

UnitedHealthcare Value & Balance Exchange Medical Policy Update Bulletin: November 2021

In This Issue

Take Note

Page

- 2022 UnitedHealthcare Individual Exchange Plan Updates – Effective Jan. 1, 2022..... 4

Medical Policy Updates

Updated

- Neuropsychological Testing Under the Medical Benefit – Effective Jan. 1, 2022 8
- Surgery of the Elbow – Effective Jan. 1, 2022 8
- Surgery of the Shoulder – Effective Jan. 1, 2022 8
- Total Artificial Disc Replacement for the Spine – Effective Nov. 1, 2021 8

Revised

- Airway Clearance Devices – Effective Jan. 1, 2022 9
- Bariatric Surgery – Effective Jan. 1, 2022 12
- Breast Imaging for Screening and Diagnosing Cancer – Effective Jan. 1, 2022 15
- Gender Dysphoria Treatment – Effective Jan. 1, 2022 16
- Genetic Testing for Hereditary Cancer – Effective Jan. 1, 2022 19
- Hearing Aids and Devices Including Wearable, Bone Anchored and Semi-Implantable – Effective Jan. 1, 2022 24
- Infertility Diagnosis and Treatment – Effective Jan. 1, 2022 26
- Omnibus Codes – Effective Jan. 1, 2022 28
- Pharmacogenetic Testing – Effective Jan. 1, 2022 31
- Visual Information Processing Evaluation and Orthoptic and Vision Therapy – Effective Jan. 1, 2022 32

Retired

- Chemosensitivity and Chemoresistance Assays in Cancer – Effective Nov. 1, 2021 33

In This Issue

Medical Benefit Drug Policy Updates

Updated

- Intravenous Iron Replacement Therapy (Feraheme®, Injectafer®, & Monoferric®) – Effective Nov. 1, 2021..... 34

Revised

- Antiemetics for Oncology – Effective Dec. 1, 2021..... 34
- Maximum Dosage and Frequency – Effective Dec. 1, 2021..... 38
- Self-Administered Medications – Effective Jan. 1, 2022..... 41
- Xolair® (Omalizumab) – Effective Dec. 1, 2021 42

Coverage Determination Guideline Updates

New

- Fertility Preservation for Iatrogenic Infertility – Effective Jan. 1, 2022 44
- Gender Dysphoria (Gender Identity Disorder) Treatment (for Washington Only) – Effective Jan. 1, 2022..... 44
- Preimplantation Genetic Testing and Related Services – Effective Jan. 1, 2022 45

Updated

- Breast Reconstruction Post Mastectomy and Poland Syndrome – Effective Nov. 1, 2021 46
- Enteral Nutrition – Effective Jan. 1, 2022..... 46
- Hospice Care – Effective Jan. 1, 2022 46

Revised

- Clinical Trials – Effective Jan. 1, 2022..... 47
- Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/ Replacements – Effective Jan. 1, 2022 50
- Habilitative Services and Outpatient Rehabilitation Therapy – Effective Jan. 1, 2022 52
- Infertility Services – Effective Jan. 1, 2022..... 57
- Power Mobility Devices – Effective Jan. 1, 2022 58
- Private Duty Nursing (PDN) Services – Effective Jan. 1, 2022 59

Retired

- Therapeutic Shoes and Inserts for Diabetes – Effective Nov. 1, 2021..... 64

In This Issue

Utilization Review Guideline Updates

Updated

- Elective Inpatient Services – Effective Nov. 1, 2021 65
- Observation Services – Effective Nov. 1, 2021 65

Revised

- Outpatient Surgical Procedures – Site of Service – Effective Feb. 1, 2022 65

Take Note

2022 UnitedHealthcare Individual Exchange Plan Updates

Effective Jan. 1, 2022, the Medical Policies, Medical Benefit Drug Policies, Coverage Determination Guidelines, and Utilization Review Guidelines for UnitedHealthcare Individual Exchange Plans (previously referred to as “UnitedHealthcare® Value & Balance Exchange Plans”) will now apply to the states of Alabama, Florida, Georgia, Illinois, Louisiana, Michigan, and Texas. The following policies have been updated to reflect the new product branding and state-specific application guidelines, as appropriate. State exclusions apply to the policies noted with an asterisk (*) below; click the policy title for complete details on applicable coverage guidelines.

Refer to the UnitedHealthcare news article titled [2022 UnitedHealthcare Individual Exchange plans](#) for additional information regarding the new Individual Exchange benefit plans.

- 17-Alpha-Hydroxyprogesterone Caproate (Makena® and 17P)
- Ablative Treatment for Spinal Pain
- Abnormal Uterine Bleeding and Uterine Fibroids
- Actemra® (Tocilizumab) Injection for Intravenous Infusion
- Adakveo® (Crizanlizumab-Tmca)
- Airway Clearance Devices
- Alpha₁-Proteinase Inhibitors
- Ambulance Services
- Amondys 45™ (Casimersen)
- Antiemetics for Oncology
- Antithrombin III (ATryn®, Thrombate III®)
- Anti-Thymocyte Globulin (Lymphocyte Immune Globulin)
- Apheresis
- Apokyn® (Apomorphine)
- Articular Cartilage Defect Repairs, Knee
- Athletic Pubalgia Surgery
- Attended Polysomnography for Evaluation of Sleep Disorders
- Autologous Cellular Therapy
- Balloon Sinus Ostial Dilation
- Bariatric Surgery*
- Beds and Mattresses
- Benlysta® (Belimumab)
- Blepharoplasty, Blepharoptosis, and Brow Ptosis Repair
- Boniva® (Ibandronate)
- Botulinum Toxins A and B
- Breast Imaging for Screening and Diagnosing Cancer
- Breast Reconstruction Post Mastectomy and Poland Syndrome
- Breast Reduction Surgery
- Breast Repair/Reconstruction Not Following Mastectomy
- Brineura® (Cerliponase Alfa)
- Bronchial Thermoplasty
- Buprenorphine (Probuphine® & Sublocade®)
- Cardiac Event Monitoring
- Cardiovascular Disease Risk Tests
- Carrier Testing for Genetic Diseases
- Catheter Ablation for Atrial Fibrillation
- Cell-Free Fetal DNA Testing
- Ceprotin® (Protein C Concentrate)
- Chelation Therapy for Non-Overload Conditions
- Chemotherapy Observation or Inpatient Hospitalization
- Chromosome Microarray Testing (Non-Oncology Conditions)
- Cimzia® (Certolizumab Pegol)
- Clinical Trials
- Cochlear Implants
- Cognitive Rehabilitation
- Collagen Crosslinks and Biochemical Markers of Bone Turnover
- Complement Inhibitors (Soliris® & Ultomiris™)
- Computed Tomographic Colonography
- Computer-Assisted Surgical Navigation for Musculoskeletal Procedures
- Computerized Dynamic Posturography
- Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes
- Core Decompression for Avascular Necrosis
- Corneal Collagen Crosslinking
- Corneal Hysteresis and Intraocular Pressure Measurement
- Cosmetic and Reconstructive Procedures
- Crysvita® (Burosumab-Twza)
- Cytogam® (Cytomegalovirus Immune Globulin)
- Cytological Examination of Breast Fluids for Cancer Screening or Diagnosis
- Deep Brain and Cortical Stimulation
- Deferoxamine Mesylate
- Denosumab (Prolia® & Xgeva®)
- Diagnostic Spinal Ultrasonography
- Discogenic Pain Treatment

Take Note

- Drug Testing
- Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/Replacements
- Elective Inpatient Services
- Electric Tumor Treatment Field Therapy
- Electrical and Ultrasound Bone Growth Stimulators
- Electrical Bioimpedance for Cardiac Output Measurement
- Electrical Stimulation and Electromagnetic Therapy for Wounds
- Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation
- Electroencephalographic (EEG) Monitoring and Video Recording
- Embolization of the Ovarian and Iliac Veins for Pelvic Congestion Syndrome
- Emergency Health Care Services and Urgent Care Center Services
- Enteral Nutrition
- Entyvio® (Vedolizumab)
- Epidural Steroid Injections for Spinal Pain
- Epiduroscopy, Epidural Lysis of Adhesions and Discography
- Erythropoiesis-Stimulating Agents
- Ethyol® (Amifostine)
- Evenity® (Romosozumab-Aqqg)
- Evkeeza™ (Evinacumab-Dgnb)
- Exondys 51® (Eteplirsen)
- Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal Conditions and Soft Tissue Wounds
- Facet Joint Injections for Spinal Pain
- Fecal Calprotectin Testing
- Fertility Preservation Iatrogenic Infertility
- Functional Endoscopic Sinus Surgery (FESS)
- GamaSTAN®, GamaSTAN S/D® (Intramuscular Immune Globulin)
- Gamifant® (Emapalumab-Lzsg)
- Gastrointestinal Motility Disorders, Diagnosis and Treatment
- Gastrointestinal Pathogen Nucleic Acid Detection Panel Testing for Infectious Diarrhea
- Gender Dysphoria (Gender Identity Disorder) Treatment (for Washington Only)*
- Gender Dysphoria Treatment*
- Genetic Testing for Cardiac Disease
- Genetic Testing for Hereditary Cancer
- Genetic Testing for Neuromuscular Disorders
- Genitourinary Pathogen Nucleic Acid Detection Panel Testing
- Givlaari® (Givosiran)
- Glaucoma Surgical Treatments
- Gonadotropin Releasing Hormone Analogs
- Gynecomastia Treatment
- Habilitative Services and Outpatient Rehabilitation Therapy
- Hearing Aids and Devices Including Wearable, Bone Anchored and Semi-Implantable*
- Hepatitis Screening
- Hereditary Angioedema (HAE), Treatment and Prophylaxis
- Home Health Care
- Home Hemodialysis
- Home Oxygen
- Home Traction Therapy
- Hospice Care
- Hysterectomy
- Ilaris® (Canakinumab)
- Ilumya™ (Tildrakizumab-Asmn)
- Immune Globulin (IVIG and SCIG)
- Implantable Beta-Emitting Microspheres for Treatment of Malignant Tumors
- Implanted Electrical Stimulator for Spinal Cord
- Implanted Spinal Drug Delivery Systems
- Infertility Diagnosis and Treatment
- Infertility Services*
- Infliximab (Avsola™, Inflectra®, Remicade®, & Renflexis®)
- Inhaled Nitric Oxide Therapy
- Injectable Anticoagulants Arixtra® (Fondaparinux), Lovenox® (Enoxaparin), Fragmin® (Dalteparin)
- Intensity-Modulated Radiation Therapy
- Intraoperative Hyperthermic Intraperitoneal Chemotherapy (HIPEC)
- Intrauterine Fetal Surgery
- Intravenous Enzyme Replacement Therapy (ERT) for Gaucher Disease
- Intravenous Iron Replacement Therapy (Feraheme®, Injectafer®, & Monoferric®)
- Intravitreal Corticosteroid Implants
- Kepivance® (Palifermin)
- Ketalar® (Ketamine) and Spravato® (Esketamine)
- Krystexxa® (Pegloticase)
- Laser Interstitial Thermal Therapy
- Lemtrada (Alemtuzumab)
- Light and Laser Therapy
- Liposuction for Lipedema
- Lithotripsy for Salivary Stones
- Long-Acting Injectable Antiretroviral Agents for HIV
- Lower Extremity Invasive Diagnostic and Endovascular Procedures
- Lung Volume Reduction Surgery
- Luxturna® (Voretigene Neparvovec-Rzyl)

Take Note

- Macular Degeneration Treatment Procedures
- Magnetic Resonance Imaging (MRI) and Computed Tomography (CT) Scan – Site of Service*
- Manipulation Under Anesthesia
- Manipulative Therapy
- Manual Wheelchairs
- Maximum Dosage and Frequency
- Mechanical Stretching Devices
- Medical Therapies for Enzyme Deficiencies
- Meniscus Implant and Allograft
- Mifeprex® (Mifepristone)
- Minimally Invasive Procedures for Gastroesophageal Reflux Disease (GERD) and Achalasia
- Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions
- Motorized Spinal Traction
- Mozobil® (Plerixafor)
- Negative Pressure Wound Therapy
- Nerve Graft to Restore Erectile Function During Radical Prostatectomy
- Neurophysiologic Testing and Monitoring
- Neuropsychological Testing Under the Medical Benefit
- Nplate® (Romiplostim)
- Nulojix® (Belatacept)
- Observation Services
- Obstructive and Central Sleep Apnea Treatment
- Occipital Nerve Injections and Ablation (Including Occipital Neuralgia and Headache)
- Ocrevus® (Ocrelizumab)
- Office Based Procedures - Site of Service*
- Off-Label/Unproven Specialty Drug Treatment
- Omnibus Codes
- Oncology Medication Clinical Coverage
- Onpattro® (Patisiran)
- Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors
- Orencia® (Abatacept) Injection for Intravenous Infusion
- Orthognathic (Jaw) Surgery
- Otoacoustic Emissions Testing
- Outpatient Surgical Procedures – Site of Service*
- Oxlumo™ (Lumasiran)
- Panhematin® (Hemin)
- Panniculectomy and Body Contouring Procedures
- Parsabiv® (Etelcalcetide)
- Patient Lifts
- Pectus Deformity Repair
- Pediatric Gait Trainers, Standing Systems and Walkers
- Pediatric Outpatient Intensive Feeding Programs
- Percutaneous Neuroablation for Severe Cancer Pain and Trigeminal Neuralgia
- Percutaneous Patent Foramen Ovale (PFO) Closure
- Percutaneous Vertebroplasty and Kyphoplasty
- Pharmacogenetic Testing
- Plagiocephaly and Craniosynostosis Treatment
- Pneumatic Compression Devices
- Power Mobility Devices*
- Preimplantation Genetic Testing
- Preimplantation Genetic Testing and Related Services
- Preventive Care Services
- Private Duty Nursing (PDN) Services*
- Prolotherapy and Platelet Rich Plasma Therapies
- Propranolol Treatment for Infantile Hemangiomas: Inpatient Protocol
- Prostate Surgeries and Interventions
- Prosthetic Devices, Wigs, Specialized, Microprocessor or Myoelectric Limbs
- Proton Beam Radiation Therapy
- Pulmonary Arterial Hypertension Agents
- Radiation Therapy: Fractionation, Image-Guidance, and Special Services
- Radicava® (Edaravone)
- Reblozyl® (Luspatercept-Aamt)
- Referral to Out-of-Network Specialists
- Repository Corticotropin Injection (Acthar® Gel)
- Respiratory Interleukins (Cinqair®, Fasenna®, & Nucala®)
- Review at Launch for New to Market Medications
- Rhinoplasty and Other Nasal Surgeries
- Rituximab (Riabni™, Rituxan®, Ruxience®, & Truxima®)
- Ryplazim® (Plasminogen, Human-Tvmh)
- Sacroiliac Joint Interventions
- Saphnelo™ (Anifrolumab-Fnia)
- Scenesse® (Afamelanotide)
- Screening Colonoscopy Procedures – Site of Service*
- Self-Administered Medications
- Sensory Integration Therapy and Auditory Integration Training
- Simponi Aria® (Golimumab) Injection for Intravenous Infusion
- Simulect® (Basiliximab)
- Skilled Care and Custodial Care Services
- Skin and Soft Tissue Substitutes
- Sodium Hyaluronate
- Somatostatin Analogs
- Speech Generating Devices
- Spinal Fusion Enhancement Products
- Spinraza® (Nusinersen)

Take Note

- Stelara® (Ustekinumab)
- Stereotactic Body Radiation Therapy and Stereotactic Radiosurgery
- Subcutaneous Implantable Naltrexone Pellets
- Sublingual Immunotherapy
- Surgery of the Ankle
- Surgery of the Elbow
- Surgery of the Foot
- Surgery of the Hand or Wrist
- Surgery of the Hip
- Surgery of the Knee
- Surgery of the Shoulder
- Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins
- Surgical Treatment for Spine Pain
- Sympathetic Blockade
- Synagis® (Palivizumab)
- Temporomandibular Joint Disorders
- Tepezza® (Teprotumumab-Trbw)
- Testosterone Replacement or Supplementation Therapy
- Thermography
- Thyrogen® (Thyrotropin Alfa)
- Total Artificial Disc Replacement for the Spine
- Total Artificial Heart and Ventricular Assist Devices
- Transcatheter Heart Valve Procedures
- Transcranial Magnetic Stimulation
- Transcutaneous Electrical Nerve/Joint Stimulators
- Transpupillary Thermotherapy
- Trogarzo® (Ibalizumab-Uiyk)
- Tysabri® (Natalizumab)
- Umbilical Cord Blood Harvesting and Storage for Future Use
- Unicondylar Spacer Devices for Treatment of Pain or Disability
- Uplizna™ (Inebilizumab-Cdon)
- Vaccines
- Vagus and External Trigeminal Nerve Stimulation
- Vertebral Body Tethering for Scoliosis
- Vibativ® (Telavancin)
- Viltespo™ (Viltolarsen)
- Virtual Upper Gastrointestinal Endoscopy
- Visual Information Processing Evaluation and Orthoptic and Vision Therapy
- Visudyne® (Verteporfin for Injection)
- Vivitrol® (Naltrexone for Extended-Release Injectable Suspension)
- Voraxaze® (Glucarpidase)
- Vyepti™ (Eptinezumab-Jjmr)
- Vyondys 53™ (Golodirsen)
- Warming Therapy and Ultrasound Therapy for Wounds
- Wheelchair Options and Accessories
- Wheelchair Seating
- White Blood Cell Colony Stimulating Factors
- Whole Exome and Whole Genome Sequencing
- Xiaflex® (Collagenase Clostridium Histolyticum)
- Xolair® (Omalizumab)
- Zilretta® (Triamcinolone Acetonide Extended Release)
- Zinplava™ (Bezlotoxumab)
- Zoledronic Acid
- Zolgensma® (Onasemnogene Apeparvovec-Xioi)
- Zulresso™ (Brexanolone)

Medical Policy Updates

Updated		
Policy Title	Effective Date	Summary of Changes
Neuropsychological Testing Under the Medical Benefit	Jan. 1, 2022	<p>Template Update</p> <ul style="list-style-type: none"> Updated policy header to reflect the most current product branding for UnitedHealthcare Individual Exchange Plans <p>Applicable States</p> <ul style="list-style-type: none"> Revised list of applicable states to encompass new benefit plans effective Jan. 1, 2022; added language to indicate this policy applies to the states of Alabama, Florida, Georgia, Illinois, Louisiana, Michigan, and Texas <p>Applicable Codes</p> <ul style="list-style-type: none"> Added CPT codes 96130 and 96131
Surgery of the Elbow	Jan. 1, 2022	<p>Template Update</p> <ul style="list-style-type: none"> Updated policy header to reflect the most current product branding for UnitedHealthcare Individual Exchange Plans <p>Applicable States</p> <ul style="list-style-type: none"> Revised list of applicable states to encompass new benefit plans effective Jan. 1, 2022; added language to indicate this policy applies to the states of Alabama, Florida, Georgia, Illinois, Louisiana, Michigan, and Texas <p>Applicable Codes</p> <ul style="list-style-type: none"> Added CPT codes 29835 and 29836 for Arthroscopy, Surgical, Elbow
Surgery of the Shoulder	Jan. 1, 2022	<p>Template Update</p> <ul style="list-style-type: none"> Updated policy header to reflect the most current product branding for UnitedHealthcare Individual Exchange Plans <p>Applicable States</p> <ul style="list-style-type: none"> Revised list of applicable states to encompass new benefit plans effective Jan. 1, 2022; added language to indicate this policy applies to the states of Alabama, Florida, Georgia, Illinois, Louisiana, Michigan, and Texas <p>Applicable Codes</p> <ul style="list-style-type: none"> Added CPT code 29821
Total Artificial Disc Replacement for the Spine	Nov. 1, 2022	<p>Coverage Rationale</p> <ul style="list-style-type: none"> Added language to clarify cervical artificial disc replacement at one level combined with cervical spinal fusion surgery at another level (adjacent or non-adjacent), <i>as part of the same surgical plan</i>, is unproven and not medically necessary due to insufficient evidence of efficacy <p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>Description of Services</i>, <i>Clinical Evidence</i>, <i>FDA</i>, and <i>References</i> sections to reflect the most current information

Medical Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Airway Clearance Devices	Jan. 1, 2022	<p>Template Update</p> <ul style="list-style-type: none"> Updated policy header to reflect the most current product branding for UnitedHealthcare Individual Exchange Plans <p>Applicable States</p> <ul style="list-style-type: none"> Revised list of applicable states to encompass new benefit plans effective Jan. 1, 2022; added language to indicate this policy applies to the states of Alabama, Florida, Georgia, Illinois, Louisiana, Michigan, and Texas <p>Coverage Rationale</p> <ul style="list-style-type: none"> Revised coverage criteria for high-frequency chest wall oscillation systems used in the management of neuromuscular diseases; added criteria to require: <ul style="list-style-type: none"> Confirmed diagnosis of one of the following neuromuscular diseases: <ul style="list-style-type: none"> Quadriplegia Muscular dystrophy Multiple sclerosis Polio or post-polio syndrome Other anterior horn cell disease Myotonic disorder or other myopathy Paralysis of the diaphragm Acid maltase deficiency 	<p>A two-month rental trial of a high-frequency chest wall oscillation system is proven and medically necessary in the management of neuromuscular diseases, when all of the following criteria have been met:</p> <ul style="list-style-type: none"> A confirmed diagnosis of one of the following neuromuscular diseases: <ul style="list-style-type: none"> Quadriplegia Muscular dystrophy Multiple sclerosis Polio or post-polio syndrome Other anterior horn cell disease Myotonic disorder or other myopathy Paralysis of the diaphragm Acid maltase deficiency Amyotrophic lateral sclerosis (ALS) Spinal muscular atrophy (SMA) and Frequent pulmonary symptom exacerbations requiring antibiotic therapy (>2 per year); and Failure of standard treatments to adequately mobilize retained secretions <p>A two-month rental trial of a high-frequency chest wall oscillation system is proven and Medically Necessary in the management of bronchiectasis, and cystic fibrosis, which are characterized by the production of excessive airway secretions, infection and inadequate airway clearance, when criteria have been met. For additional medical necessity clinical coverage criteria, refer to the InterQual® 2021, Oct. 2021 Release CP: Durable Medical Equipment, Secretion Clearance Devices.</p> <p>Click here to view the InterQual® criteria.</p> <p>For all indications for a high-frequency chest wall oscillation system, an initial two-month rental trial must confirm individual tolerance and efficacy in using the device before ongoing medical necessity can be determined. For medical necessity determination to address ongoing use, refer to the InterQual Criteria.</p>

Medical Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Airway Clearance Devices (continued)	Jan. 1, 2022	<ul style="list-style-type: none"> ▪ Amyotrophic lateral sclerosis (ALS) ▪ Spinal muscular atrophy (SMA) <p>and</p> <ul style="list-style-type: none"> ○ Frequent pulmonary symptom exacerbations requiring antibiotic therapy (> 2 per year); and ○ Failure of standard treatments to adequately mobilize retained secretions <ul style="list-style-type: none"> ● Revised language pertaining to medical necessity clinical coverage criteria for high-frequency chest wall oscillation systems used in the management of bronchiectasis and cystic fibrosis; replaced “InterQual® <i>Client Defined 2021</i>, CP: Durable Medical Equipment, Secretion Clearance Devices (<i>Custom</i>) - <i>UHG</i>” with “InterQual® 2021, <i>Oct. 2021 Release</i>, CP: Durable Medical Equipment, Secretion Clearance Devices” ● Replaced language indicating “an initial two-month rental trial must confirm individual tolerance and efficacy in using the device” with “<i>for all indications for a high-frequency chest wall oscillation system</i>, an initial two-month rental trial must confirm individual 	Intrapulmonary percussive ventilation (IPV) devices for home use are considered unproven and not Medically Necessary.

Medical Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Airway Clearance Devices (continued)	Jan. 1, 2022	<p>tolerance and efficacy in using the device <i>before ongoing medical necessity can be determined; for medical necessity determination to address ongoing use, refer to the InterQual Criteria</i></p> <ul style="list-style-type: none"> Removed language indicating an acoustical or mechanical percussor, positive expiratory pressure and aerosol drug delivery system combination device (e.g., Vibralung®) is considered Medically Necessary to provide airway clearance in the management of bronchiectasis, cystic fibrosis, and neuromuscular diseases; for medical necessity clinical coverage criteria, refer to the InterQual® Client Defined 2021, CP: Durable Medical Equipment, Secretion Clearance Devices (Custom) – UHG Removed language pertaining to HCPCS code E0481 <p>Definitions</p> <ul style="list-style-type: none"> Added definition of “Bronchiectasis” <p>Applicable Codes</p> <ul style="list-style-type: none"> Removed HCPCS code E1399 Added ICD-10 diagnosis codes G71.8, G72.41, G72.89, G73.1, G73.3, G73.7, J98.6, M33.02, M33.12, M33.22, M33.92, M34.82, 	

Medical Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Airway Clearance Devices (continued)	Jan. 1, 2022	<p>and M35.03</p> <ul style="list-style-type: none"> Removed ICD-10 diagnosis code G12.9 <p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>Description of Services</i>, <i>Clinical Evidence</i>, <i>FDA</i>, and <i>References</i> sections to reflect the most current information 	
Bariatric Surgery	Jan. 1, 2022	<p>Template Update</p> <ul style="list-style-type: none"> Updated policy header to reflect the most current product branding for UnitedHealthcare Individual Exchange Plans <p>Applicable States</p> <ul style="list-style-type: none"> Revised list of applicable states: <ul style="list-style-type: none"> Added language to indicate this policy applies to the states of Illinois and Michigan (new benefit plans effective Jan. 1, 2022) Removed language indicating this policy applies to the states of Oklahoma, Tennessee, Virginia and Washington 	<p>The following bariatric surgical procedures are proven and medically necessary for treating obesity:</p> <ul style="list-style-type: none"> Biliopancreatic bypass/Biliopancreatic diversion with duodenal switch Gastric bypass (includes robotic-assisted gastric bypass) Laparoscopic adjustable gastric banding for individuals ≥ 18 years of age; refer to the <i>U.S. Food and Drug Administration (FDA)</i> section of the policy for additional information Sleeve gastrectomy (vertical sleeve gastrectomy) Vertical banded gastroplasty <p>In adults, bariatric surgery using one of the procedures identified above for treating obesity is proven and medically necessary when all of the following criteria are met:</p> <ul style="list-style-type: none"> Class III obesity; or Class II obesity in the presence of one or more of the following co-morbidities: <ul style="list-style-type: none"> Type 2 diabetes; or Cardiovascular disease [e.g., stroke, myocardial infarction, poorly controlled hypertension (systolic blood pressure-greater than 140 mm Hg or diastolic blood pressure 90 mm Hg or greater, despite pharmacotherapy)]; or History of coronary artery disease with a surgical intervention such as coronary artery bypass or percutaneous transluminal coronary angioplasty; or History of cardiomyopathy; or

Medical Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Bariatric Surgery (continued)	Jan. 1, 2022		<ul style="list-style-type: none"> ○ Obstructive Sleep Apnea (OSA) confirmed on polysomnography with an AHI or RDI of ≥ 30 and ● The individual must also meet the following criteria: <ul style="list-style-type: none"> ○ Both of the following: <ul style="list-style-type: none"> ▪ Completion of a preoperative evaluation that includes a detailed weight history along with dietary and physical activity patterns; and ▪ Psychosocial-behavioral evaluation by an individual who is professionally recognized as part of a behavioral health discipline to provide screening and identification of risk factors or potential postoperative challenges that may contribute to a poor postoperative outcome or ○ Participation in a multi-disciplinary surgical preparatory regimen <p>In Adolescents, the bariatric surgical procedures identified above are proven and medically necessary for treating obesity when all of the following criteria are met:</p> <ul style="list-style-type: none"> ● Class III obesity; or ● Class II obesity in the presence of one or more of the following co-morbidities: <ul style="list-style-type: none"> ○ Type 2 diabetes; or ○ Cardiovascular disease [e.g., stroke, myocardial infarction, poorly controlled hypertension (systolic blood pressure-greater than 140 mm Hg or diastolic blood pressure 90 mm Hg or greater, despite pharmacotherapy)]; or ○ History of coronary artery disease with a surgical intervention such as coronary artery bypass or percutaneous transluminal coronary angioplasty; or ○ History of cardiomyopathy; or ○ Obstructive Sleep Apnea confirmed on polysomnography with an AHI or RDI of ≥ 30 and ● The individual must also receive an evaluation at, or in consultation with, a

Medical Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Bariatric Surgery (continued)	Jan. 1, 2022		<p>multidisciplinary center focused on the surgical treatment of severe childhood obesity. This may include adolescent centers that have received accreditation by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) or can demonstrate similar programmatic components.</p> <p>Revisional Bariatric Surgery using one of the procedures identified above is proven and medically necessary when due to a Technical Failure or Major Complication from the initial bariatric procedure.</p> <p>The following procedures are unproven and not medically necessary for treating obesity due to insufficient evidence of efficacy:</p> <ul style="list-style-type: none"> • Revisional Bariatric Surgery for any other indication than those listed above • Bariatric surgery as the primary treatment for any condition other than obesity • Bariatric surgical interventions for the treatment of obesity including but not limited to: <ul style="list-style-type: none"> ○ Bariatric artery embolization (BAE) ○ Gastric electrical stimulation with an implantable gastric stimulator (IGS) ○ Intra-gastric balloon ○ Laparoscopic greater curvature plication, also known as total gastric vertical plication ○ Mini-gastric bypass (MGB)/laparoscopic mini-gastric bypass (LMGBP) ○ Single-Anastomosis Duodenal Switch (also known as duodenal switch with single anastomosis, or stomach intestinal pylorus sparing surgery [SIPS]) ○ Stomach aspiration therapy (AspireAssist®) ○ Transoral endoscopic surgery (includes TransPyloric Shuttle® (TPS®) Device) ○ Vagus Nerve Blocking VBLOC® <p>Gastrointestinal liners (EndoBarrier®) are investigational, unproven and not medically necessary for treating obesity due to lack of U.S. Food and Drug Administration (FDA) approval, and insufficient evidence of efficacy.</p>

Medical Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Breast Imaging for Screening and Diagnosing Cancer	Jan. 1, 2022	<p>Template Update</p> <ul style="list-style-type: none"> Updated policy header to reflect the most current product branding for UnitedHealthcare Individual Exchange Plans <p>Applicable States</p> <ul style="list-style-type: none"> Revised list of applicable states to encompass new benefit plans effective Jan. 1, 2022; added language to indicate this policy applies to the states of Alabama, Florida, Georgia, Illinois, Louisiana, Michigan, and Texas <p>Coverage Rationale</p> <ul style="list-style-type: none"> Added instruction to refer to the <i>Cardiology and Radiology Imaging Guidelines – Breast Imaging Guidelines</i> for 3D rendering of the breast <p>Unproven and Not Medically Necessary</p> <ul style="list-style-type: none"> Added language to indicate computed tomography (CT) of the breast is unproven and not medically necessary Updated list of examples of molecular breast imaging; added “Breast Specific Gamma Imaging” <p>Definitions</p> <ul style="list-style-type: none"> Added definition of “Computed Tomography (CT)” <p>Supporting Information</p>	<p>Note: This policy does not address preventive benefit for breast cancer screening (including mammography); refer to the Coverage Determination Guideline titled <i>Preventive Care Services</i> for more information.</p> <p>The following are proven and medically necessary for the following individuals:</p> <ul style="list-style-type: none"> Digital mammography for individuals with dense breast tissue Diagnostic Breast Ultrasound Breast Magnetic Resonance Imaging (MRI) for individuals who are high risk for breast cancer as defined as having any of the following: <ul style="list-style-type: none"> Prior thoracic radiation therapy between the ages 10 and 30 Lifetime risk estimated at greater than or equal to 20% as defined by models that are largely dependent on family history (e.g., Gail, Claus, Tyrer-Cuzick or BRCAPRO) Personal history of breast cancer (not treated with bilateral mastectomy) Personal history with any of the following: <ul style="list-style-type: none"> Li-Fraumeni Syndrome (TP53 mutation) Confirmed BRCA 1 or BRCA 2 gene mutations Peutz-Jehgers Syndrome (STK11, LKB1 gene variations) PTEN gene mutation Family history with any of the following: <ul style="list-style-type: none"> At least one first-degree relative who has a <i>BRCA1</i> or <i>BRCA2</i> mutation First-degree relative who carries a genetic mutation in the TP53 or PTEN genes (Li-Fraumeni syndrome and Cowden and Bannayan-Riley-Ruvalcaba syndromes, or Peutz-Jehgers Syndrome) At least two first-degree relatives with breast or ovarian cancer One first-degree relative with bilateral breast cancer, or both breast and ovarian cancer First or second-degree male relative (father, brother, uncle, grandfather) diagnosed with breast cancer <p>The following are unproven and not medically necessary due to insufficient evidence of efficacy:</p>

Medical Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Breast Imaging for Screening and Diagnosing Cancer (continued)	Jan. 1, 2022	<ul style="list-style-type: none"> Updated <i>Clinical Evidence</i>, <i>FDA</i>, and <i>References</i> sections to reflect the most current information 	<ul style="list-style-type: none"> Automated Breast Ultrasound system Breast Magnetic Resonance Imaging (MRI) for individuals with dense breast tissue not accompanied by defined risk factors as described above Computer-Aided Detection (CAD) Computer-Aided Tactile Breast Imaging Computed Tomography (CT) of the breast Electrical Impedance Scanning (EIS) Magnetic Resonance Elastography (MRE) Molecular Breast Imaging (e.g., Breast Specific Gamma Imaging, Scintimammography, Positron Emission Mammography) <p>Note: For breast Computed Tomography (CT), 3D rendering of the breast, or additional indications for breast MRI, refer to the <i>Cardiology and Radiology Imaging Guidelines – Breast Imaging Guidelines</i>.</p>
Gender Dysphoria Treatment	Jan. 1, 2022	<p>Template Update</p> <ul style="list-style-type: none"> Updated policy header to reflect the most current product branding for UnitedHealthcare Individual Exchange Plans <p>Applicable States</p> <ul style="list-style-type: none"> Revised list of applicable states: <ul style="list-style-type: none"> Added language to indicate this policy applies to the states of Florida, Illinois and Michigan (new benefit plans effective Jan. 1, 2022) Removed language indicating this policy applies to the states of Arizona, North Carolina, Oklahoma and Tennessee <p>Coverage Rationale and Benefit Considerations</p> <ul style="list-style-type: none"> Added notation to indicate this 	<p>Notes:</p> <ul style="list-style-type: none"> This medical policy does not apply to individuals with ambiguous genitalia or disorders of sexual development. This Medical Policy does not apply to fully-insured group policies in the state of Washington. Refer to the Coverage Determination Guideline titled <i>Gender Dysphoria (Gender Identity Disorder) Treatment (for Washington Only)</i>. <p>Surgical treatment for Gender Dysphoria may be indicated for individuals who provide the following documentation:</p> <ul style="list-style-type: none"> For breast surgery, a written psychological assessment from at least one Qualified Behavioral Health Providers experienced in treating Gender Dysphoria* is required. The assessment must document that an individual meets all of the following criteria: <ul style="list-style-type: none"> Persistent, well-documented Gender Dysphoria Capacity to make a fully informed decision and to consent for treatment Must be at least 18 years of age (age of majority) Favorable psychosocial-behavioral evaluation to provide screening and identification of risk factors or potential postoperative challenges For genital surgery, a written psychological assessment from at least two Qualified Behavioral Health Providers experienced in treating Gender

Medical Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Gender Dysphoria Treatment (continued)	Jan. 1, 2022	<p>Medical Policy does not apply to fully-insured group policies in the state of Washington; refer to the Coverage Determination Guideline titled <i>Gender Dysphoria (Gender Identity Disorder) Treatment (for Washington Only)</i></p> <p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>Description of Services, Clinical Evidence, and References</i> sections to reflect the most current information 	<p>Dysphoria*, who have independently assessed the individual, is required. The assessment must document that an individual meets all of the following criteria:</p> <ul style="list-style-type: none"> Persistent, well-documented Gender Dysphoria Capacity to make a fully informed decision and to consent for treatment Must be at least 18 years of age (age of majority) Favorable psychosocial-behavioral evaluation to provide screening and identification of risk factors or potential postoperative challenges Complete at least 12 months of successful continuous full-time real-life experience in the desired gender Complete 12 months of continuous cross-sex hormone therapy appropriate for the desired gender (unless medically contraindicated) <ul style="list-style-type: none"> Treatment plan that includes ongoing follow-up and care by a Qualified Behavioral Health Providers experienced in treating Gender Dysphoria* <p>When the above criteria are met, the following surgical procedures to treat Gender Dysphoria are medically necessary and covered as a proven benefit:</p> <ul style="list-style-type: none"> Bilateral mastectomy or breast reduction* Clitoroplasty (creation of clitoris) Hysterectomy (removal of uterus) Labioplasty (creation of labia) Laser or electrolysis hair removal in advance of genital reconstruction prescribed by a physician for the treatment of Gender Dysphoria Metoidioplasty (creation of penis, using clitoris) Orchiectomy (removal of testicles) Penectomy (removal of penis) Penile prosthesis Phalloplasty (creation of penis) Salpingo-oophorectomy (removal of fallopian tubes and ovaries) Scrotoplasty (creation of scrotum) Testicular prostheses Urethroplasty (reconstruction of female urethra) Urethroplasty (reconstruction of male urethra) Vaginectomy (removal of vagina)

Medical Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Gender Dysphoria Treatment (continued)	Jan. 1, 2022		<ul style="list-style-type: none"> Vaginoplasty (creation of vagina) Vulvectomy (removal of vulva) <p>*When bilateral mastectomy or breast reduction is performed as a stand-alone procedure, without genital reconstruction procedures, completion of hormone therapy prior to the breast procedure is not required.</p> <p>Certain ancillary procedures, including but not limited to the following, are considered cosmetic and not medically necessary, when performed as part of surgical treatment for Gender Dysphoria:</p> <p>Refer to <i>Benefit Considerations</i> section of the policy; member specific benefit plan language may vary.</p> <ul style="list-style-type: none"> Abdominoplasty (also refer to the Coverage Determination Guideline titled <i>Panniculectomy and Body Contouring Procedures</i>) Blepharoplasty (also refer to the Coverage Determination Guideline titled <i>Blepharoplasty, Blepharoptosis and Brow Ptosis Repair</i>) Body contouring (e.g., fat transfer, lipoplasty, panniculectomy) (also refer to the Coverage Determination Guideline titled <i>Panniculectomy and Body Contouring Procedures</i>) Breast enlargement, including augmentation mammoplasty and breast implants Brow lift Calf implants Cheek, chin and nose implants Injection of fillers or neurotoxins (also refer to the Medical Benefit Drug Policy titled <i>Botulinum Toxins A and B</i>) Face/forehead lift and/or neck tightening Facial bone remodeling for facial feminization Laser or electrolysis hair removal not related to genital reconstruction Hair transplantation Lip augmentation Lip reduction Liposuction (suction-assisted lipectomy) (also refer to the Coverage

Medical Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Gender Dysphoria Treatment (continued)	Jan. 1, 2022		<p>Determination Guideline titled <i>Panniculectomy and Body Contouring Procedures</i>)</p> <ul style="list-style-type: none"> • Mastopexy • Pectoral implants for chest masculinization • Rhinoplasty (also refer to the Coverage Determination Guideline titled <i>Rhinoplasty and Other Nasal Surgeries</i>) • Skin resurfacing (e.g., dermabrasion, chemical peels, laser) • Thyroid cartilage reduction/reduction thyroid chondroplasty/trachea shave (removal or reduction of the Adam’s apple) • Voice modification surgery (e.g., laryngoplasty, glottoplasty or shortening of the vocal cords) • Voice lessons and voice therapy
Genetic Testing for Hereditary Cancer	Jan. 1, 2022	<p>Template Update</p> <ul style="list-style-type: none"> • Updated policy header to reflect the most current product branding for UnitedHealthcare Individual Exchange Plans • Removed <i>CMS</i> section <p>Applicable States</p> <ul style="list-style-type: none"> • Revised list of applicable states to encompass new benefit plans effective Jan. 1, 2022; added language to indicate this policy applies to the states of Alabama, Florida, Georgia, Illinois, Louisiana, Michigan, and Texas <p>Coverage Rationale</p> <ul style="list-style-type: none"> • Added language to indicate single gene testing and known mutation testing for familial cancer is proven and medically necessary • Replaced language indicating “genetic testing for <i>BRCA1</i> and 	<p>Genetic counseling is strongly recommended prior to these tests in order to inform persons being tested about the advantages and limitations of the test as applied to a unique person.</p> <p>Single gene testing and known mutation testing for familial cancer is proven and medically necessary.</p> <p>Hereditary Breast and Ovarian Cancer Panel Testing</p> <p>Genetic testing Panels for High Penetrance Breast Cancer Susceptibility Genes for individuals with a personal history of a BRCA-Related Cancer are proven and medically necessary in the following situations:</p> <ul style="list-style-type: none"> • At least one first- or second-degree relative with a BRCA-Related Cancer; or • Ashkenazi Jewish ancestry; or • An unknown or Limited Family History; or • A BRCA 1/2 pathogenic mutation detected in tumor tissue; or • A personal history of pancreatic cancer; or • Men with a personal history of Breast Cancer; or • Men with a personal history of metastatic prostate cancer; or • Women with a personal history of Ovarian Cancer; or • Women with a personal history of Breast Cancer in any of the following situations: <ul style="list-style-type: none"> ○ Metastatic Breast Cancer; or

Medical Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Genetic Testing for Hereditary Cancer (continued)	Jan. 1, 2022	<p><i>BRCA2</i> or <i>Multi-Gene</i> hereditary cancer Panels with RNA testing is unproven and not medically necessary for all indications” with “RNA Panel testing for hereditary cancers is unproven and not medically necessary for all indications”</p> <p><i>Hereditary Breast and Ovarian Cancer Panel Testing</i></p> <ul style="list-style-type: none"> Replaced references to “genetic testing for <i>BRCA1</i> and <i>BRCA2</i>” with “genetic testing <i>Panels</i> for <i>High Penetrance Breast Cancer Susceptibility Genes</i>” Revised list of proven and medically necessary indications for: <p>Individuals With a Personal History of a BRCA-Related Cancer</p> <ul style="list-style-type: none"> Added “women with a personal history of lobular breast cancer with personal or family history of diffuse gastric cancer” Removed “a known <i>BRCA1/BRCA2</i> mutation in a Close Blood Relative” Replaced “women with a personal history of Triple-Negative Breast Cancer diagnosed at age <i>60 or younger</i>” with “women with a personal history of Triple- 	<ul style="list-style-type: none"> Breast Cancer diagnosed at age 45 or younger; or An additional Breast Cancer primary (prior diagnosis or bilateral cancer); or Triple-Negative Breast Cancer diagnosed at any age Lobular breast cancer with personal or family history of diffuse gastric cancer Individual has a Tyrer-Cuzick, BRCAPro or Penn11 Score of 2.5% or greater for a <i>BRCA1/2</i> pathogenic variant. <p>Genetic testing Panels for High Penetrance Breast Cancer Susceptibility Genes for individuals without a personal history of a related cancer are proven and medically necessary in the following situations:</p> <ul style="list-style-type: none"> At least one first- or second-degree relative with a BRCA-Related Cancer; or Ashkenazi Jewish ancestry and at least one Close Blood Relative with a BRCA-Related Cancer; or Individual has a Tyrer-Cuzick, BRCAPro or Penn11 Score of 5% or greater for a BRCA1/2 pathogenic variant <p>Genetic testing Panels for High Penetrance Breast Cancer Susceptibility Genes are unproven and not medically necessary for all other indications including:</p> <ul style="list-style-type: none"> Screening for cancer risk for individuals not listed in the proven indications above; or Risk assessment of other cancers; or Confirmation of direct to consumer genetic testing without meeting any of the proven indications above. <p>Other Hereditary Cancer Syndrome Multi-Gene Panel Testing</p> <p>Genetic testing with a Multi-Gene hereditary cancer Panel in individuals with a personal history of a primary solid tumor cancer is proven and medically necessary if all the following criteria are met:</p> <ul style="list-style-type: none"> The suspected hereditary cancer syndromes can be diagnosed by testing two or more genes included in the specific hereditary cancer panel; and <ul style="list-style-type: none"> A personal history of at least two different primary solid tumor cancers; or

Medical Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Genetic Testing for Hereditary Cancer (continued)	Jan. 1, 2022	<p>Negative Breast Cancer diagnosed at <i>any</i> age”</p> <p>Individuals Without a Personal History of a Related Cancer</p> <ul style="list-style-type: none"> Removed “a known BRCA1/BRCA2 mutation in a Close Blood Relative” <p>Other Hereditary Cancer Syndrome Multi-Gene Panel Testing</p> <ul style="list-style-type: none"> Replaced language indicating: <ul style="list-style-type: none"> “Genetic testing with a Multi-Gene hereditary cancer Panel in individuals with a personal history of cancer is proven and medically necessary if all the [listed] criteria are met” with “genetic testing with a Multi-Gene hereditary cancer Panel in individuals with a personal history of <i>a primary solid tumor</i> cancer is proven and medically necessary if all the [listed] criteria are met” “Genetic testing with a Multi-Gene hereditary cancer Panel in individuals without a personal history of cancer is proven and medically necessary if all the [listed] criteria are met” with “genetic testing with a Multi-Gene hereditary cancer Panel in 	<ul style="list-style-type: none"> A personal history of BRCA-related cancer diagnosed at age 40 or younger; or A personal history of BRCA-related cancer and at least one Close Blood Relative with a cancer associated with Lynch Syndrome; or At least one Close Blood Relative diagnosed with a BRCA-Related Cancer at age 40 or younger; or At least two Close Blood Relatives (in addition to affected individual), on the same side of the family, diagnosed with any primary solid tumor cancer; or A personal history of cancer associated with Lynch Syndrome; or A personal history of cancer where tumor testing results demonstrate that the cancer was MSI-high or had immunohistochemical staining showing the absence of one or more mismatch repair proteins (MLH1, MSH2, MSH6 or PMS2); or A personal history of colorectal polyposis with at least 10 adenomatous polyps, at least 2 hamartomatous polyps or at least 5 serrated polyps/lesions proximal to the rectum; or The individual has a PREMM5, MMRpro or MMRpredict Score of 2.5% or greater for having a Lynch syndrome gene mutation. <p>Genetic testing with a Multi-Gene hereditary cancer Panel in individuals without a personal history of a primary solid tumor cancer is proven and medically necessary if all the following criteria are met:</p> <ul style="list-style-type: none"> The suspected hereditary cancer syndromes can be diagnosed by testing two or more genes included in the specific hereditary cancer Panel; and <ul style="list-style-type: none"> At least one first-degree relative diagnosed with at least two different primary solid tumor cancers; or At least one first- or second-degree relative diagnosed with a BRCA-Related Cancer at age 40 or younger; or At least three Close Blood Relatives, on the same side of the family, diagnosed with any primary solid tumor cancer; or At least one first-degree relative with a cancer associated with Lynch Syndrome; or

Medical Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Genetic Testing for Hereditary Cancer (continued)	Jan. 1, 2022	<p>individuals without a personal history of <i>a primary solid tumor</i> cancer is proven and medically necessary if all the [listed] criteria are met”</p> <ul style="list-style-type: none"> ● Revised coverage criteria: <ul style="list-style-type: none"> ● Individuals With a Personal History of a Primary Solid Tumor Cancer <ul style="list-style-type: none"> ○ Replaced criterion requiring: <ul style="list-style-type: none"> ▪ “A personal history of at least two different cancers (<i>e.g., Breast and Ovarian</i>)” with “a personal history of at least two different <i>primary solid tumor</i> cancers” ▪ “At least <i>three</i> Close Blood Relatives (<i>in addition to affected individual</i>) on the same side of the family diagnosed with any <i>primary solid tumor</i> cancer” with “at least <i>two</i> Close Blood Relatives on the same side of the family diagnosed with any cancer” ● Individuals Without a Personal History of a Primary Solid Tumor Cancer <ul style="list-style-type: none"> ○ Added criterion requiring at least one first-degree relative 	<ul style="list-style-type: none"> ○ At least one second-degree relative with a cancer associated with Lynch Syndrome diagnosed at age 50 or younger; or ○ At least one second-degree relative with at least two cancers associated with Lynch Syndrome; or ○ Two or more second-degree relatives with a cancer associated with Lynch Syndrome; or ○ At least one first- or second-degree relative with a clinical diagnosis of Familial Adenomatous Polyposis, Attenuated Familial Adenomatous Polyposis, Juvenile Polyposis Syndrome or Peutz-Jeghers Syndrome; or ○ The individual has a PREMM5, MMRpro or MMRpredict Score of 5% or greater for having a Lynch syndrome gene mutation. <p>Genetic testing with a Multi-Gene hereditary cancer Panel in individuals diagnosed with cancer at age 18 or younger is proven and medically necessary.</p> <p>Multi-Gene hereditary cancer Panels are unproven and not medically necessary for all other indications.</p> <p>RNA Panel testing for hereditary cancers is unproven and not medically necessary for all indications.</p>

Medical Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Genetic Testing for Hereditary Cancer (continued)	Jan. 1, 2022	<p>diagnosed with at least two different primary solid tumor cancers</p> <ul style="list-style-type: none"> ○ Replaced criterion requiring: <ul style="list-style-type: none"> ▪ “At least three Close Blood Relatives, on the same side of the family, diagnosed with any cancer” with “at least three Close Blood Relatives, on the same side of the family, diagnosed with any <i>primary solid tumor</i> cancer” ▪ “At least one <i>first- or</i> second-degree relative with a cancer associated with Lynch Syndrome diagnosed at age 50 or younger” with “at least one second-degree relative with a cancer associated with Lynch Syndrome diagnosed at age 50 or younger” ▪ “At least one <i>first- or</i> second-degree relative with at least two cancers associated with Lynch Syndrome” with “at least one second-degree relative with at least two cancers associated with 	

Medical Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Genetic Testing for Hereditary Cancer (continued)	Jan. 1, 2022	<p>Lynch Syndrome”</p> <ul style="list-style-type: none"> “Two or more <i>first- or</i> second-degree relatives with a cancer associated with Lynch Syndrome” with “two or more second-degree relatives with a cancer associated with Lynch Syndrome” <p>Definitions</p> <ul style="list-style-type: none"> Added definition of “High Penetrance Breast Cancer Susceptibility Genes” <p>Applicable Codes</p> <p><i>BRCA1 and BRCA2</i></p> <ul style="list-style-type: none"> Removed CPT codes 81212, 81215, and 81217 <p><i>Multi-Gene Panel</i></p> <ul style="list-style-type: none"> Added CPT code 81479 <p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>Description of Services</i>, <i>Clinical Evidence</i>, and <i>References</i> sections to reflect the most current information 	
Hearing Aids and Devices Including Wearable, Bone Anchored and Semi-Implantable	Jan. 1, 2022	<p>Template Update</p> <ul style="list-style-type: none"> Updated policy header to reflect the most current product branding for UnitedHealthcare Individual Exchange Plans <p>Applicable States</p> <ul style="list-style-type: none"> Revised list of applicable states: 	<p>Wearable air-conduction Hearing Aids required for the correction of a Hearing Impairment are proven and medically necessary.</p> <p>When used according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings, and precautions, the following are proven and Medically Necessary for hearing loss in an individual who is not a candidate for an air-conduction Hearing Aid:</p> <ul style="list-style-type: none"> Bilateral fully or partially implantable bone-anchored Hearing Aids for Conductive or Mixed Hearing Loss in both ears

Medical Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Hearing Aids and Devices Including Wearable, Bone Anchored and Semi-Implantable (continued)	Jan. 1, 2022	<ul style="list-style-type: none"> ○ Added language to indicate this policy applies to the states of Illinois, Louisiana and Texas (new benefit plans effective Jan. 1, 2022) ○ Removed language indicating this policy applies to the states of Virginia and Washington 	<ul style="list-style-type: none"> ● Bilateral or unilateral bone-anchored Hearing Aids utilizing a headband (without osseointegration) ● Semi-implantable electromagnetic Hearing Aid for Sensorineural Hearing Loss ● Unilateral fully or partially implantable bone-anchored Hearing Aids for Conductive or Mixed Hearing Loss in one or both ears ● Unilateral fully or partially implantable bone-anchored Hearing Aids for Sensorineural Hearing Loss in one ear <p>The following are unproven and not Medically Necessary for treating hearing loss due to insufficient evidence of efficacy:</p> <ul style="list-style-type: none"> ● Intraoral bone conduction Hearing Aids ● Laser or light-based Hearing Aids ● Totally implanted middle ear hearing systems <p>Repair/Replacement</p> <p>The original hearing aid shall be replaced by a provider only under the following conditions:</p> <ul style="list-style-type: none"> ● Routine wear on the equipment renders it non-functional and the member still requires the equipment. <ul style="list-style-type: none"> ○ Vendors/manufacturers are responsible for repairs, and replacements covered by warranty ● Replacement of Hearing Aid is for the same or similar type of equipment ● Unless otherwise stated, Hearing Aids have a Reasonable Useful Lifetime (RUL) of 3 years <p>Note: For state specific information on mandated coverage of Hearing Aids, check the member specific benefit plan.</p> <ul style="list-style-type: none"> ● The physician provides documentation that the condition of the member changes (e.g., impaired function necessitates an upgrade) <p>Repair or replacement is not covered for the following:</p> <ul style="list-style-type: none"> ● Malicious damage, neglect or abuse ● Reconditioned hearing aids <p>Equipment Upgrades</p>

Medical Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Hearing Aids and Devices Including Wearable, Bone Anchored and Semi-Implantable (continued)	Jan. 1, 2022		<ul style="list-style-type: none"> A change in the member’s medical condition and equipment needs requires the same documentation as a new request Equipment upgrades are equivalent to a new service
Infertility Diagnosis and Treatment	Jan. 1, 2022	<p>Template Update</p> <ul style="list-style-type: none"> Updated policy header to reflect the most current product branding for UnitedHealthcare Individual Exchange Plans <p>Applicable States</p> <ul style="list-style-type: none"> Revised list of applicable states to encompass new benefit plans effective Jan. 1, 2022; added language to indicate this policy applies to the states of Alabama, Florida, Georgia, Illinois, Louisiana, Michigan, and Texas <p>Coverage Rationale</p> <ul style="list-style-type: none"> Added language to indicate sperm capacitation test is unproven and not medically necessary for diagnosing or treating Infertility <p>Applicable Codes</p> <ul style="list-style-type: none"> Added CPT code 0255U <p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>Clinical Evidence</i> and <i>References</i> sections to reflect the most current information 	<p>For medical necessity reviews, refer to the Clinical Guideline titled Fertility Solutions Medical Necessity Clinical Guideline: Infertility.</p> <p>The following tests or procedures are proven and medically necessary for diagnosing or treating Infertility:</p> <ul style="list-style-type: none"> Antisperm antibodies Antral follicle count Cryopreservation of sperm, semen, or embryos for individuals who are undergoing treatment with assisted reproductive technologies or are planning to undergo therapies that threaten their reproductive health, such as cancer chemotherapy Cryopreservation of <i>mature</i> oocytes (eggs) for women under the age of 42 who are undergoing treatment with assisted reproductive technologies or are planning to undergo therapies that threaten their reproductive health, such as cancer chemotherapy Genetic screening tests: <ul style="list-style-type: none"> Cystic fibrosis gene mutations Karyotyping for chromosomal abnormalities Y-chromosome microdeletion testing Hormone level tests: <ul style="list-style-type: none"> Antimüllerian hormone (AMH) Estradiol Follicle-stimulating hormone (FSH) Luteinizing hormone (LH) Progesterone Prolactin Testosterone (total and free) Thyroid-stimulating hormone (TSH)

Medical Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Infertility Diagnosis and Treatment (continued)	Jan. 1, 2022		<ul style="list-style-type: none"> • Hysterosalpingogram (HSG) • Diagnostic hysteroscopy • Diagnostic laparoscopy with or without chromotubation • Leukocyte count in semen • Pelvic ultrasound (transabdominal or transvaginal) • Post-ejaculatory urinalysis • Scrotal, testicular or transrectal ultrasound • Semen analysis • Sonohysterogram or saline infusion ultrasound • Testicular biopsy • Vasography <p>Due to insufficient evidence of efficacy, the following are unproven and not medically necessary for diagnosing or treating Infertility:</p> <ul style="list-style-type: none"> • Co-culture of embryos • Computer-assisted sperm analysis (CASA) • Cryopreservation of immature oocytes (eggs), ovarian tissue, or testicular tissue • EmbryoGlue® • Hyaluronan binding assay (HBA) • In vitro maturation (IVM) of oocytes • Inhibin B • Postcoital cervical mucus penetration test • Reactive oxygen species (ROS) test • Sperm acrosome reaction test • Sperm capacitation test • Sperm DNA integrity/fragmentation tests [e.g., sperm chromatin structure assay (SCSA), single-cell gel electrophoresis assay (Comet), deoxynucleotidyl transferase-mediated dUTP nick end labeling assay (TUNEL), sperm chromatin dispersion (SCD) or Sperm DNA Decondensation™ Test (SDD)] • Sperm penetration assays • Uterine/endometrial receptivity testing • Treatments to improve uterine/endometrial receptivity (e.g., immunotherapy,

Medical Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Infertility Diagnosis and Treatment (continued)	Jan. 1, 2022		endometrial scratching, uterine artery vasodilation)
Omnibus Codes	Jan. 1, 2022	<p>Template Update</p> <ul style="list-style-type: none"> Updated policy header to reflect the most current product branding for UnitedHealthcare Individual Exchange Plans <p>Applicable States</p> <ul style="list-style-type: none"> Revised list of applicable states to encompass new benefit plans effective Jan. 1, 2022; added language to indicate this policy applies to the states of Alabama, Florida, Georgia, Illinois, Louisiana, Michigan, and Texas <p>Coverage Rationale</p> <ul style="list-style-type: none"> Added guidelines for: <ul style="list-style-type: none"> <i>3D Volumetric Imaging and Reconstruction of Breast or Axillary Lymph Node Tissue (CPT code 0694T) (new to policy)</i> <ul style="list-style-type: none"> Added language to indicate three-dimensional (3D) volumetric imaging and reconstruction of breast or axillary lymph node tissue is unproven and not medically necessary due to insufficient evidence of safety and/or efficacy 	Refer to the policy for complete details.

Medical Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Omnibus Codes (continued)	Jan. 1, 2022	<p><i>Comprehensive Full-Body Motion Analysis (CPT code 0693T) (new to policy)</i></p> <ul style="list-style-type: none"> ○ Added language to indicate comprehensive full-body, computer-based, markerless 3D kinematic and kinetic motion analysis is unproven and not medically necessary for all indications due to insufficient evidence of safety and/or efficacy <p><i>External Upper Limb Tremor Stimulators of the Peripheral Nerves of the Wrist (CPT codes K1018 and K1019) (new to policy)</i></p> <ul style="list-style-type: none"> ○ Added language to indicate external upper limb tremor stimulators of the peripheral nerves of the wrist and the related monthly supplies to treat essential tremor are unproven and not medically necessary due to insufficient evidence of safety and/or efficacy <p><i>PureWick™ Female External Catheter and the PureWick™ Urine Collection System (CPT code K1006) (new to policy)</i></p>	

Medical Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Omnibus Codes (continued)	Jan. 1, 2022	<ul style="list-style-type: none"> ○ Added language to indicate the PureWick™ Female External Catheter and the PureWick™ Urine Collection System are unproven and not medically necessary for managing urinary incontinence due to insufficient evidence of efficacy <i>Radiofrequency (RF) Therapy (CPT codes 0672T, 53860, 53899, and 58999) (new to policy)</i> ○ Added language to indicate radiofrequency (RF) therapy, including but not limited to cryogen-cooled monopolar radiofrequency (CMRF), monopolar RF, multipolar RF, RF-lifting and temperature controlled RF therapies for the treatment of stress urinary incontinence (SUI) is unproven and not medically necessary due to insufficient evidence of safety and/or efficacy ● Updated list of applicable CPT codes for: <ul style="list-style-type: none"> <i>Aquapheresis (Ultrafiltration) (CPT codes 0692T, 37799, and 90999)</i> ○ Added 0692T (annual edit) <i>UroCuff Test (CPT codes</i> 	

Medical Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Omnibus Codes (continued)	Jan. 1, 2022	<p>53899 and 55899)</p> <ul style="list-style-type: none"> ○ Added 55899 <p>Supporting Information</p> <ul style="list-style-type: none"> ● Updated <i>Clinical Evidence</i> and <i>References</i> sections to reflect the most current information for Implantable Cardiac Devices for Percutaneous Closure (Occlusion) of the Left Atrial Appendage (LAA) (CPT codes 33340 and 33999) 	
Pharmacogenetic Testing	Jan. 1, 2022	<p>Template Update</p> <ul style="list-style-type: none"> ● Updated policy header to reflect the most current product branding for UnitedHealthcare Individual Exchange Plans ● Removed <i>CMS</i> section <p>Applicable States</p> <ul style="list-style-type: none"> ● Revised list of applicable states to encompass new benefit plans effective Jan. 1, 2022; added language to indicate this policy applies to the states of Alabama, Florida, Georgia, Illinois, Louisiana, Michigan, and Texas <p>Coverage Rationale</p> <ul style="list-style-type: none"> ● Added language to indicate the use of the PrismRA[®] molecular signature test is unproven and not medically necessary for evaluating likelihood of inadequate response to anti-TNF therapies for rheumatoid arthritis due to 	<p>The use of pharmacogenetic Multi-Gene Panels to guide therapy decisions is proven and medically necessary for antidepressant and antipsychotic medications when all the following criteria are met:</p> <ul style="list-style-type: none"> ● The individual has a diagnosis of major depressive disorder or generalized anxiety disorder; and ● The individual has failed at least one prior medication to treat their condition; and ● The Multi-Gene Panel has no more than 15 relevant genes <p>The use of pharmacogenetic Multi-Gene Panels for genetic polymorphisms for any other indication, including but not limited to pain management, cardiovascular drugs, anthracyclines, or polypharmacy, is unproven and not medically necessary for evaluating drug-metabolizer status due to insufficient evidence of efficacy.</p> <p>Examples of these Panels include, but are not limited to the following:</p> <ul style="list-style-type: none"> ● GeneSight[®] Analgesic ● GeneSight[®] ADHD ● SureGene Test ● Pain Medication DNA Insights[®] ● PharmacoDx ● NeuroIDgenetix

Medical Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Pharmacogenetic Testing (continued)	Jan. 1, 2022	<p>insufficient evidence of efficacy</p> <p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>Clinical Evidence</i> and <i>References</i> sections to reflect the most current information 	<p>The use of the PrismRA® molecular signature test is unproven and not medically necessary for evaluating likelihood of inadequate response to anti-TNF therapies for rheumatoid arthritis due to insufficient evidence of efficacy.</p>
Visual Information Processing Evaluation and Orthoptic and Vision Therapy	Jan. 1, 2022	<p>Template Update</p> <ul style="list-style-type: none"> Updated policy header to reflect the most current product branding for UnitedHealthcare Individual Exchange Plans Removed <i>CMS</i> section <p>Applicable States</p> <ul style="list-style-type: none"> Revised list of applicable states to encompass new benefit plans effective Jan. 1, 2022; added language to indicate this policy applies to the states of Alabama, Florida, Georgia, Illinois, Louisiana, Michigan, and Texas <p>Coverage Rationale</p> <ul style="list-style-type: none"> Revised list of unproven and not medically necessary indications: <ul style="list-style-type: none"> Added “remote, online and/or digital therapy for Amblyopia” Replaced “visual information processing to diagnose reading or learning disabilities” with “visual information processing <i>evaluation</i> to diagnose reading or <i>other</i> learning disabilities” <p>Definitions</p>	<p>Some plans specifically exclude benefits for vision therapy (orthoptic training). Check benefit plan descriptions for allowable number of visits where benefit is available.</p> <p>The following are proven and medically necessary:</p> <ul style="list-style-type: none"> Occlusion Therapy or Pharmacologic Penalization Therapy for treating Amblyopia Orthoptic Therapy or Vision Therapy for treating Convergence Insufficiency Prism Adaptation Therapy for treating Esotropia <p>The following are unproven and not medically necessary due to insufficient evidence of efficacy:</p> <ul style="list-style-type: none"> Orthoptic Therapy or Vision Therapy for treating all other indications not listed above Virtual perception therapy for treating any type of learning disability or language disorder Vision Restoration Therapy (VRT) for treating visual field deficits following stroke or neurotrauma Visual information processing evaluation to diagnose reading or other learning disabilities Remote, online and/or digital therapy for Amblyopia

Medical Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Visual Information Processing Evaluation and Orthoptic and Vision Therapy (continued)	Jan. 1, 2022	<ul style="list-style-type: none"> Updated definition of: <ul style="list-style-type: none"> Amblyopia Esotropia Occlusion Therapy Orthoptic Therapy Pharmacologic Penalization Therapy Vision Restoration Therapy (VRT) Vision Therapy Applicable Codes <ul style="list-style-type: none"> Updated list of applicable CPT codes to reflect annual edits; added 0687T, 0688T, 0704T, 0705T, and 0706T Supporting Information <ul style="list-style-type: none"> Updated Description of Services, Clinical Evidence, and References sections to reflect the most current information 	
Retired			
Policy Title	Effective Date	Summary of Changes	
Chemosensitivity and Chemoresistance Assays in Cancer	Nov. 1, 2022	<ul style="list-style-type: none"> Policy retired; chemosensitivity and chemoresistance assays no longer require clinical review 	

Medical Benefit Drug Policy Updates

Updated																			
Policy Title	Effective Date	Summary of Changes																	
Intravenous Iron Replacement Therapy (Feraheme®, Injectafer®, & Monoferric®)	Nov. 1, 2021	Applicable Codes <ul style="list-style-type: none"> Removed HCPCS codes C9399 and J3490 																	
Revised																			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale																
Antiemetics for Oncology	Dec. 1, 2021	Coverage Rationale Medical Necessity Plans <ul style="list-style-type: none"> Changed product status for Aloxi injection from “non-preferred” to “preferred” 	<p>This policy refers to the following products used as antiemetics for oncology use:</p> <ul style="list-style-type: none"> Akynzeo® (palonosetron/fosnetupitant) injection Akynzeo® (palonosetron/netupitant) capsule Aloxi® (palonosetron) injection Cinvanti™ (aprepitant) injectable emulsion Emend® (fosaprepitant) injection, capsule Sustol® (granisetron extended release) injection Kytril® (granisetron) injection, tablets Varubi® (rolapitant) tablet Zofran® (ondansetron) injection, tablets <p>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.</p> <table border="1"> <thead> <tr> <th>Preferred Product(s)</th> <th>Non-Preferred Product(s)</th> </tr> </thead> <tbody> <tr> <td colspan="2">Neurokinin 1 Receptor Antagonist (NK1 RA)</td> </tr> <tr> <td>Emend injection</td> <td>Cinvanti injectable emulsion</td> </tr> <tr> <td>Emend capsules</td> <td>Varubi tablets</td> </tr> <tr> <td colspan="2">5-Hydroxytryptamine Receptor Antagonist (5HT3 RA)</td> </tr> <tr> <td>Aloxi injection</td> <td>Sustol injection</td> </tr> <tr> <td>Kytril injection</td> <td></td> </tr> <tr> <td>Kytril tablets</td> <td></td> </tr> </tbody> </table>	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	Sustol injection	Kytril injection		Kytril tablets	
Preferred Product(s)	Non-Preferred Product(s)																		
Neurokinin 1 Receptor Antagonist (NK1 RA)																			
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Kytril injection																			
Kytril tablets																			

Medical Benefit Drug Policy Updates

Revised				
Policy Title	Effective Date	Summary of Changes	Coverage Rationale	
Antiemetics for Oncology (continued)	Dec. 1, 2021		Zofran injection	
			Zofran tablets	
			NK1 RA/5HT3 RA Combination	
			Akynzeo injection	
			Akynzeo capsule	
			<p>Coverage for antiemetics will be provided contingent on the coverage criteria in the Diagnosis-Specific Criteria section.</p> <p>Preferred Product</p> <p>Coverage for Cinvanti and Varubi will be provided contingent on the criteria in this section and the coverage criteria in the Diagnosis-Specific Criteria section.</p> <p>Coverage of Aloxi and Sustol will be provided contingent on the criteria in this section and the coverage criteria in the Diagnosis-Specific Criteria section.</p> <p>NK1 RA/5HT3 RA combination (Akynzeo): Coverage of Akynzeo will be provided contingent on the criteria in this section and the coverage criteria in the Diagnosis-Specific Criteria section.</p> <p>Preferred Product Criteria</p> <p>Treatment with non-preferred NK1 RA, 5HT3 RA, or NK1 RA/5HT3 RA combination product is medically necessary for the indications specified in the policy when <i>one</i> of the following is met:</p> <ul style="list-style-type: none"> ● Both of the following: <ul style="list-style-type: none"> ○ 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: 	

Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Antiemetics for Oncology (continued)	Dec. 1, 2021		<ul style="list-style-type: none"> ○ 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. <p>Diagnosis-Specific Criteria</p> <p>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.</p> <p>Antiemetics are proven and medically necessary for the following indications:</p> <p>NK1 RA (Emend, Cinvanti, Varubi) may be indicated when one of following are present:</p> <ul style="list-style-type: none"> ● Both of the following: <ul style="list-style-type: none"> ○ Prevention of chemotherapy-induced nausea and vomiting due to High Emetic Risk parenteral anticancer agents; and ○ In combination with a 5HT3 RA; <p>or</p> ● All of the following: <ul style="list-style-type: none"> ○ 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: <ul style="list-style-type: none"> ▪ 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 <p>5HT3 RA (Aloxi, Kytril, Sustol, Zofran) may be indicated when one of the following are present:</p>

Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Antiemetics for Oncology (continued)	Dec. 1, 2021		<ul style="list-style-type: none"> ● Both of the following: <ul style="list-style-type: none"> ○ Prevention of chemotherapy-induced nausea and vomiting due to High Emetic Risk parenteral anticancer agents; and ○ In combination with a NK1 RA or ● Prevention of chemotherapy-induced nausea and vomiting due to Moderate Emetic Risk parenteral anticancer agents or ● All of the following: <ul style="list-style-type: none"> ○ Prevention of chemotherapy-induced nausea and vomiting due to Moderate Emetic Risk parenteral anticancer agents; and ○ In combination with a NK1 RA; and <ul style="list-style-type: none"> ▪ One of the risk factors for anticancer-agent induced nausea/vomiting: <ul style="list-style-type: none"> - 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 ○ Treatment of breakthrough nausea and/or vomiting due to anticancer agent(s) <p>NK1 RA/5HT3 RA combination product (Akynzeo) may be indicated when one of the following are present:</p> <ul style="list-style-type: none"> ● Prevention of chemotherapy-induced nausea and vomiting due to High Emetic Risk parenteral anticancer agents; or ● Both of the following: <ul style="list-style-type: none"> ○ 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: <ul style="list-style-type: none"> ▪ Younger age (< 55 years)

Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Antiemetics for Oncology (continued)	Dec. 1, 2021		<ul style="list-style-type: none"> ▪ 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
Maximum Dosage and Frequency	Dec. 1, 2021	<p>Coverage Rationale</p> <ul style="list-style-type: none"> • Revised list of: <ul style="list-style-type: none"> <i>Maximum Allowed Quantities by HCPCS Units</i> Simponi Aria (golimumab) <ul style="list-style-type: none"> ○ Changed maximum allowed amount from “256 HCPCS units” to “300 HCPCS units” Xolair (omalizumab) <ul style="list-style-type: none"> ○ Added: <ul style="list-style-type: none"> ▪ Diagnosis: Nasal polyps ▪ Maximum Dosage Per Administration: 600 mg ▪ HCPCS Code: J2357 ▪ Maximum Allowed: 120 HCPCS units (5 mg per unit) <i>Maximum Allowed Quantities for National Drug Code (NDC) Billing</i> Rituxan (rituximab) <ul style="list-style-type: none"> ○ Replaced NDC “50242-0051-01” with “50242-0051-10” (code correction only) Reclast/Zometa (zoledronic acid) <ul style="list-style-type: none"> ○ Replaced NDC “00078-0425- 	Refer to the policy for complete details.

Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Maximum Dosage and Frequency (continued)	Dec. 1, 2021	<p>61” with “00078-0435-61” (code correction only)</p> <p>Xolair (omalizumab)</p> <p><i>Asthma</i></p> <ul style="list-style-type: none"> ○ Revised values for: <ul style="list-style-type: none"> ▪ NCD 50242-0040-62: Replaced <i>Maximum Allowed</i> amount of “2 vials” with “3 vials” ▪ NCD 50242-0214-01: <ul style="list-style-type: none"> - Changed <i>How Supplied</i> value from “75 mg PFS” to “75 mg/0.5 mL PFS” - Changed maximum allowed amount from “1 mL” to “0.5 mL” ▪ NCDs 50242-0215-01 and 50242-0215-86: Changed <i>How Supplied</i> value from “150 mg PFS” with “150 mg/ 1 mL PFS” <p><i>Chronic Urticaria</i></p> <ul style="list-style-type: none"> ○ Removed NDC 0242-0214-01 ○ Revised NCDs 50242-0215-01 and 50242-0215-86: Changed <i>How Supplied</i> value from “150 mg PFS” to “150 mg/1 mL PFS” <p><i>Nasal Polyps</i></p> <ul style="list-style-type: none"> ○ Added: <ul style="list-style-type: none"> ▪ NDC 50242-0040-62: <ul style="list-style-type: none"> - How Supplied: 150 mg 	

Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Maximum Dosage and Frequency (continued)	Dec. 1, 2021	<ul style="list-style-type: none"> vials - Maximum Allowed: 4 vials ▪ NDC 50242-0214-01: <ul style="list-style-type: none"> - How Supplied: 75 mg/0.5 mL pre-filled syringe (PFS) - Maximum Allowed: 0.5 mL ▪ NDC 50242-0215-01: <ul style="list-style-type: none"> - How Supplied: 150 mg/1 mL PFS - Maximum Allowed: 4 mL <p><i>Maximum Allowed Frequencies</i></p> <p>Simponi Aria (golimumab)</p> <ul style="list-style-type: none"> ○ Added maximum frequency for the diagnosis of juvenile idiopathic arthritis to allow administration at 0, 4, then every 8 weeks thereafter <p>Xolair (omalizumab)</p> <ul style="list-style-type: none"> ○ Added maximum frequency for the diagnosis of nasal polyps to allow administration once every 2 or 4 weeks, depending on body weight and IgE levels <p>Supporting Information</p> <ul style="list-style-type: none"> ● Updated <i>References</i> section to reflect the most current information 	

Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Self-Administered Medications	Jan. 1, 2022	<p>Template Update</p> <ul style="list-style-type: none"> Updated policy header to reflect the most current product branding for UnitedHealthcare Individual Exchange Plans Added <i>Benefit Considerations</i> section Removed <i>CMS</i> section <p>Applicable States</p> <ul style="list-style-type: none"> Revised list of applicable states to encompass new benefit plans effective Jan. 1, 2022; added language to indicate this policy applies to the states of Alabama, Florida, Georgia, Illinois, Louisiana, Michigan, and Texas <p>Applicable Codes</p> <ul style="list-style-type: none"> Revised <i>Self-Administered Medication List</i> (medications that are usually self-administered and excluded from payment) <ul style="list-style-type: none"> For All States <ul style="list-style-type: none"> Removed HCPCS code C9399 For the States of Illinois, Maryland, and North Carolina Only <ul style="list-style-type: none"> Added: <ul style="list-style-type: none"> Bravelle (urofollitropin) (HCPCS code J3355) Cetrotide (cetorelix acetate) (HCPCS code J3490) 	<p>Self-administered medications are excluded from standard medical benefit plans.</p> <p>We will determine if a medication is self-administered based on the following:</p> <ul style="list-style-type: none"> Medication is not typically administered or directly supervised by a qualified provider or licensed/certified health professional in an outpatient setting; and Medication does not require continuous or periodic monitoring immediately before, during, or after administration by a qualified provider or licensed/certified health professional in an outpatient setting; and Route of administration (e.g., oral, inhaled, intranasal, topical, rectal, subcutaneous or self-injectable intramuscular injections); and Dosage form (e.g., prefilled syringe, auto-injector, tablet, capsule, suppository, nasal spray, metered dose inhaler, nebulized solution); and Acuity of condition (e.g., chronic disease); and Frequency of administration; and The medication is not specifically allowed under the medical benefit; and Standards of medical practice allowing for self-administration (e.g., self-infused hemophilia factor); and Evaluation of any established medical literature or compendia including but not limited to: <ul style="list-style-type: none"> FDA approved prescribing information Manufacturer provided medical literature Peer reviewed medical literature Evidence-based practice guidelines Self-administration utilization statistics Compendia (e.g., IBM Micromedex® DRUGDEX®, Clinical Pharmacology)

Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Self-Administered Medications (continued)	Jan. 1, 2022	<ul style="list-style-type: none"> ▪ Follistim AQ (follitropin beta) (HCPCS codes J3490 and S0128) ▪ Ganirelix acetate (HCPCS codes J3490 and S0132) ▪ Gonal-f (all formulations) (follitropin alfa) (HCPCS codes J3490 and S0126) ▪ Menopur (menotropins) (HCPCS codes J3490 and S0122) ▪ Novarel (chorionic gonadotropin) (HCPCS code J0725) ▪ Ovidrel (choriogonadotropin alpha) (HCPCS code J3490) ▪ Pregnyl (chorionic gonadotropin) (HCPCS code J0725) ○ Removed Vyleesi (bremelanotide) (HCPCS code J3490) for North Carolina only 	
Xolair® (Omalizumab)	Dec. 1, 2021	<p>Applicable Codes</p> <ul style="list-style-type: none"> • Revised list of Maximum Allowed Quantities by National Drug Code (NDC) Units; added values for: <i>NCD 50242-0214-01</i> Moderate to Severe Asthma and Nasal Polyps ○ How Supplied: 75 mg/0.5 mL pre-filled syringe (PFS) 	Refer to the policy for complete details.

Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Xolair® (Omalizumab) (continued)	Dec. 1, 2021	<ul style="list-style-type: none"> ○ Maximum Allowed: 0.5 mL <p><i>NCD 50242-0215-01 and NCD 50242-0215-86</i></p> <p>Chronic Urticaria and Moderate to Severe Asthma</p> <ul style="list-style-type: none"> ○ How Supplied: 150 mg/1 mL PFS ○ Maximum Allowed: 2 mL <p>Nasal Polyps</p> <ul style="list-style-type: none"> ○ How Supplied: 150 mg/1 mL PFS ○ Maximum Allowed: 4 mL 	

Coverage Determination Guideline Updates

New		
Policy Title	Effective Date	Coverage Rationale
Fertility Preservation for Iatrogenic Infertility	Jan. 1, 2022	<p>Indications for Coverage</p> <p>Certain plans may include coverage for fertility preservation. Refer to the member specific benefit plan document to determine if this coverage applies.</p> <p><i>Fertility Preservation for Iatrogenic Infertility</i></p> <p>Benefits are available for fertility preservation for medical reasons that cause irreversible infertility such as chemotherapy, radiation treatment, and bilateral oophorectomy due to cancer. Services include the following procedures, when provided by or under the care or supervision of a Physician:</p> <ul style="list-style-type: none"> • Collection of sperm • Cryo-preservation of sperm • Ovarian stimulation, retrieval of eggs and fertilization • Oocyte cryo-preservation • Embryo cryo-preservation <p>Benefits for medications related to the treatment of fertility preservation are considered under the Outpatient Prescription Drug benefit or under the Pharmaceutical Products. Check the member specific benefit plan document for inclusion or exclusion.</p> <p>For medical necessity criteria, refer to the Fertility Solutions Medical Necessity Clinical Guideline: Infertility.</p> <p>Coverage Limitations and Exclusions</p> <ul style="list-style-type: none"> • Benefits are not available for embryo transfer • Benefits are not available for long-term storage costs (greater than one year) • Benefits are further limited to one cycle of fertility preservation for Iatrogenic Infertility per covered person during the entire period of time he or she is enrolled for coverage under the policy
Gender Dysphoria (Gender Identity Disorder) Treatment (for Washington Only)	Jan. 1, 2022	<p>Effective June 25, 2014</p> <p>Washington Office of the Insurance Commissioner, Commissioner’s Letter Gender Identity Non Discrimination Requirements: https://www.insurance.wa.gov/sites/default/files/documents/gender-identity-discrimination-letter.pdf</p> <p>Washington Administrative Code 284-43-5622 https://apps.leg.wa.gov/wac/default.aspx?cite=284-43-5622</p> <p>A health benefit plan must not be offered if the commissioner determines that:</p> <p>(a) It creates a risk of biased selection based on health status;</p>

Coverage Determination Guideline Updates

New		
Policy Title	Effective Date	Coverage Rationale
Gender Dysphoria (Gender Identity Disorder) Treatment (for Washington Only) (continued)	Jan. 1, 2022	<p>(b) The benefits within an essential health benefit category are limited so that the coverage for the category is not a meaningful health benefit; or</p> <p>(c) The benefit has a discriminatory effect in practice, outcome or purpose in relation to age, present or predicted disability, and expected length of life, degree of medical dependency, quality of life or other health conditions, race, gender, national origin, sexual orientation and gender identity or in the application of Section 511 of Public Law 110-343 (the federal Mental Health Parity and Addiction Equity Act of 2008).</p>
Preimplantation Genetic Testing and Related Services	Jan. 1, 2022	<p>Indications for Coverage</p> <p>Certain plans may include coverage for:</p> <ul style="list-style-type: none"> • Preimplantation genetic testing • PGT-M or PGT-SR. PGT-M or PGT-SR as it may be considered a covered expense if the fetus is at risk for a genetic disorder <p>Refer to the member specific benefit plan document to determine if the coverage applies.</p> <p><i>Preimplantation Genetic Testing (PGT) and Related Services</i></p> <p>Preimplantation Genetic Testing (PGT) performed to identify and to prevent genetic medical conditions from being passed onto offspring. To be eligible for benefits the following must be met:</p> <ul style="list-style-type: none"> • PGT must be ordered by a Physician after genetic counseling • The genetic medical condition, if passed onto offspring, would result in significant health problems or severe disability and be caused by a single gene (detectable by PGT-M) or structural changes of a parents' chromosome (detectable by PGT-SR) • Benefits are limited to PGT for the specific genetic disorder and the following related services when provided by or under the supervision of a Physician: <ul style="list-style-type: none"> ○ Ovulation induction (or controlled ovarian stimulation) ○ Egg retrieval, fertilization and embryo culture ○ Embryo biopsy ○ Embryo transfer ○ Cryo-preservation and short-term embryo storage (less than one year) <p>Refer to the Medical Policy titled <i>Preimplantation Genetic Testing</i> for additional information.</p> <p>For medical necessity criteria, refer to the Fertility Solutions Medical Necessity Clinical Guideline: Infertility.</p> <p>Coverage Limitations and Exclusions</p> <ul style="list-style-type: none"> • Benefits are not available for long-term storage costs (greater than one year)

Coverage Determination Guideline Updates

New		
Policy Title	Effective Date	Coverage Rationale
Preimplantation Genetic Testing and Related Services (continued)	Jan. 1, 2022	<ul style="list-style-type: none"> Benefits are not available for Preimplantation Genetic Testing – Aneuploidy (PGT-A)
Updated		
Policy Title	Effective Date	Summary of Changes
Breast Reconstruction Post Mastectomy and Poland Syndrome	Nov. 1, 2021	<p>Related Policies</p> <ul style="list-style-type: none"> Added reference link to the Coverage Determination Guideline titled <i>Gynecomastia Treatment</i> <p>Coverage Rationale</p> <ul style="list-style-type: none"> Updated list of examples of a dermal matrix; replaced “Allomax” with “Cortiva® (AlloMax™)”
Enteral Nutrition	Jan. 1, 2022	<p>Template Update</p> <ul style="list-style-type: none"> Updated policy header to reflect the most current product branding for UnitedHealthcare Individual Exchange Plans <p>Applicable States</p> <ul style="list-style-type: none"> Revised list of applicable states to encompass new benefit plans effective Jan. 1, 2022; added language to indicate this policy applies to the states of Alabama, Florida, Georgia, Illinois, Louisiana, Michigan, and Texas <p>Coverage Rationale</p> <p><i>Coverage Limitations and Exclusions</i></p> <ul style="list-style-type: none"> Added notation to indicate Illinois provides coverage for donor breast milk; refer to the member specific benefit plan document for coverage
Hospice Care	Jan. 1, 2022	<p>Template Update</p> <ul style="list-style-type: none"> Updated policy header to reflect the most current product branding for UnitedHealthcare Individual Exchange Plans <p>Applicable States</p> <ul style="list-style-type: none"> Revised list of applicable states to encompass new benefit plans effective Jan. 1, 2022; added language to indicate this policy applies to the states of Alabama, Florida, Georgia, Illinois, Louisiana, Michigan, and Texas <p>Coverage Rationale</p> <p><i>Covered Hospice Services</i></p> <ul style="list-style-type: none"> Updated list of examples of core hospice services; added “hospice referral visit” <p>Applicable Codes</p> <ul style="list-style-type: none"> Added HCPCS codes S0255 and S9126

Coverage Determination Guideline Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Clinical Trials	Jan. 1, 2022	<p>Template Update</p> <ul style="list-style-type: none"> Updated policy header to reflect the most current product branding for UnitedHealthcare Individual Exchange Plans <p>Applicable States</p> <ul style="list-style-type: none"> Revised list of applicable states to encompass new benefit plans effective Jan. 1, 2022; added language to indicate this policy applies to the states of Alabama, Florida, Georgia, Illinois, Louisiana, Michigan, and Texas <p>Coverage Rationale</p> <p><i>Criteria for Approved Clinical Trials</i></p> <ul style="list-style-type: none"> Revised coverage criteria; added language to indicate: <ul style="list-style-type: none"> Louisiana <ul style="list-style-type: none"> The clinical trial must have a written protocol that describes a scientifically sound study: <ul style="list-style-type: none"> [The clinical trial] must have been approved by all relevant institutional review boards (IRBs) which operates in Louisiana and which has a multiple project assurance contracts approved by the Office of Protection from research risks before you 	Refer to the policy for complete details.

Coverage Determination Guideline Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Clinical Trials (continued)	Jan. 1, 2022	<ul style="list-style-type: none"> are enrolled in the trial <ul style="list-style-type: none"> ▪ [UnitedHealthcare] may, at any time, request documentation about the trial ○ Facility and personnel providing the protocol must provide the treatment within their scope of practice, experience, and training; they must be capable of doing so by virtue of their experience, training and volume of patients treated to maintain expertise ○ There must be no clearly superior, non-investigational approach ○ The available clinical or pre-clinical data provide a reasonable expectation that the treatment will be at least as efficacious as the non-investigational alternative ○ The covered person has signed an IRB approved consent form <p>North Carolina</p> <ul style="list-style-type: none"> ○ Covered Clinical Trials must be conducted in a setting and by personnel that maintain a high level of expertise because of their training, experience, and volume of patients 	

Coverage Determination Guideline Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Clinical Trials (continued)	Jan. 1, 2022	<ul style="list-style-type: none"> ○ The drug, however, must be approved by the FDA and must have been proven effective and accepted for treatment of the specific type of cancer for which the drug has been prescribed in any one of the following established reference compendia: <ul style="list-style-type: none"> ▪ The National Comprehensive Cancer Network Drugs & Biologics Compendium ▪ The Thomson Micromedex DrugDex ▪ The Elsevier Gold Standard's Clinical Pharmacology ▪ Any other authoritative compendia as recognized periodically by the United States Secretary of Health and Human Services Virginia ○ An institutional review board of an institution in the Commonwealth of Virginia that has a multiple project assurance contract approved by the Office of Protection from Research Risks of the NCI 	

Coverage Determination Guideline Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/ Replacements	Jan. 1, 2022	<p>Template Update</p> <ul style="list-style-type: none"> Updated policy header to reflect the most current product branding for UnitedHealthcare Individual Exchange Plans <p>Applicable States</p> <ul style="list-style-type: none"> Revised list of applicable states to encompass new benefit plans effective Jan. 1, 2022; added language to indicate this policy applies to the states of Alabama, Florida, Georgia, Illinois, Louisiana, Michigan, and Texas <p>Coverage Rationale</p> <p><i>Mobility Devices</i></p> <ul style="list-style-type: none"> Added language to clarify mobility assistive equipment including manual wheelchairs, power wheelchairs, transfer chairs, scooters/power-operated vehicles (POV), canes, and walkers <i>may be</i> a Covered Health Care Service when Medically Necessary: <ul style="list-style-type: none"> For power mobility devices, refer to the Coverage Determination Guideline titled <i>Power Mobility Devices</i> For manual wheelchairs, refer to the Coverage Determination Guideline titled <i>Manual Wheelchairs</i> <i>These documents include state-specific applicability,</i> 	Refer to the policy for complete details.

Coverage Determination Guideline Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/ Replacements (continued)	Jan. 1, 2022	<p>check the member specific benefit plan document for coverage</p> <p><i>Orthotic Braces</i></p> <ul style="list-style-type: none"> • Added language to indicate: <ul style="list-style-type: none"> ○ Orthotic braces that stabilize an injured body part and braces to treat curvature of the spine are considered DME; refer to <i>Coverage Limitations and Exclusions</i> section of the policy ○ Examples of orthotic braces include but are not limited to: <ul style="list-style-type: none"> ▪ Ankle Foot Orthotic (AFO) ▪ Knee orthotics (KO) ▪ Lumbar-sacral orthotic (LSO) ▪ Necessary adjustments to shoes to accommodate braces ▪ Thoracic-lumbar-sacral orthotic (TLSO) ○ There are specific codes defined by HCPCS as orthotics that UnitedHealthcare covers as DME <p><i>Ventilators and Respiratory Assist Devices</i></p> <ul style="list-style-type: none"> • Added language to indicate the coverage guidelines in this section of the policy apply to individuals 2 years of age and older 	

Coverage Determination Guideline Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/ Replacements (continued)	Jan. 1, 2022	<ul style="list-style-type: none"> Replaced language indicating “ventilators are not covered when used to deliver continuous or intermittent positive airway pressure” with “ventilators are not covered when used <i>only</i> to deliver continuous or intermittent positive airway pressure <i>for adults and children 2 years of age and older</i>” <p>Supporting Information</p> <ul style="list-style-type: none"> Updated <i>References</i> section to reflect the most current information 	
Habilitative Services and Outpatient Rehabilitation Therapy	Jan. 1, 2022	<p>Template Update</p> <ul style="list-style-type: none"> Updated policy header to reflect the most current product branding for UnitedHealthcare Individual Exchange Plans <p>Applicable States</p> <ul style="list-style-type: none"> Revised list of applicable states to encompass new benefit plans effective Jan. 1, 2022; added language to indicate this policy applies to the states of Alabama, Florida, Georgia, Illinois, Louisiana, Michigan, and Texas <p>Coverage Rationale</p> <ul style="list-style-type: none"> Removed medical necessity criteria for Physical and Occupational Therapy <p>Indications for Coverage</p> <ul style="list-style-type: none"> Replaced language indicating “for plans that provide coverage for habilitative services, benefits are provided <i>for inpatient and outpatient habilitative services</i> when all of the [listed] criteria are met” with “for plans that provide coverage for habilitative services <i>and/or outpatient rehabilitation therapy</i>, benefits are provided when all of the [listed] criteria are met” <p>Treatment Plan</p> <ul style="list-style-type: none"> Added language to indicate: <ul style="list-style-type: none"> [UnitedHealthcare] may require that a treatment plan be provided, request medical records, clinical notes, or other necessary data to allow us to substantiate that initial or continued medical treatment is Medically Necessary: <ul style="list-style-type: none"> When the treating provider expects that continued treatment is or will be required to allow the covered person to achieve progress that is capable of being demonstrated (measurable progress), we may request a treatment plan that includes: <ul style="list-style-type: none"> Diagnosis 	

Coverage Determination Guideline Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Habilitative Services and Outpatient Rehabilitation Therapy (continued)	Jan. 1, 2022	<ul style="list-style-type: none"> - Expected treatment goals - Frequency of treatment plan updates - Proposed treatment by type, frequency, and expected duration of treatment o Certain state mandates may limit the frequency for requesting plan treatment progress <p><i>Habilitative Services</i></p> <ul style="list-style-type: none"> • Revised list of benefits for outpatient and inpatient habilitative services; added: <ul style="list-style-type: none"> o Cognitive therapy o Manipulative treatment • Added language to indicate certain plans may not include coverage for all of the [listed therapies] and state mandates may require coverage for the therapies not [listed in the policy] <p><i>Speech Therapy – Habilitative</i></p> <ul style="list-style-type: none"> • Replaced language indicating “speech <i>and language</i> therapy for the treatment of disorders of speech, language, voice, communication and auditory processing are covered [when criteria are met]” with “<i>habilitative</i> speech therapy for the treatment of disorders of speech, language, voice, communication and auditory processing are covered [when criteria are met]” • Revised list of covered indications: <ul style="list-style-type: none"> o Updated list of examples of congenital anomalies; added “tongue tie” o Removed: <ul style="list-style-type: none"> ▪ Cancer ▪ Injury (including but not limited to the following): <ul style="list-style-type: none"> - Otitis media resulting in hearing loss documented by testing (such as audiogram or notes of such testing) - Vocal cord injuries (e.g., edema, nodules, polyps) - Trauma - Cerebral palsy - Static encephalopathy ▪ Stroke <p><i>Rehabilitation Services – Outpatient</i></p> <ul style="list-style-type: none"> • Revised list of benefits for outpatient rehabilitation services; added: <ul style="list-style-type: none"> o Cognitive rehabilitation therapy when Medically Necessary following a post-traumatic brain injury or cerebral vascular accident (stroke) o Manipulative Treatment • Added language to indicate certain plans may not include coverage for all of the [listed therapies] and state mandates may require coverage for the therapies not [listed in the policy] 	

Coverage Determination Guideline Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Habilitative Services and Outpatient Rehabilitation Therapy (continued)	Jan. 1, 2022	<p><i>Speech Therapy Criteria</i></p> <ul style="list-style-type: none"> ● Revised language to indicate: <ul style="list-style-type: none"> ○ Services of a Speech-Language Pathologist or other licensed healthcare professional acting within the scope of his/her licensure to treat the above disorders may be covered when: <ul style="list-style-type: none"> ▪ There is a need for the supervision of a licensed therapist for speech–language therapy, swallowing or feeding rehabilitative or Restorative Therapy services ▪ The services are part of a plan of care with documented goals for functional improvement of the individual’s condition, e.g., speech, articulation, swallowing or communication with or without alternative methods ▪ The teaching of an individual and/or caregiver is required to strengthen muscles, improve feeding techniques or improve speech-language skills to progress toward the documented treatment plan goals: <ul style="list-style-type: none"> - Once the individual and/or caregiver are trained, the services are no longer skilled, therefore custodial, and not a covered health service - Refer to the Coverage Determination Guideline titled <i>Skilled Care and Custodial Care Services</i> ○ Speech Therapy discharge criteria includes but is not limited to the following: <ul style="list-style-type: none"> ▪ Treatment goals and objectives have been met ▪ Speech, language, communication, or feeding and Swallowing Disorder are within normal limits or is consistent with the individual’s baseline ▪ Communication abilities have become comparable to those of others of the same chronological age and gender, ethnicity, or cultural and linguistic background ▪ The desired level of enhanced communication skills has been reached ▪ The speech, language, communication, and/or feeding and swallowing skills no longer affect the individual’s health status ▪ The individual is unwilling to participate in treatment, requests discharge, or exhibits behavior that interferes with improvement or participation in treatment (e.g., noncompliance, non-attendance) ▪ The level of service does not require a Speech-Language Pathologist or other licensed healthcare professional (within the scope of his/her licensure) ▪ The individual is unable to tolerate treatment because of a serious medical, psychological, or other condition ▪ The individual will get services from a different provider ○ Rehabilitation services or Restorative Therapy services are covered for: <ul style="list-style-type: none"> ▪ Swallowing Disorders (dysphagia) ▪ Feeding disorders including problems with gathering food and sucking, chewing, or swallowing food; for example, a child who cannot pick up food and get it to his/her mouth or cannot completely close his/her lips to keep food from falling out of his/her mouth may have a feeding disorder 	

Coverage Determination Guideline Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Habilitative Services and Outpatient Rehabilitation Therapy (continued)	Jan. 1, 2022	<ul style="list-style-type: none"> ▪ Auditory (Aural) rehabilitation which includes speech–language therapy, e.g., when an auditory implant or cochlear implant is a covered healthcare service; refer to the Medical Policy titled <i>Cochlear Implants</i> <p>Additional Information</p> <ul style="list-style-type: none"> • Revised list of applicable places of service for habilitative and rehabilitation therapy services; added: <ul style="list-style-type: none"> ○ Outpatient therapy in a Physician’s office, or other outpatient setting (outpatient hospital or Alternate Facility) ○ In an inpatient setting, these benefits are the same as the applicable inpatient benefit category in the plan (hospital inpatient, skilled nursing facility/inpatient rehabilitation facility benefit) ○ Certain states may require coverage of habilitative services in other locations • Added language to indicate: <ul style="list-style-type: none"> ○ Coverage of durable medical equipment and prosthetic devices, when used as a component of habilitative services or rehabilitation therapy, are described under the <i>Durable Medical Equipment (DME) Orthotics and Supplies or Prosthetic Devices</i> benefit sections of the member specific benefit plan document, and may require a separate review ○ Pulmonary therapy does not include respiratory therapy; respiratory therapy is a therapeutic service and not included in the benefit limits for pulmonary therapy <p>For Medical Necessity Clinical Coverage Criteria</p> <ul style="list-style-type: none"> • Revised language pertaining medical necessity clinical coverage criteria: <ul style="list-style-type: none"> ○ Added reference to the InterQual® 2021, LOC: Outpatient Rehabilitation & Chiropractic ○ Removed reference to the: <ul style="list-style-type: none"> ▪ InterQual® Client Defined 2021, LOC: Outpatient Rehabilitation & Chiropractic, Habilitation (Adult/Adolescent/School age) (Custom) - UHG ▪ InterQual® 2021, Apr. 2021 Release, LOC: Outpatient Rehabilitation & Chiropractic, Pediatric: Rehabilitation (Pediatric) <p>Coverage Limitations and Exclusions</p> <ul style="list-style-type: none"> • Revised list of exclusions for habilitative services and rehabilitation therapy to reflect/include: <ul style="list-style-type: none"> ○ Services that are considered non-skilled or Custodial Care ○ Services that are solely educational or vocational in nature or otherwise paid under state or federal law for purely educational services ○ Services that do not meet criteria for coverage as indicated in the <i>Indications for Coverage</i> section [in the policy] and the member specific benefit plan document ○ Services that are considered by UnitedHealthcare to be Unproven, Investigational or Experimental ○ Custodial Care, respite care, day care, vocational training, and residential treatment ○ Therapeutic recreation (examples include, but are not limited to arts/crafts, dance, drama, music, swimming, and 	

Coverage Determination Guideline Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Habilitative Services and Outpatient Rehabilitation Therapy (continued)	Jan. 1, 2022	<ul style="list-style-type: none"> sports) ○ Services that continue once the treatment plan goals are met ○ Physiological modalities and procedures that result in similar or redundant therapeutic effects when performed on the same body region during the same visit or office encounter; an example includes, but is not limited to, the same day combined use of hot packs, ultrasound and iontophoresis in the treatment of strain ○ Programs that do not require the supervision of Physician and/or a licensed therapy provider ○ Work Hardening ○ Confinement, treatment, services or supplies that are required: a) only by a court of law, or b) only for insurance, travel, employment, and school or camp purposes ○ Services beyond any visits limits on the plan ○ Gym and fitness club memberships and fees, health club fees, exercise equipment or supplies ○ Biofeedback services ○ Devices and computers to assist in communication and speech (refer to the Coverage Determination Guideline titled <i>Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/Replacements</i>) ○ Speech Therapy if the provider is school based (check benefit language and state mandates) ○ Idiopathic Developmental Delay (no illness to explain the cause of Developmental Delay in speech-language) ○ Sign language interpreter services (does not require the services of a licensed or certified healthcare professional) ○ Bilingualism is not considered to be a developmental speech or Developmental Delay and speech therapy is usually not a covered health service, except when other criteria for speech therapy are met ○ Therapy in the home, solely for the convenience of a provider or member <p><i>Additional Limitations and Exclusions for Habilitative Services</i></p> <ul style="list-style-type: none"> ● Added language to indicate: <ul style="list-style-type: none"> ○ A service that does not help the covered person to meet or maintain functional goals in a treatment plan within a prescribed time frame is not a habilitative service ○ In the absence of a disabling condition, services to improve general physical condition are excluded from coverage <p><i>Additional Limitations and Exclusions for Rehabilitation Therapy</i></p> <ul style="list-style-type: none"> ● Revised list of exclusions for rehabilitation therapy only to reflect/include: <ul style="list-style-type: none"> ○ Services that are not considered to be rehabilitation therapy (refer to the <i>Indications for Coverage</i> section of the policy) ○ Maintenance therapy as it is not a rehabilitation therapy service and is excluded from the rehabilitation therapy benefit (for additional information on maintenance therapy, refer to the <i>Habilitative Services</i> section of the policy) ○ Rehabilitation therapy services that are done for preventive reasons 	

Coverage Determination Guideline Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Habilitative Services and Outpatient Rehabilitation Therapy (continued)	Jan. 1, 2022	<ul style="list-style-type: none"> ○ Confinement, treatment, services or supplies related to learning and intellectual disabilities ○ General education and training (video or computerized interactive program); viewing of films or videotapes, listening to audiotapes, and completing interactive computer programs ○ Services to improve general physical condition that are provided to reduce potential risk factors, where significant therapeutic improvement is not expected <p>Definitions</p> <ul style="list-style-type: none"> ● Added definition of: <ul style="list-style-type: none"> ○ Alternate Facility ○ Cognitive Rehabilitation ○ Congenital Anomaly ○ Experimental or Investigational Service(s) ○ Stuttering ○ Unproven Service(s) ● Updated definition of “Restorative Therapy/Rehabilitation” ● Removed definition of: <ul style="list-style-type: none"> ○ Aural Rehabilitation ○ Duplicate Services ○ Functional or Physical Impairment ○ Group Therapy ○ Occupational Therapy ○ Physical Therapy ○ Significant Change in Functional Level ○ Standardized Assessments <p>Applicable Codes</p> <ul style="list-style-type: none"> ● Added CPT codes 97129, 97130, 98925, 98926, 98927, 98928, 98929, 98940, 98941, 98942, and 98943 <p>Supporting Information</p> <ul style="list-style-type: none"> ● Updated <i>References</i> section to reflect the most current information 	
Infertility Services	Jan. 1, 2022	<p>Template Update</p> <ul style="list-style-type: none"> ● Updated policy header to reflect the most current product branding for UnitedHealthcare Individual Exchange Plans 	Refer to the policy for complete details.

Coverage Determination Guideline Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Infertility Services (continued)	Jan. 1, 2022	<p>Applicable States</p> <ul style="list-style-type: none"> Revised list of applicable states: <ul style="list-style-type: none"> Added language to indicate this policy applies to the state of Illinois (new benefit plan effective Jan. 1, 2022) Removed language indicating this policy applies to the states of Arizona, North Carolina, Oklahoma, Tennessee, Virginia, and Washington 	
Power Mobility Devices	Jan. 1, 2022	<p>Template Update</p> <ul style="list-style-type: none"> Updated policy header to reflect the most current product branding for UnitedHealthcare Individual Exchange Plans <p>Applicable States</p> <ul style="list-style-type: none"> Removed language indicating this policy applies to the states of Arizona, North Carolina, Oklahoma and Washington 	<p>Indications for Coverage</p> <p>Power Mobility Devices are proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® 2021, July 2021 Release, Medicare: Durable Medical Equipment, Power Mobility Devices.</p> <p>Click here to view the InterQual® criteria.</p> <p>Repair, Replacement, and Upgrade</p> <p>Replacement</p> <p>Replacement of DME is for the same or similar type of equipment which is beyond its reasonable useful life span and has become irreparable.</p> <p>Upgrade</p> <p>The physician provides documentation that the condition of the member changes (e.g., impaired function necessitates an upgrade to an electric wheelchair from a manual one).</p> <p>General Criteria</p> <ul style="list-style-type: none"> Routine wear on the equipment renders it non-functional and the member still requires the equipment. <ul style="list-style-type: none"> Vendors/manufacturers are responsible for repairs, replacements, and

Coverage Determination Guideline Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Power Mobility Devices (continued)	Jan. 1, 2022		<p>maintenance for rented equipment and for purchased equipment covered by warranty</p> <ul style="list-style-type: none"> ○ Coverage includes DME obtained in a physician’s office, DME vendor, or any other provider authorized to provide/dispense DME <ul style="list-style-type: none"> ● Unless otherwise stated, DME has a Reasonable Useful Lifetime (RUL) of 5 years <p>Note: A new prescription isn't needed if the needs of the patient are the same.</p> <p>Equipment Upgrades</p> <ul style="list-style-type: none"> ● A change in the member’s medical condition and equipment needs requires the same documentation as a new request ● Equipment upgrades are equivalent to a new service <p>Coverage Limitations and Exclusions</p> <p>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 electric wheelchair vs. custom wheelchair.</p> <p>The following services are excluded from coverage:</p> <ul style="list-style-type: none"> ● Replacement of items due to malicious damage, neglect or abuse. ● Replacement of lost or stolen items. ● Upgrade or replacement of DME when the existing equipment is still functional. Refer to the <i>Repair, Replacement, and Upgrade</i> section of the policy.
Private Duty Nursing (PDN) Services	Jan. 1, 2022	<p>Template Update</p> <ul style="list-style-type: none"> ● Updated policy header to reflect the most current product branding for UnitedHealthcare Individual Exchange Plans <p>Applicable States</p> <ul style="list-style-type: none"> ● Revised list of applicable states: <ul style="list-style-type: none"> ○ Added language to indicate this policy applies to the states 	<p>Check the member specific benefit plan document or any applicable federal or state contractual or regulatory requirements. In the event of a conflict, the federal, state or contractual definitions for benefit plan coverage supersede this Coverage Determination Guideline.</p> <p>Indications for Coverage</p> <p>When benefits are available, Private Duty Nursing (PDN) services are covered and considered Medically Necessary for members requiring individual and continuous Skilled Care when ordered by the member’s primary care and/or</p>

Coverage Determination Guideline Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Private Duty Nursing (PDN) Services (continued)	Jan. 1, 2022	<p>of Illinois, Louisiana, and Michigan (new benefit plans effective Jan. 1, 2022)</p> <ul style="list-style-type: none"> ○ Removed language indicating this policy applies to the states of Arizona, Tennessee, and Washington <p>Applicable Codes</p> <ul style="list-style-type: none"> ● Added HCPCS code T1004 	<p>treating physician as part of a Treatment Plan and the member meets ALL of the following criteria:</p> <ul style="list-style-type: none"> ● Needs Skilled Care that exceeds the scope of Intermittent Care; and ● Needs services that require the professional proficiency and skills of a licensed nurse (RN or LPN); and ● Is unable to have their care tasks provided through Intermittent Care or self-directed care; and ● Has a complex medical need and/or unstable medical condition that requires four (4) or more continuous hours of Skilled Care which can be safely provided outside an institution; and ● Requires Skilled Care that is Medically Necessary for the member's disease, illness, or injury, as defined by the member's physician; and ● Has family or other appropriate support that has the ability and availability to be trained to care for the member and assume a portion of the care (Note: The intent of PDN services is to support, not replace, the caregiver); and ● Face-to-face visit with the patient within 90 days prior to the start of care, or within 30 days after the start of care; and ● Periodically reviewed treatment plan that is updated every 60 days by the treating physician; and ● The services are more cost-effective in the Home than in an alternative setting such as a hospital or a facility that provides Skilled Care (Note: Refer to federal, state or contractual requirements for benefit coverage, as applicable) ● Home care agency can safely deliver the required care at home; and ● Home environment is safe, accessible, and can be modified to accommodate the home care plan <p>Documentation Requirements</p> <p><i>Initial Request for Authorization</i></p> <p>Initial service requests of PDN services (i.e., the first time the member is requesting services with UnitedHealthcare for PDN services) must be submitted with all of the following clinical documentation:</p> <ul style="list-style-type: none"> ● Home Health Certification and Plan of Care, such as a CMS-485 form,

Coverage Determination Guideline Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Private Duty Nursing (PDN) Services (continued)	Jan. 1, 2022		<p>signed by a physician (M.D. or D.O.); and</p> <ul style="list-style-type: none"> • Comprehensive documentation of the member’s medical diagnoses and health status including but not limited to documentation of the Skilled Care needs and medication administration record that support the need for skilled home care nursing services; and • Discharge summary or recent progress note if member is being discharged from an inpatient setting (Note: If member is requesting PDN services for discharge from inpatient setting, subspecialist visit notes are not required); and • Consultation notes if the member is receiving services from subspecialist; and • Delineated scope and duration of PDN hours being requested; and • An assessment of the available support system must include but not limited to the following: <ul style="list-style-type: none"> ○ Availability of the member’s primary caregiver; and ○ Ability of the member’s primary caregiver to provide care; and ○ School attendance and availability of coverage for services by school district, if applicable; and ○ Primary caregiver’s work schedules, as applicable <p>Additional documentation for renewal and transition of services clarifying clinical status (such as well child check and/or specialist visit notes, seizure log, and ventilator, BIPAP, CPAP logs) may be requested if clinical documentation provided does not clearly support the hours being requested.</p> <p>Coverage Limitations and Exclusions</p> <ul style="list-style-type: none"> • Requested services are defined as non-Skilled Care or Custodial Care in the member’s state contractual language such as but not limited to: <ul style="list-style-type: none"> ○ Members who are on continuous or bolus nasogastric (NG) or gastrostomy tube (GT) feedings and do not have other Skilled Care needs (Note: Transition after discharge from an inpatient setting to the Home may be considered Medically Necessary for these members when there is a need to train the member’s family or caregiver to administer the NG or GT feedings);

Coverage Determination Guideline Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Private Duty Nursing (PDN) Services (continued)	Jan. 1, 2022		<ul style="list-style-type: none"> ○ PDN services become maintenance or Custodial Care and not Medically Necessary when any one of the following situations occur: <ul style="list-style-type: none"> ▪ Medical and nursing documentation shows that the member's condition is stable/predictable/controlled and that a licensed nurse is not required to monitor the condition; ▪ The Plan of Care does not require a licensed nurse to be in continuous attendance; and/or ▪ The Plan of Care does not require hands-on nursing interventions (Note: Observation in case an intervention is required is not considered Skilled Care) ○ The following are examples of services that do not require the skill of a licensed nurse and therefore do not meet the Medical Necessity requirements for PDN services: <ul style="list-style-type: none"> ▪ Any duplication of care which is already provided by supply or infusion companies ▪ Care of an established colostomy/ileostomy ▪ Care of an established gastrostomy/jejunostomy/nasogastric tube (intermittent or continuous) feedings ▪ Care of an established indwelling bladder catheter (including emptying/changing containers and clamping tubing) ▪ Care of an established tracheostomy (including intermittent suctioning) ▪ Help with daily living activities, such as but not limited to walking, grooming, bathing, dressing, getting in or out of bed, toileting, eating, or preparing foods ▪ Institutional care, including room and board for rest cures, adult day care and convalescent care ▪ Respite care, adult (or child) day care, or convalescent care ▪ Routine administration of maintenance medications including insulin [this applies to oral (PO), subcutaneous (SQ), and intramuscular (IM) medications] ▪ Routine patient care such as changing dressings, periodic turning and positioning in bed, administering oral medications

Coverage Determination Guideline Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Private Duty Nursing (PDN) Services (continued)	Jan. 1, 2022		<ul style="list-style-type: none"> ▪ Watching or protecting a member • Respite care and convenience care unless mandated (Note: Respite care relieves the caregiver of the need to provide services to the member) • Services beyond the plan benefits (hours or days) or member is no longer eligible for benefits • Services that can be provided safely and effectively by a non-clinically trained person are not skilled when a non-skilled caregiver is not available such as but not limited to: <ul style="list-style-type: none"> ○ Member must have one caregiver willing and able to accept responsibility for the member’s care when the nurse is not available. If parent/caregiver cannot or will not accept responsibility for the care, PDN will not be authorized as this is deemed an unsafe environment ○ Placement of the nurse in the home is for the convenience of the family caregiver, including solely to allow the member’s family or caregiver to go to work or school ○ Primary caregiver is identified as available and able, but is not willing to provide care to the member ○ There is no person available to assume the role of caregiver • Services that involve payment of family members or non-professional caregivers for services performed for the member unless required by state contract • Services involving shared coverage with multiple care agencies <p>Renewal of Services</p> <p>Requests for renewal of PDN services (i.e., any request for PDN services subsequent to the initial request for PDN services made to UnitedHealthcare) will require submission of all of the following specific clinical documentation to support Medical Necessity:</p> <ul style="list-style-type: none"> • Home Health Certification and Plan of Care, such as a CMS-485, form signed by a physician (M.D. or D.O.); and Nurses’ notes, logs and daily care flow sheets; and • Nurses’ notes, logs and daily care flow sheets, as applicable <p>Transition Services</p>

Coverage Determination Guideline Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Private Duty Nursing (PDN) Services (continued)	Jan. 1, 2022		<p>If a member is transitioning from another health plan and is already receiving PDN services, then all of the following documentation must be submitted before the end of the required continuity of care period:</p> <ul style="list-style-type: none"> • Home Health Certification and Plan of Care, such as a CMS-485, signed by a physician (M.D. or D.O.); and Nurses' notes, logs and daily care flow sheets; and • Nurses' notes, logs and daily care flow sheets, as applicable
Retired			
Policy Title	Effective Date	Summary of Changes	
Therapeutic Shoes and Inserts for Diabetes	Nov. 1, 2021	<ul style="list-style-type: none"> • Policy retired; therapeutic shoes and inserts for individuals with diabetes no longer require clinical review 	

Utilization Review Guideline Updates

Updated			
Policy Title	Effective Date	Summary of Changes	
Elective Inpatient Services	Nov. 1, 2021	Coverage Rationale <ul style="list-style-type: none"> Replaced notation indicating “this policy does not apply to <i>obstetric conditions</i>” with “this policy does not apply to an <i>obstetric member during pregnancy, childbirth, or the post-partum period</i>” 	
Observation Services	Nov. 1, 2021	Coverage Rationale <ul style="list-style-type: none"> Replaced notation indicating “this policy does not apply to <i>obstetric conditions</i>” with “this policy does not apply to an <i>obstetric member during pregnancy, childbirth, or the post-partum period</i>” 	
Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Outpatient Surgical Procedures – Site of Service	Feb. 1, 2022	Coverage Rationale <ul style="list-style-type: none"> Revised list of medically necessary indications for planned surgical procedures performed in a hospital outpatient department; replaced “brittle diabetes” with “uncontrolled diabetes with recurrent diabetic ketoacidosis (DKA) or severe hypoglycemia” Definitions <ul style="list-style-type: none"> Removed definition of “Brittle Diabetes” Updated definition of “Obstructive Sleep Apnea (OSA)” Supporting Information <ul style="list-style-type: none"> Updated <i>References</i> section to reflect the most current information 	<p>UnitedHealthcare members may choose to receive surgical procedures in an ambulatory surgical center (ASC) or other locations. We are conducting site of service medical necessity reviews; however, to determine whether the outpatient hospital department is medically necessary, in accordance with the terms of the member’s benefit plan. If the outpatient hospital department is not considered medically necessary, this location will not be covered under the member’s plan.</p> <p>Certain planned surgical procedures performed in a hospital outpatient department are considered medically necessary for an individual who meets any of the following criteria:</p> <ul style="list-style-type: none"> Advanced liver disease (MELD Score > 8) Advance surgical planning determines an individual requires overnight recovery and care following a surgical procedure Anticipated need for transfusion Bleeding disorder requiring replacement factor or blood products or special infusion products to correct a coagulation defect Cardiac arrhythmia (symptomatic arrhythmia despite medication) Chronic obstructive pulmonary disease (COPD) (FEV1 <50%) Coronary artery disease ([CAD]/peripheral vascular disease [PVD]) (ongoing cardiac ischemia requiring medical management or recently placed [within 1 year] drug eluting stent) Developmental stage or cognitive status warranting use of a hospital outpatient department End stage renal disease ([hyperkalemia above reference range] receiving peritoneal or hemodialysis)

Utilization Review Guideline Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Outpatient Surgical Procedures – Site of Service (continued)	Feb. 1, 2022		<ul style="list-style-type: none"> History of cerebrovascular accident (CVA) or transient ischemic attack (TIA) (recent event [$<$ 3 months]) History of myocardial infarction (MI) (recent event [$<$ 3 months]) Individuals with drug eluting stents (DES) placed within one year or bare metal stents (BMS) or plain angioplasty within 90 days unless acetylsalicylic acid and antiplatelet drugs will be continued by agreement of surgeon, cardiologist and anesthesia Ongoing evidence of myocardial ischemia Poorly Controlled asthma (FEV1 $<$ 80% despite medical management) Pregnancy Prolonged surgery ($>$ 3 hours) Resistant hypertension (Poorly Controlled) Severe valvular heart disease Sleep apnea (moderate to severe Obstructive Sleep Apnea (OSA) Uncompensated chronic heart failure (CHF) (NYHA class III or IV) Uncontrolled diabetes with recurrent diabetic ketoacidosis (DKA) or severe hypoglycemia Under 18 years of age <p>A planned surgical procedure performed in a hospital outpatient department is considered medically necessary if there is an inability to access an ambulatory surgical center for the procedure due to any one of the following:</p> <ul style="list-style-type: none"> There is no geographically accessible ambulatory surgical center that has the necessary equipment for the procedure; or There is no geographically accessible ambulatory surgical center available at which the individual’s physician has privileges; or An ASC’s specific guideline regarding the individual’s weight or health conditions that prevents the use of an ASC <p>Planned Surgical Procedures List</p> <p>Site of service medical necessity reviews will be conducted for surgical procedures only when performed in an outpatient hospital setting. For the complete list of surgical procedures codes requiring prior authorization, refer to UHCPProvider.com > Exchange Plans Advanced Notification/Prior Authorization</p>

Utilization Review Guideline Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Outpatient Surgical Procedures – Site of Service (continued)	Feb. 1, 2022		<p>Requirements.</p> <p>Documentation Requirements</p> <p>Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The documentation requirements outlined below are used to assess whether the member meets the clinical criteria for coverage, but do not guarantee coverage of the service requested.</p> <p>Provide medical notes documenting all of the following:</p> <ul style="list-style-type: none"> • History • Physical examination including patient weight and co-morbidities • Surgical plan • Physician privileging information related to the need for the use of the hospital outpatient department • American Society of Anesthesiologists (ASA) score, as applicable <p>In addition to the above, additional documentation requirements may apply for the following codes. Review the below listed policies in conjunction with the guidelines in this document.</p> <ul style="list-style-type: none"> • For CPT code 15576, refer to the Coverage Determination Guideline titled <i>Cosmetic and Reconstructive Procedures</i>. • For CPT codes 17106, 17107, and 17108, refer to the Medical Policy titled <i>Light and Laser Therapy</i>. • For CPT codes 20551, 29800, and 29804, refer to the Medical Policy titled <i>Temporomandibular Joint Disorders</i>. • For CPT codes 20605, 20606, 20610, and 201611, refer to the Medical Benefit Drug Policy titled <i>Sodium Hyaluronate</i>. • For CPT codes 22513 and 22514, refer to the Medical Policy titled <i>Percutaneous Vertebroplasty and Kyphoplasty</i>. • For CPT codes 23700 and 27570, refer to the Medical Policy titled <i>Manipulation Under Anesthesia</i>. • For CPT code 42145, refer to the Medical Policy titled <i>Obstructive and Central Sleep Apnea Treatment</i>.

Utilization Review Guideline Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Outpatient Surgical Procedures – Site of Service (continued)	Feb. 1, 2022		<ul style="list-style-type: none"> For CPT code 58263, refer to the Medical Policy titled <i>Hysterectomy</i>.

General Information

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

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

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

Policy Update Classifications

New

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

Updated

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

Revised

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

Replaced

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

Retired

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



The complete library of UnitedHealthcare Value & Balance Exchange Medical Policies, Medical Benefit Drug Policies, Coverage Determination Guidelines, and Utilization Review Guidelines is available at UHCprovider.com > Policies and Protocols > Exchange Plans Policies > [Medical & Drug Policies and Coverage Determination Guidelines for UnitedHealthcare® Value & Balance Exchange Plans](#).