapy that exceeds 14 days per cycle • Beyond 4 cycles for individuals age < 38, 2 cycles for individuals age 38-39, individuals >40 years of age • In the setting of very poor/futile prognosis, defined as an FSH level ≥ 15 mIU/ml if ≥ 40 years of age or FSH level ≥ 20 mIU/ml if < 40 years of age ***Hypogonadotropic Hypogonadism*** Gonadotropins are proven and medically necessary for the treatment of hypogonadotropic hypogonadism when all of the following criteria are met: • One of the following: ○ Diagnosis of primary hypogonadotropic hypogonadism; or ○ Diagnosis of secondary hypogonadotropic hypogonadism and • For the induction of spermatogenesis; and • Infertility is not due to primary testicular failure.
Genetic Testing for Neuromuscular Disorders	Oct. 1, 2021	Notice of Revision: The following summary of changes has been modified. Revisions to the previous policy update announcement are outlined in red below. Please take note of the additional updates to be applied on Oct. 1, 2021. Coverage Rationale	Multi-gene panel testing for the diagnosis of Neuromuscular Disorders is proven and medically necessary for the following: • Suspected dystroglycanopathy (e.g., Walker Warburg syndrome, muscle-eye-brain disease, Fukuyama congenital muscular dystrophy, congenital muscular dystrophy 1C and 1D) in individuals with: ○ Age of onset of symptoms at 2 years old or less; or ○ Hypotonia, low muscle tone; or ○ Gross developmental delay; and ○ Evidence of muscle weakness; and

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Genetic Testing for Neuromuscular Disorders (continued)	Oct. 1, 2021	• Revised coverage criteria for: *Suspected Congenital Muscular Dystrophy or Myopathy* ○ Replaced criterion requiring "there is a high likelihood that the condition is inherited" with "non-heritable causes have been ruled out" *Suspected Mitochondrial Disease* ○ Added criterion requiring: ▪ Mitochondrial testing ordered by or in consultation with a board-certified medical geneticist or neurologist ▪ High degree of suspicion of having a mitochondrial disease based on medical history, family history, laboratory or other clinical tests ▪ The clinical presentation does not support use of single gene or targeted genetic analysis ○ Replaced criterion requiring "progressive external ophthalmoplegia, proximal weakness, or muscle cramping/fatigue/exercise intolerance," with "*the*	○ Elevated serum creatine kinase (CK) levels; and ○ One or more of the following: ▪ structural eye abnormalities ▪ intellectual disabilities ▪ epilepsy ▪ brain malformation • Suspected congenital muscular dystrophy or myopathy in individuals with: ○ Age of onset of symptoms 2 years old or less; or ○ Hypotonia, low muscle tone; or ○ Gross developmental delay; or ○ Evidence of muscle weakness; and ○ Additional clinical testing such as muscle biopsy or electromyelogram (EMG) is not available or is equivocal and does not aid in the differential diagnosis; and ○ Non-heritable causes have been ruled out; and ○ Targeted single gene genetic testing is negative; or ○ The phenotype could be explained by more than one gene found in the requested multi-gene panel • Suspected Limb Girdle Muscular Dystrophy (LGMD) in individuals with: ○ Muscle weakness or wasting of the shoulders, upper arms, pelvic area, and thighs; and ○ One or more of the following: ▪ Muscle biopsy is not available or not informative for a specific LGMD sub-type ▪ Initial targeted genetic testing is not informative • Suspected glycogen storage disease in individuals with: ○ Adolescent or adult with exercise intolerance, muscle weakness, and muscle cramps; and ▪ Normal or equivocal CK results; and ▪ One of the following conditions is met: – Exercise testing is unavailable or uninformative; or – Muscle biopsy is unavailable or uninformative; or – Targeted genetic testing was negative

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Genetic Testing for Neuromuscular Disorders (continued)	Oct. 1, 2021	*individual has clinical features consistent with a mitochondrial disease such as one of the following conditions*: proximal weakness, muscle cramping/fatigue/exercise intolerance, progressive external ophthalmoplegia, or *sensorineural hearing loss*" ○ Removed criterion requiring one of the following conditions is met: ▪ Muscle biopsy or other clinical testing was uninformative ▪ Persistently unexplained elevated lactic acid ▪ Targeted genetic testing was negative *Suspected Distal Myopathy or Myofibrillar Myopathy* ○ Replaced references to "myofibrillar" with "myofibrillar *myopathy*" Documentation Requirements • Updated list of *Required Clinical Information* Supporting Information • Updated *Clinical Evidence* and *References* sections to reflect the most current information	○ Infant or child with unexplained liver disease, or muscle weakness, or heart dysfunction; and ○ One of the following conditions is met: ▪ Muscle biopsy is unavailable or uninformative; or ▪ Enzyme testing was unavailable or uninformative; or ▪ Targeted genetic testing was negative • Suspected mitochondrial disease in individuals with all of the following: ○ Mitochondrial testing ordered by or I consultation with a board-certified medical geneticist or neurologist; and ○ High degree of suspicion of having a mitochondrial disease based on medical history, family history, laboratory or other clinical tests; and ○ The clinical presentation does not support use of single gene or targeted genetic analysis; and ○ The individual has clinical features consistent with a mitochondrial disease such as one of the following conditions: ▪ Proximal weakness; or ▪ Muscle cramping, fatigue, or exercise intolerance; or ▪ Progressive external ophthalmoplegia; or ○ Sensorineural hearing loss • Suspected hereditary peripheral neuropathy in individuals with: ○ A high degree of suspicion of having a hereditary neuropathy based on medical history, family history, and other clinical tests; or ○ Electrodiagnostic testing is not possible, or results are equivocal; or ○ Targeted genetic testing was negative • Suspected hereditary spastic paraplegia (HSP) or ataxia in individuals with: ○ Peripheral neuropathy; or ○ Ataxia; and ○ One of the following conditions is met: ▪ A family history suggestive of a HSP or ataxia where a diagnosis has not been determined; or ▪ Other clinical testing such as routine lab tests, imaging, muscle biopsy, or nerve conduction tests are inconclusive; or ▪ Targeted genetic testing was negative

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Genetic Testing for Neuromuscular Disorders (continued)	Oct. 1, 2021		• Suspected distal myopathy or myofibrillar myopathy in individuals with: ○ Muscle weakness or wasting of the distal muscles i.e., hands, feet; and ○ One or more of the following: ▪ Clinical features do not suggest a specific distal myopathy or myofibrillar myopathy sub-type ▪ Muscle biopsy is not informative for a specific distal myopathy or myofibrillar myopathy sub-type ▪ Initial targeted genetic testing is not informative ▪ Cardiomyopathy Multi-gene neuromuscular disease panels are unproven and not medically necessary for all other indications due to insufficient evidence of efficacy.
Human Menopausal Gonadotropins (hMG)	Nov. 1, 2021	Coverage Rationale *Controlled Ovarian Stimulation* • Revised coverage criteria: ○ Replaced criterion requiring "gonadotropins are used *alone or* in conjunction with intrauterine insemination (IUI)" with "gonadotropins are used in conjunction with intrauterine insemination (IUI)" ○ Removed criterion requiring the treatment is for individuals ≥ 40 years of age in conjunction with ART • Revised list of unproven and not medically necessary indications; replaced "beyond 4 cycles for individuals age < 38, 2 cycles for individuals age 38-39, individuals > 40 years of age *without ART*" with "beyond 4 cycles for individuals	Oxford has engaged Optum to perform reviews of requests for prior authorization (Oxford continues to be responsible for decisions to limit or deny coverage and for appeals). All prior authorization requests are handled by Optum. To obtain prior authorization for a procedure related to the treatment of infertility, please call Optum at 877-512-9340. This policy refers to the following hMG agent: • Menopur® (menotropins for injection) The clinically appropriate dosing for hMG when used in an ART cycle without an FSH product is 450 IU/day or less for not more than 14 days of treatment. The total dose of gonadotropin (hMG and FSH) should not exceed 450 IU per day when used in any mixed stimulation protocol. When used as part of a mixed stimulation protocol (hMG + FSH) or when used alone for ovulation induction or controlled ovarian stimulation the clinically appropriate maximum dosing for hMG agents is 150 IU/day. Exceeding this daily dose and duration of treatment has not been proven to be efficacious in terms of pregnancy outcome. hMG agents will be referred to as "gonadotropins" in the following medical necessity language.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Human Menopausal Gonadotropins (hMG) (continued)	Nov. 1, 2021	age < 38, 2 cycles for individuals age 38-39, individuals > 40 years of age"	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. The following information pertains to medical necessity review: **General Requirements (applicable to all medical necessity requests)** For initial and continuation of therapy, all of the following must be met for consideration of treatment: • Prognosis for conception must be ≥ 5%; and • Adequate ovarian reserve as indicated but not limited to at least one the following markers (one or more of the following within the previous 6 months: ○ FSH level < 15 mIU/ml if > 35 years of age; or ○ FSH level < 20 mIU/ml if ≤ 35 years of age; or ○ AMH level > 0.3 ng/ml; or ○ Antral follicle count > 6 and • Evidence of adequate ovarian response to stimulation if there has been previously monitored, medicated-stimulated infertility treatment within the previous 6 months. Examples of adequate ovarian response are: ○ One follicle ≥ 15 mm diameter for IUI ○ Minimum of 1 follicle ≥ 15 mm diameter for ART **Diagnosis-Specific Requirements** The information below indicates additional requirements for those indications having specific medical necessity criteria in the list of proven indications. hMG gonadotropins are proven and medically necessary for: ***Ovulation Induction*** Gonadotropins are proven and medically necessary for the treatment of

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Human Menopausal Gonadotropins (hMG) (continued)	Nov. 1, 2021		ovulatory dysfunction when all of the following criteria are met:
			• Failure to ovulate with both Clomid (clomiphene citrate) and Femara (letrozole);* and
			• One of the following:
			  ○ Anovulation; or
			  ○ Oligo-ovulation; or
			  ○ Both of the following:
			  ▪ Amenorrhea; and
			  ▪ Other specific causative factors (e.g., thyroid disease, hyperprolactinemia) have been excluded or treated;
			and
			• One of the following:
			  ○ For assisted reproductive technologies (ART), dose does not exceed 450 IU/day, for no more than 14 days per cycle; or
			  ○ For ovulation induction, dose does not exceed 225 IU/day, for no more than 14 days per cycle.
			
			* PCOS, anovulatory or oligo-ovulatory patients who fail to ovulate with clomiphene after dosage adjustment up to 150 mg per day should attempt ovulation induction with letrozole before proceeding to gonadotropins. Patients diagnosed with hypothalamic amenorrhea (failure to withdraw to progesterone) who demonstrate hypoestrogenemia may move directly to gonadotropins.
			
			Gonadotropins are unproven and not medically necessary for the treatment of ovulatory dysfunction in the following situations:
			• Beyond the 6th gonadotropin induced ovulatory cycle
			• When there are ≥ 4 follicles which are ≥ 15 mm in diameter from a previously gonadotropin-induced ovulation, despite a dosage adjustment (e.g., doses of gonadotropin down to 37.5 IU per day)
			• When used alone for individuals with unexplained infertility
			• When there is a failure to respond to ovulation stimulation (e.g., doses of gonadotropins up to 225 IU per day and no follicles ≥ 15 mm in diameter)
			• In lieu of clomiphene or letrozole to correct a thin endometrial lining

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Human Menopausal Gonadotropins (hMG) (continued)	Nov. 1, 2021		• An estradiol level < 100 pg/ml/follicle ≥ 15 mm in diameter • Doses that exceed 450 IU/day for ART or 225 IU/day for ovulation induction, respectively • Duration of therapy that exceeds 14 days per cycle; a longer than 14-day stimulation may be considered in the setting of hypothalamic amenorrhea ***Controlled Ovarian Stimulation*** Gonadotropins are proven and medically necessary for the treatment of controlled ovarian stimulation when all of the following criteria are met: • Used in conjunction with intrauterine insemination (IUI); and • One of the following: ○ Treatment in individuals with diminished ovarian reserve that have not responded to clomiphene or letrozole; or ○ Initial treatment for individuals with diminished ovarian reserve; or ○ In the setting of unilateral proximal tubal disease in conjunction with IUI when there is no evidence of tubal compromise on the patent side when at least 2 cycles of oral agents (clomiphene or letrozole) have failed to yield a dominant follicle on the side with a patent fallopian tube and • One of the following: ○ For assisted reproductive technologies (ART), total gonadotropin dose does not exceed 450 IU/day, for no more than 14 days per cycle; or ○ For controlled ovulation stimulation, dose does not exceed 150 IU/day, for no more than 14 days per cycle. Gonadotropins are unproven and not medically necessary for the treatment of controlled ovarian stimulation in the following situations: • Treatment in individuals with unexplained infertility, endometriosis, bilateral tubal factor infertility, recurrent pregnancy loss, male factor infertility • In lieu of clomiphene or letrozole to correct a thin endometrial lining • When there is a failure to respond to ovarian stimulation (e.g., doses of gonadotropins up to 150 IU per day and no follicles ≥ 15 mm in diameter) • An estradiol level < 100 pg/ml/follicle ≥ 15 mm in diameter

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Human Menopausal Gonadotropins (hMG) (continued)	Nov. 1, 2021		• When there are ≥ 4 follicles which are ≥ 15 mm in diameter from a previously gonadotropin-induced ovulation, despite a dosage adjustment. • Following ART cycles that fail to result in conception due to poor ovarian response or poor-quality oocytes or embryos • Doses that exceed 450 IU/day for ART or 150 IU/day for controlled ovulation stimulation, respectively • Duration of therapy that exceeds 14 days per cycle • Beyond 4 cycles for individuals age < 38, 2 cycles for individuals age 38-39, individuals > 40 years of age • In the setting of very poor/futile prognosis, defined as a FSH level ≥ 15 mIU/ml if ≥ 40 years of age or FSH level ≥ 20 mIU/ml if < 40 years of age ***Hypogonadotropic Hypogonadism*** Gonadotropins are proven and medically necessary for the treatment of hypogonadotropic hypogonadism when all of the following criteria are met: • One of the following: ○ Diagnosis of primary hypogonadotropic hypogonadism; or ○ Diagnosis of secondary hypogonadotropic hypogonadism and • For the induction of spermatogenesis; and • Infertility is not due to primary testicular failure.
Intrauterine Fetal Surgery	Nov. 1, 2021	Coverage Rationale • Added language to indicate fetoscopic endoluminal tracheal occlusion (FETO) is proven and medically necessary for the intrauterine treatment of congenital diaphragmatic hernia (CDH) when the following criteria are met: ○ Diagnosis of CDH before 30 weeks of gestation	Intrauterine fetal surgery (IUFS) is proven and medically necessary for treating the following conditions: • Congenital Cystic Adenomatoid Malformation (CCAM) and Extralobar Pulmonary Sequestration (EPS): Fetal lobectomy or thoracoamniotic shunt placement for CCAM and thoracoamniotic shunt placement for EPS • Pleural Effusion: Thoracoamniotic shunt placement • Sacrococcygeal Teratoma (SCT): SCT resection • Urinary Tract Obstruction (UTO): Urinary decompression via vesicoamniotic shunt placement • Twin-Twin Transfusion Syndrome (TTTS): Fetoscopic laser surgery (Stages II, III, IV in pregnancies at < 26 weeks of gestation)

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Intrauterine Fetal Surgery (continued)	Nov. 1, 2021	○ Severe pulmonary hypoplasia defined as a quotient of the observed-to-expected lung-to-head ratios of less than 25.0% ○ No other major structural or chromosomal defects are present • Replaced language indicating "intrauterine fetal surgery (IUFS) is unproven and not medically necessary *for CDH*" with "intrauterine fetal surgery (IUFS) is unproven and not medically necessary *when the FETO criteria above are not met or for other approaches to intrauterine CDH surgery*" **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	• Twin Reversed Arterial Perfusion (TRAP): Ablation or occlusion of anastomotic vessels (e.g., laser coagulation or radiofrequency ablation) • Myelomeningocele (MMC) repair Fetoscopic endoluminal tracheal occlusion (FETO) is proven and medically necessary for the intrauterine treatment of congenital diaphragmatic hernia (CDH) when the following criteria are met: • Diagnosis of CDH before 30 weeks of gestation • Severe pulmonary hypoplasia defined as a quotient of the observed-to-expected lung-to-head ratios of less than 25.0% • No other major structural or chromosomal defects are present Due to insufficient evidence of efficacy, IUFS is unproven and not medically necessary for treating all other conditions, including but not limited to: • Congenital diaphragmatic hernia when the FETO criteria above are not met or for other approaches to intrauterine CDH surgery • Congenital heart disease (CHD)
Maximum Dosage and Frequency	Oct. 1, 2021	**Coverage Rationale** • Revised list of medications with associated *Maximum Allowed Frequencies*: ○ Updated brand medications for bevacizumab; removed Mvasi and Zirabev ○ Updated maximum frequencies for vascular endothelial growth factor (VEGF) inhibitors; replaced "maximum of 9 doses" with	Refer to the policy for complete details.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Maximum Dosage and Frequency (continued)	Oct. 1, 2021	"maximum of 12 doses"	
Medical Therapies for Enzyme Deficiencies	Oct. 1, 2021	Coverage Rationale • Added language to indicate Nexviazyme (avalglucosidase alfa-ngpt) has been added to the Review at Launch program • Removed reference link to the Medical Benefit Drug Policy titled *Review at Launch for New to Market Medications* for Nulibry (fosdenopterin) • 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 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)	Refer to the policy for complete details.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Medical Therapies for Enzyme Deficiencies (continued)	Oct. 1, 2021	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 United States Food and Drug Administration approved labeling ▪ Initial authorization will be for no more than 12 months ○ For continuation of therapy, all 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.,	

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Medical Therapies for Enzyme Deficiencies (continued)	Oct. 1, 2021	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 **Prior Authorization Requirements** • Added language for Nexviazyme to indicate: ○ Prior to Jan. 1, 2022: Prior authorization is not required, however it is strongly recommended ▪ While no penalty will be imposed for failure to request a pre-service review, if one is not requested, a medical necessity review will be conducted post-service to determine coverage ▪ It is the referring physician's responsibility to provide medical documentation to demonstrate clinical necessity for the medication; refer to the	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Medical Therapies for Enzyme Deficiencies (continued)	Oct. 1, 2021	Clinical Policy titled *Review at Launch for New to Market Medications* ○ On or after Jan. 1, 2022: Prior authorization for Nulibry is required in all sites of service • Revised language for Nulibry to indicate prior authorization is required in all sites of service **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	
Medical Therapies for Enzyme Deficiencies	Jan. 1, 2022	**Coverage Rationale** • Removed reference link to the Clinical Policy titled *Review at Launch for New to Market Medications* for Nexviazyme **Prior Authorization Requirements** • Removed language indicating prior authorization is not required, however it is strongly recommended for Nexviazyme ○ While no penalty will be imposed for failure to request a pre-service review, if one is not	Refer to the policy for complete details.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Medical Therapies for Enzyme Deficiencies (continued)	Jan. 1, 2022	requested, a medical necessity review will be conducted post-service to determine coverage ○ It is the referring physician's responsibility to provide medical documentation to demonstrate clinical necessity for the medication	
Minimally Invasive Procedures for Gastroesophageal Reflux Disease (GERD) and Achalasia	Nov. 1, 2021	**Coverage Rationale** • Added language to indicate peroral endoscopic myotomy (POEM) is considered unproven and not medically necessary for all other indications (e.g., Zenker's diverticula) due to insufficient evidence • Replaced reference to "InterQual® 2021, Apr. 2021 Release, CP: Procedures, Antireflux *Procedures, Endoscopic*" with "InterQual® 2021, Apr. 2021 Release, CP: Procedures, Antireflux *Surgery or Hiatal Hernia Repair*" **Supporting Information** • Updated *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	The Per Oral Endoscopic Myotomy (POEM) procedure is proven and medically necessary for Achalasia or Diffuse Esophageal Spasm. For medical necessity clinical coverage criteria, refer to the InterQual® Client Defined 2021, CP: Procedures, Minimally Invasive Procedures for Gastroesophageal Reflux Disease and Achalasia (GERD) (Custom) - UHG. Click here to view the InterQual® criteria. Per Oral Endoscopic Myotomy (POEM) is considered unproven and not medically necessary for all other indications (e.g., Zenker's diverticula) due to insufficient evidence. The following are unproven and not medically necessary for treating Gastroesophageal Reflux Disease (GERD) due to insufficient evidence of efficacy: • Endoscopic therapies • Injection or implantation techniques • LINX Reflux Management System Endoluminal therapy with GERDx™ is investigational, unproven and not medically necessary for treating GERD as it has not received U.S. Food and Drug Administration (FDA) approval. For medical necessity clinical coverage criteria, refer to the InterQual® 2021, Apr. 2021 Release, CP: Procedures, Antireflux Surgery or Hiatal Hernia Repair.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Minimally Invasive Procedures for Gastroesophageal Reflux Disease (GERD) and Achalasia (continued)	Nov. 1, 2021		Click here to view the InterQual® criteria. Refer to the Clinical Policy titled Bariatric Surgery for information regarding endoscopic therapies for the treatment of obesity.
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 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)"	Oxford has engaged Optum to perform prior authorization* reviews for injectable chemotherapy drugs administrated by participating providers in an office, outpatient or home setting to treat a cancer diagnosis. Oxford continues to be responsible for claims payment decisions and for appeals. *Note: Prior authorization is not required for injectable chemotherapy drugs administrated by a non-participating provider in an office or outpatient setting however prior authorization will be provided upon request. All prior authorization requests for injectable chemotherapy drugs are handled by Optum. Providers are encouraged to obtain prior authorization through uhcprovider.com, log in and access the *Prior Authorization and Notification* tool. Then select the *Radiology, Cardiology + Oncology* box to be directed to a new website to process these authorization requests. Requests can be submitted online beginning Jul. 30, 2021 for dates of service on or after Aug. 1, 2021. Providers may also obtain prior authorization by calling 1-888-397-8129. For members with an alpha-numeric Group Number, providers should obtain prior authorization by calling the number on the back of the members ID card. Optum uses the National Comprehensive Cancer Network's (NCCN) guidelines in their decision-making process. These guidelines provide independent recommendations for evidence-based cancer treatment. The guidelines are continually updated to be consistent with the current treatment options. Providers and patients may access and view the NCCN guidelines at NCCN.org. **Description** This policy provides parameters for coverage of injectable oncology medications

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Oncology Medication Clinical Coverage (continued)	Nov. 1, 2021		[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 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 clinical 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; refer to the Clinical Guideline titled Chimeric Antigen Receptor T-cell Therapy. **Coverage Criteria** The Oncology Products table below lists Oxford preferred oncology products and respective non-preferred products. Coverage will be provided for the Oxford 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. Members new to therapy will be required to utilize the Oxford preferred oncology product unless they meet the criteria in this section. ***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 the Oxford's preferred oncology products; and

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

Preferred Oncology Product(s)	Non-Preferred Oncology Product(s)
Mvasi (bevacizumab-awwb)	Avastin (bevacizumab) Zirabev (bevacizumab-bvzr)
Kanjinti (trastuzumab-anns) Trazimera (trastuzumab-qyyp)	Herceptin (trastuzumab) Herceptin Hylecta (trastuzumab and hyaluronidase-oysk) Herzuma (trastuzumab-pkrb) Ogivri (trastuzumab-dkst) Ontruzant (trastuzumab-dttb)
Kanjinti (trastuzumab-anns) + Perjeta (pertuzumab) Phesgo (pertuzumab, trastuzumab, hyaluronidase-zzxf)** Trazimera (trastuzumab-qyyp) + Perjeta (pertuzumab)	Herceptin (trastuzumab) + Perjeta (pertuzumab) Herceptin Hylecta (trastuzumab and hyaluronidase-oysk) + Perjeta (pertuzumab) Herzuma (trastuzumab-pkrb) + Perjeta (pertuzumab) Ogivri (trastuzumab-dkst) + Perjeta (pertuzumab) Ontruzant (trastuzumab-dttb) + Perjeta (pertuzumab)
Ruxience (rituximab-pvvr)	Rituxan (rituximab)

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Oncology Medication Clinical Coverage (continued)	Nov. 1, 2021		

Truxima (rituximab-abbs)	Rituxan Hycela (rituximab/hyaluronidase human, recombinant) Riabni (rituximab-arrx)
Gemcitabine	Infugem (gemcitabine in sodium chloride injection)
Leucovorin	Levoleucovorin
Eligard, Lupron Depot 7.5 mg (J9217),	Lupron Depot 3.75 mg (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.

**Phesgo is a combination product of pertuzumab + trastuzumab.

Diagnosis-Specific Criteria

Injectable Oncology Medications

Oxford 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.

Oxford 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 Oxford preferred oncology products that have therapeutically equivalent and/or biosimilar products available.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Oncology Medication Clinical Coverage (continued)	Nov. 1, 2021		If the drug regimen being requested does not have a NCCN 1, 2a, or 2b NCCN Guideline recommendation, refer to the following Clinical and Administrative Policies titled: • Clinical Trials • Experimental/Investigational Treatment • Experimental/Investigational Treatment for NJ Plans
Radiology Procedures Requiring Prior Authorization for eviCore healthcare Arrangement	Dec. 1, 2021	**Applicable Codes** • Revised list of radiology CPT codes requiring prior authorization through eviCore healthcare; added 0623T, 0624T, 0625T, 0626T, 0648T and 0649T	Oxford has engaged eviCore healthcare to perform initial reviews of requests for prior authorization and medical necessity reviews that may include a site of service review. (Oxford continues to be responsible for decisions to limit or deny coverage and for appeals). Refer to the Clinical Policy titled Magnetic Resonance Imaging (MRI) and Computed Tomography (CT) Scan – Site of Service. All prior authorization requests are handled by eviCore healthcare. To prior authorize a radiology procedure, contact eviCore healthcare via one of the two options listed below: • Providers can call eviCore healthcare at 1-877-PRE-AUTH (1-877-773-2884); or • Providers can log onto the eviCore healthcare web page using the Prior Authorization and Notification App. Note: It is eviCore healthcare's policy not to accept prior authorization requests from persons or entities other than referring physicians. eviCore healthcare has established an infrastructure to support the review, development, and implementation of comprehensive outpatient imaging criteria. The radiology evidence-based guidelines and management criteria are available on the eviCore healthcare web site using the Prior Authorization and Notification App. **Accreditation Requirements for Participating Providers** Note: Hospitals are currently excluded from the accreditation requirements listed below.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Radiology Procedures Requiring Prior Authorization for eviCore healthcare Arrangement (continued)	Dec. 1, 2021		• All MRI, PET, and CT studies must be performed on an American College of Radiology ACR), Intersocietal Accreditation Commission (IAC), RadSite or The Joint Commission (TJC) accredited unit or at accredited facilities. Refer to the Administrative Policy titled *Accreditation Requirements for Radiology Services*. • Nuclear Medicine procedures noted with an * are only reimbursable to facilities with one of the following accreditations: ○ American College of Radiology (ACR) ○ Intersocietal Accreditation Commission (IAC) ○ Intersocietal Commission for the Accreditation of Nuclear Medicine (ICANL) • Nuclear Medicine procedures noted with an * are only reimbursable to cardiologists with one of the following certifications: ○ American Board of Radiology (ABR) ○ American Osteopathic Board of Radiology (AOBR) ○ American Board of Nuclear Medicine (ABNM) ○ American Osteopathic Board of Nuclear Medicine (AOBNM) ○ American Board of Internal Medicine (or any of the above) with Certification Board of Nuclear Cardiology (CBNC) [formerly known as the Certification Council of Nuclear Cardiology (CCNC)] Oxford has engaged eviCore healthcare to manage the accreditation process for our provider network. Accreditations should be submitted directly to the eviCore healthcare website. To ensure prompt handling of the accreditation, ensure that all applicable facility and physician information is included. The Oxford Radiology Prior Notification/Authorization Crosswalk Table contains a list of CPT® codes that are interchangeable for prior authorization. If a provider obtains prior authorization for a procedure that corresponds with the Crosswalk Table, then the substitution is appropriate.
Respiratory Interleukins (Cinqair®, Fasenra®, & Nucala®)	Nov. 1, 2021	Coverage Rationale • Added language for treatment of chronic rhinosinusitis with nasal	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)	Nov. 1, 2021	polyps (CRSwNP) with Nucala to indicate: ○ Nucala for provider administration is proven for patients who meet the following criteria: ▪ Diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) ▪ Will be used as add-on maintenance therapy ▪ Patient has had an inadequate response to nasal corticosteroids [e.g., Flonase (fluticasone), Rhinocort (budesonide), Nasonex (mometasone)] ▪ Patient is not receiving Nucala in combination with any of the following: – Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)] – Anti-IgE therapy [e.g., Xolair (omalizumab)] – Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)] ○ Nucala for provider administration is medically necessary when all of the following criteria are met:	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Respiratory Interleukins (Cinqair®, Fasenra®, & Nucala®) (continued)	Nov. 1, 2021	▪ Diagnosis of chronic rhinosinusitis with polyps (CRSwNP) ▪ Patient remains symptomatic despite at least an 8-week trial of, or history of contraindication or intolerance to nasal corticosteroids [e.g., Flonase (fluticasone), Rhinocort (budesonide), Nasonex (mometasone)] ▪ Patient is currently on and will continue current maintenance therapy ▪ Patient has had at least 1 surgery for the removal of nasal polyps within the previous 10 years ▪ Patient has nasal obstruction symptoms with a visual analog scale (VAS) score of > 5 ▪ Patient has a bilateral nasal polyp score (NPS) ≥ 5 with NPS ≥ 2 in each nostril ▪ Patient is not receiving Nucala in combination with any of the following: – Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Respiratory Interleukins (Cinqair®, Fasenra®, & Nucala®) (continued)	Nov. 1, 2021	(benralizumab)] – Anti-IgE therapy [e.g., Xolair (omalizumab)] – Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)] ▪ Nucala dosing for CRSwNP is in accordance with the United States Food and Drug Administration approved labeling ▪ Prescribed by or in consultation with an allergist/ immunologist/ otolaryngologist/ pulmonologist ▪ Initial authorization will be for no more than 6 months ○ For patients currently on Nucala for the treatment of CRSwNP, authorization for continued use will be approved based on all of the following criteria: ▪ Documentation of positive clinical response to Nucala therapy (e.g., improved sense of smell, improved VAS symptom score) ▪ Patient will continue to receive Nucala as add-on maintenance therapy	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Respiratory Interleukins (Cinqair®, Fasenra®, & Nucala®) (continued)	Nov. 1, 2021	▪ Patient is not receiving Nucala in combination with any of the following: – Anti-interleukin 5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab)] – Anti-IgE therapy [e.g., Xolair (omalizumab)] – Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)] ▪ Nucala dosing for CRSwNP is in accordance with the United States Food and Drug Administration approved labeling ▪ Prescribed by or in consultation with allergist/ immunologist/ otolaryngologist/ pulmonologist ▪ Reauthorization will be for no more than 12 months **Applicable Codes** • Added ICD-10 diagnosis codes J31.0, J32.0, J32.1, J32.2, J32.3, J32.4, J32.8, J32.9, J33.0, J33.1, J33.8, and J33.9 **Supporting Information** • Updated *Background*, *Clinical Evidence*, *FDA*, and *References*	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Respiratory Interleukins (Cinqair®, Fasenra®, & Nucala®) (continued)	Nov. 1, 2021	sections to reflect the most current information	
Ryplazim® (Plasminogen, Human-Tvmh)	Jan. 1, 2022	**Coverage Rationale** • Removed reference link to the Clinical Policy titled *Review at Launch for New to Market Medications* **Prior Authorization Requirements** • Revised language to indicate prior authorization is required in all sites of service ○ Home infusion of Ryplazim requires prior authorization for the home care services ○ Additional prior authorization requirements apply to requests for hospital outpatient facility infusion of Ryplazim; refer to the Clinical Policy titled *Provider Administered Drugs - Site of Care* ○ New Jersey Small group plan members should refer to their Certificate of Coverage for prior authorization and quantity limit guidelines	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)	Jan. 1, 2022	**Coverage Rationale** • Removed reference link to the Clinical Policy titled *Review at Launch for New to Market Medications*	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:

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Saphnelo™ (Anifrolumab-Fnia) (continued)	Jan. 1, 2022	**Prior Authorization Requirements** • Revised language to indicate prior authorization is required in all sites of service ○ Home infusion of Saphnelo requires prior authorization for the home care services ○ Participating providers in the office setting: Prior authorization is required for services performed in the office of a participating provider ○ Non-participating/out-of-network providers in the office setting: Prior authorization is not required but is encouraged for out-of-network services; if Prior authorization is not obtained, Oxford will review for out-of-network benefits and medical necessity after the service is rendered ○ Additional prior authorization requirements apply to requests for hospital outpatient facility infusion of Saphnelo; refer to the Clinical Policy titled *Provider Administered Drugs - Site of Care* ○ New Jersey Small group plan members should refer to their Certificate of Coverage for	○ 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 ○ 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**
Saphnelo™ (Anifrolumab-Fnia) (continued)	Jan. 1, 2022	prior authorization and quantity limit guidelines	
Sodium Hyaluronate	Nov. 1, 2021	**Coverage Rationale** • Replaced language indicating "authorization is for a single *injection* course once per joint for 6 months" with "authorization is for a single *treatment* course once per joint for 6 months"; refer to the list in the policy of FDA approved sodium hyaluronate products and their respective FDA labeled dosage (number of injections) per treatment course per joint	Coverage for Durolane, Euflexxa, and Gelsyn-3 is contingent on criteria in the Diagnosis-Specific Criteria section; prior authorization is not required in the office setting. Coverage for Gel-One, GenVisc 850, Hyalgan, Hymovis, Monovisc, Orthovisc, Supartz, Synojoynt, Synvisc or Synvisc-One, Triluron, TriVisc, or Visco-3 is contingent on Medical Necessity Criteria and Diagnosis-Specific 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 criteria below. **Medical Necessity Criteria** Treatment with Gel-One, GenVisc 850, Hyalgan, Hymovis, Monovisc, Orthovisc, Supartz, Synojoynt, Synvisc or Synvisc-One, Triluron, TriVisc, or Visco-3 is medically necessary for the indications specified in this policy 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 ○ 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 Gel-One, GenVisc 850, Hyalgan, Hymovis, Monovisc, Orthovisc, Supartz, Synojoynt, Synvisc or Synvisc-One, Triluron, TriVisc, or Visco-3

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Sodium Hyaluronate (continued)	Nov. 1, 2021		**Diagnosis-Specific Criteria** ***Initial Authorization (sodium hyaluronate naïve patients)*** Intra-articular injections of sodium hyaluronate are proven and medically necessary when all of the following are met: • Diagnosis of knee osteoarthritis; and • The member has not responded adequately to conservative therapy which may include physical therapy or pharmacotherapy (e.g., non-steroidal anti-inflammatory drugs [NSAIDs], acetaminophen and/or topical capsaicin cream) or injection of intra-articular steroids and such therapy has not resulted in functional improvement after at least 3 months, or the member is unable to tolerate conservative therapy because of adverse side effects; and • The member reports pain which interferes with functional activities (e.g., ambulation, prolonged standing); and • The pain is attributed to degenerative joint disease/primary osteoarthritis of the knee; and • There are no contraindications to the injections (e.g., active joint infection, bleeding disorder); and • Dosing is in accordance with the US FDA approved labeling as shown in the table below; and • Initial authorization is for a single treatment course once per joint for 6 months (see table below). ***Reauthorization/Continuation*** Repeated courses of intra-articular hyaluronan injections may be considered when all of the following are met: • Diagnosis of knee osteoarthritis; and • Documentation of positive clinical response to therapy (e.g., significant pain relief was achieved with the prior course of injections); and • Pain has recurred; and • At least 6 months have passed since the prior course of treatment for the respective joint; and • Dosing is in accordance with the US FDA approved labeling as shown in the table below; and

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Sodium Hyaluronate (continued)	Nov. 1, 2021		• Continuing authorization is for a single treatment course once per joint for 6 months (see table below). The table below shows the FDA approved sodium hyaluronate products and their respective FDA labeled dosage per treatment course per joint:

FDA Labeling*					
Durolane	1 injection	Hymovis	2 injections	Synvisc One	1 injection
Euflexxa	3 injections	Monovisc	1 injection	Triluron	3 injections
Gel One	1 injection	Orthovisc	3 to 4 injections	TriVisc	3 injections
Gelsyn-3	3 injections	Supartz	3 to 5 injections	Visco-3	3 injections
GenVisc 850	3 to 5 injections	Synojoynt	3 injections		
Hyalgan	5 injections	Synvisc	3 injections		

Intra-articular injections of sodium hyaluronate are unproven and not medically necessary for treating any other indication due to insufficient evidence of efficacy including but not limited to the following.

- Hip osteoarthritis
- Temporomandibular joint osteoarthritis
- Temporomandibular joint disc displacement

Hyaluronic acid gel preparations to improve the skin's appearance, contour and/or reduce depressions due to acne, scars, injury or wrinkles are considered cosmetic and are not covered.

Revised

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 doses 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 will be needed; and • One of the following clinical situations: ◦ Prematurity: ▪ Infants born before 29 weeks, 0 day's gestations 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: Palivizumab is medically necessary for use in pre-term infants born at < 32 weeks, 0 day's gestation who are ≥ 12 to < 24 months of age who required at least 28 days of oxygen after birth and who continue to require supplemental oxygen,

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Synagis® (Palivizumab) (continued)	Nov. 1, 2021		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 who 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 that use cardiopulmonary bypass 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 younger than 24 months of age: ▪ Synagis may be administered when used for prophylaxis in children 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

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Synagis® (Palivizumab) (continued)	Nov. 1, 2021		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 persist when stable. – Weight for length less than the 10th percentile on a pediatric growth chart. Synagis is unproven and not medically necessary 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. • Children in the second year of life unless otherwise indicated under medically necessary as noted 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

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Synagis® (Palivizumab) (continued)	Nov. 1, 2021		prematurity) (<29 weeks, 0 day's gestation) is present]. • Routine use of prophylaxis in children with cystic fibrosis (unless indications noted in medically necessary 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. • 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.

Clinical Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Synagis® (Palivizumab) (continued)	Nov. 1, 2021		• 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.

Administrative Policy Updates

Updated

Policy Title	Effective Date	Summary of Changes
Extended Benefits for Total Disability & Succeeding Carrier for Inpatient Admissions	Oct. 1, 2021	Definitions • Removed definition of “Inpatient Stay” • Revised definition of “Total Disability/Totally Disabled”

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Acquired Rare Disease Drug Therapy Exception Process	Nov. 1, 2021	Prior Authorization Requirements • Added language to indicate this policy applies to Oxford New York Commercial plan membership *(omitted from previous policy version in error upon content transfer to new template)*	After receiving a request for experimental treatment of an Acquired Rare Disease, an Oxford Medical Director will review the relevant clinical and patient information. As part of that review, the Medical Director, in his/her discretion, will determine whether the disease is an Acquired Rare Disease and whether the proposed drug therapy is clinically reasonable. For purposes of this policy, clinically reasonable means: • The drug is FDA approved and is not contraindicated for the proposed use. • There is evidence of early success with the drug therapy and at least a small number of patients with the same Acquired Rare Disease have responded to treatment but there is not enough information to have a peer review published study at this time. • The evidence showing early success is from a Center of Excellence which treats members with the same Acquired Rare Disease. • The benefit likely exceeds the risk to the member in receiving the drug therapy. • The treatment results will be available for use by the medical community by establishment of a patient registry to evaluate the effectiveness of the drug therapy for patients with this Acquired Rare Disease. • The member has not failed a previous course or trial of the drug therapy. • The member does not have any other comorbidity which would preclude the proposed drug therapy. • The member has signed an informed consent. The Medical Director will consult with the specialist who has received early success with use of the proposed treatment if possible and/or an outside consultant. The specialist/consultant must have credentials in the specific

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

Acquired Rare Disease Drug Therapy Exception Process (continued)	Nov. 1, 2021		discipline of medicine that treats the member's Acquired Rare Disease. That specialist or consultant will be asked to certify that the basis of the medical documents submitted that:
			• The member has an Acquired Rare Disease.
			• There have not been, and are not likely to be in the period of time during which the member must be treated, either clinical trials or articles published in the peer reviewed medical literature showing that the proposed treatment is likely to benefit patients who have the specific rare disease.
			• The requested drug therapy protocol is clinically reasonable to treat the member's Acquired Rare Disease, with stated rationales that support that conclusion.
			• Based on the consultant's opinion, the benefits of the treatment are likely to outweigh the risks of treatment.
			• The specialist/consultant has treated patients with this condition.
			
			Prior authorization will be required for each course of drug therapy. If the member does not respond to the initial prescribed course of drug therapy, Oxford will not continue to approve the therapy and the therapy will be denied as an unproven therapy.
			
			Documentation
			The following documentation must be submitted to Oxford demonstrating the criteria below have been satisfied. Without all such documentation, Oxford will deny any such request.
			
			Necessary Information
			The following supporting documentation must be provided by the member and/or the member's provider for consideration of the drug therapy:
			• Certification from the member's attending physician* which includes:
			  ○ A statement that the member has an Acquired Rare Disease.
			  ○ A statement of the evidence relied upon to recommend the proposed drug therapy and a statement of why any standard therapy available would not be beneficial, would be ineffective or would be inappropriate,

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Acquired Rare Disease Drug Therapy Exception Process (continued)	Nov. 1, 2021		including an assessment of the risks and benefits of the proposed treatment. ○ A copy of any available medical and scientific evidence, upon which the attending physician based his recommendation for the proposed treatment. *The attending physician must be a board certified or board eligible physician qualified to practice in the area of practice appropriate to treat the member's condition. • A written description of the proposed treatment (or protocol if available), which must include: ○ Specific goals ○ A rationale and background for the plan ○ Criteria for patient selection ○ Specific directions for administering the therapy ○ Specific directions for the monitoring of patients ○ A definition of quantitative measures for determining treatment or intervention response ○ Methods for documenting and treating adverse reactions to the treatment or intervention • A copy of the member's informed consent form. • A copy of the member's medical and treatment records, including results of tests or studies, showing the member's current condition and any treatment the member has received for the condition. • The available clinical or pre-clinical data that indicate the effectiveness of the proposed drug therapy for treatment of the member's condition and the contact information for the specialist who can discuss the evidence of early success of the drug therapy with an Oxford Medical Director. • Depending upon the nature of the proposed drug therapy and/or the member's disease, the specialist/consultant or Oxford may require additional documentation to review the requested therapy. Oxford will also accept and consider any additional pertinent clinical documentation, peer review publications and/or relevant data concerning the

Administrative Policy Updates

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Acquired Rare Disease Drug Therapy Exception Process (continued)	Nov. 1, 2021		protocol that the member and/or the member's physician would like to provide in support of the request for the drug therapy.

Autism Spectrum Disorder and Developmental Disabilities	Nov. 1, 2021	Title Change
		• Previously titled *Autism*
		Coverage Rationale
		Connecticut (CT) Products
		• Revised coverage details for Applied Behavioral Analysis (ABA) Therapy:
		  ○ Added language to indicate a licensed psychologist is considered a qualified practitioner of ABA
		  ○ Replaced language indicating "practitioners of ABA are considered qualified when they are *credentialed* by the National Behavior Analyst Certification Board (BACB)" with "practitioners of ABA are considered qualified when they are *licensed* by the National Behavior Analyst Certification Board (BACB)"
		• Removed reference link to the Clinical Policy titled *Physical, Occupational, and Speech Therapy including Cognitive/Neuropsychological Rehabilitation for New Jersey Small Group Members*
			Refer to the policy for complete details.

Administrative Policy Updates

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

Autism Spectrum Disorder and Developmental Disabilities (continued)	Nov. 1, 2021	*New York (NY) Products*
		• Updated list of services addressed in this policy; replaced "Physical, Speech, and Occupational Therapy (PT/OT/ST) Services" with "*Therapeutic Care including* Physical, Speech, and Occupational Therapy (PT/OT/ST) Services"
		• Removed reference link to the Clinical Policy titled *Physical, Occupational, and Speech Therapy including Cognitive/Neuropsychological Rehabilitation for New Jersey Small Group Members*
		• Revised coverage details for Screening and Diagnosis; replaced language indicating "coverage will be provided for assessments, evaluations *or* tests to diagnose whether an individual has Autism Spectrum Disorder" with "coverage will be provided for assessments, evaluations *and* tests to diagnose whether an individual has Autism Spectrum Disorder"
		Definitions
		• Added definition of:
		  ○ Autism Spectrum Disorder (NJ)
		  ○ Developmental Disability (NJ)
		• Updated definition of:	

Administrative Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Autism Spectrum Disorder and Developmental Disabilities (continued)	Nov. 1, 2021	○ Applied Behavioral Analysis (ABA) (CT and NY) ○ Autism Spectrum Disorder (CT) **Applicable Codes** ***Autism Spectrum Disorder*** • Revised description for ICD-10 diagnosis code F84.2 ***Other Developmental Disability for CT and NJ Products*** • Replaced notation indicating "[this] list of diagnosis codes applies to *autism* services provided for CT and NJ products only" with "[this] list of diagnosis codes applies to *developmental disability related* services provided for CT and NJ products only" • Added ICD-10 diagnosis codes A50.42, F80.81, F80.82, F81.0, F81.2, F81.81, F81.89, F81.9, F88, F89, F90.0, F90.1, F90.2, F90.8, F90.9, F95.0, F95.1, F95.2, F95.8, F95.9, F98.4, G12.20, G12.22, G12.29, G31.84, Q93.51, Q93.59, Q93.51, Q93.59, and R41.841 • Removed ICD-10 diagnosis codes F84.2, G93.5, Q93.5, S06.1X0A, S06.1X1A, S06.1X2A, S06.1X3A, S06.1X4A, S06.1X5A, S06.1X6A, S06.1X7A, S06.1X8A, and S06.1X9A **Supporting Information**	

Administrative Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Autism Spectrum Disorder and Developmental Disabilities (continued)	Nov. 1, 2021	• Updated *References* section to reflect the most current information	

New

Policy Title	Effective Date	Coverage Rationale
National Drug Code (NDC) Requirement	Jan. 1, 2022	The NDC is a unique numeric identifier assigned to medications listed under Section 510 of the United States Federal Food, Drug and Cosmetic Act. The 11-digit NDC is separated into three segments in a 5-4-2 format. They are as follows: • The first five digits identify the manufacturer of the drug and are assigned by the Food and Drug Administration (FDA). • The remaining 6 digits are assigned by the manufacturer and identify the specific product and package size Sometimes the NDC on the label does not include the 11 digits. If this occurs, it will be necessary to add a leading zero to the appropriate section to create a 5-4-2 configuration (i.e., 66733-0948-23 in the following sample). A valid NDC without spaces or hyphens should be placed on the medical claim. The NDC number on the container may be different than the NDC number on the external package; therefore, the NDC submitted must be the actual valid NDC number on the container from which the medication was administered (i.e., If a medication has both an exterior and interior packaging containing an NDC, the interior packaging NDC should be listed on the claim.) XXXX-XXXX-XX = 0XXXX-XXXX-XX XXXXX-XXX-XX = XXXXX-0XXX-XX XXXXX-XXXX-X = XXXXX-XXXX-0X **NDC Unit of Measure (UOM)** UOM / Description / General Guidelines F2 / International unit / International units will mainly be used when billing for Factor VIII-Antihemophilic Factors GR / Gram / Grams are usually used when an ointment, cream, inhaler, or bulk powder in a jar are dispensed. This unit of measure will primarily be used in the retail pharmacy setting and not for physician-administered drug billing. ML / Milliliter / If a drug is supplied in a vial in liquid form, bill in millimeters. UN / Unit / If a drug is supplied in a vial in powder form, and must be reconstituted before administration, bill each vial (unit/each) used. Note: ME is also a valid unit of measure, but we recommend using the appropriate UN or ML indictor as this is generally how drugs are priced. **NDC Units Dispensed** The actual decimal quantity administered, and the units of measurement are required on the claim. If reporting a partial unit, use a decimal point. (i.e., if three 0.5 ml vials are dispensed, report ML1.5).

New

Policy Title	Effective Date	Coverage Rationale
National Drug Code (NDC) Requirement (continued)	Jan. 1, 2022	• GR0.045 • ML1.5 • UN2.0 The number of digits for the quantity is limited to eight digits before the decimal and three digits after the decimal. If entering a whole number, do not use a decimal. Do not use commas. Do not zero fill, leave remaining positions blank. Please refer to the following examples: • 1234.56 • 2 • 12345678.123 Requiring the NDC information will differentiate drugs that share the same HCPCS, CPT, or Revenue codes for drug preferences and enhance reimbursement processes. The NDC requirement will not apply to child and adult immunization drug codes. If the NDC information is missing, invalid, incomplete, or does not match the HCPCS or CPT submitted, the claim may be denied. If the claim is denied, it can be resubmitted with the appropriate NDC information for reconsideration of reimbursement. **Maximum Units per Package** Units submitted for a drug should not exceed the package maximum units available based on the NDC number or in increments associated with the drug package. Maximum units will be applied for specific drugs where a specific and standard number of units should be submitted per the NDC of the package. When units submitted exceed the maximum units allowed per package or when units submitted are not in increments of the package, the units over the maximum unit will be denied. **NDC Numbers for Packaged Drugs with Maximum Units:**

NDC Number	HCPCS Code	Max Unit 1	Max Unit 2	Max Unit 3	NDC Number	HCPCS Code	Max Unit 1	Max Unit 2	Max Unit 3
59148001871	J0401	300			59148001870	J0401	300		

Reimbursement Policy Updates

New

Policy Title	Effective Date	Coverage Rationale									
National Drug Code (NDC) Requirement (continued)	Jan. 1, 2022	59148004580	J0401	300			55513071001	J0897	60		
		55513053001	J1442	300	600	900	55513053010	J1442	300	600	900
		55513092401	J1442	300	600	900	55513092491	J1442	300	600	900
		55513092410	J1442	300	600	900	63459091011	J1447	300	600	900
		63459091036	J1447	300	600	900	63459091017	J1447	300	600	900
		63459091015	J1447	300	600	900	15054106003	J1930	60		
		15054109003	J1930	90			00074210803	J1950	2		
		00074228203	J1950	3			00074244003	J1950	4		
		00074364103	J1950	1			00074366303	J1950	3		
		00074377903	J1950	3			00078081881	J2353	20	40	60
		00074334603	J9217	3			00078081181	J2353	10		
		50242008287	J2778	3	6		50242008203	J2778	3		
		50242008288	J2778	3	6		00023590411	J3315	3		
		00023590412	J3315	3			00023590203	J3315	1		
		00023590204	J3315	1			58468009001	J7325	16	32	
		66267092103	J7325	16	32		35356003401	J7325	16	32	
		54569394300	J9202	1			70720095036	J9202	1		
		62935022104	J9217	3			62935022004	J9217	3		
		00074368303	J9217	4			00074364203	J9217	1		
		62935030330	J9217	4			62935030529	J9217	4		
		62935075375	J9217	1			62935075474	J9217	1		
		62935022305	J9217	3							

Reimbursement Policy Updates

Updated		
Policy Title	**Effective Date**	**Summary of Changes**
Co-Surgeon/Team Surgeon (CES)	Oct. 1, 2021	Reimbursement Guidelines • Replaced *Co-Surgeon* and *Team Surgeon* CPT/HCPCS code lists with reference link to the CMS *PFS Relative Value Files* for edits administered by this policy
Injection and Infusion Services (CES)	Oct. 1, 2021	Reimbursement Guidelines • Added reference link to the Reimbursement Policy titled *Procedure/Technical Component (CES)* for additional guidelines pertaining to CPT codes 96360-96379 performed in a facility setting *Injection and Infusion Services (96360-96549) and HCPCS Supplies* • Added the following lists of CPT/HCPCS codes (previously located in *Applicable Codes* section of the policy): ○ Inclusive Supplies ○ E/M Codes for Injections
Site of Service Differential	Oct. 1, 2021	Policy • Replaced list of applicable CPT/HCPCS codes with reference link to the CMS *PFS Relative Value Files* for edits administered by this policy • Added list of *Facility Place of Service Codes* (previously located in *Applicable Codes* section of the policy)

General Information

The inclusion of a health service (e.g., test, drug, device or procedure) in this bulletin indicates only that UnitedHealthcare Oxford® is adopting a new policy and/or updated, revised, replaced or retired an existing policy; it does not imply that UnitedHealthcare Oxford® 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 Oxford® reserves the right to review the clinical evidence supporting the safety and effectiveness of a medical technology prior to rendering a coverage determination.

UnitedHealthcare Oxford® 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 Policy Update Bulletin was developed to share important information regarding UnitedHealthcare Oxford® Clinical, Administrative, and Reimbursement Policy updates. When information in this bulletin conflicts with applicable state and/or federal law, UnitedHealthcare Oxford® 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 Oxford® Medical and Administrative Policies is available at OxfordHealth.com > Providers > Tools & Resources > Medical Information > Medical and Administrative Policies or at UHCprovider.com > Policies and Protocols > Commercial Policies > UnitedHealthcare Oxford Clinical, Administrative and Reimbursement Policies. Refer to the back of the member's health care ID card for the applicable website.