United Healthcare Community Plan

UnitedHealthcare Community Plan

Medical Policy Update Bulletin: April 2022

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Quarterly CPT® and HCPCS Code Updates

Effective Apr. 1, 2022, the following Medical Policies and Medical Benefit Drug Policies have been updated to reflect the quarterly Current Procedural Terminology (CPT®) and Healthcare Common Procedure Coding System (HCPCS) code additions, revisions, and deletions. Refer to the following sources for information on the code updates:

- American Medical Association. Current Procedural Terminology: CPT®
- Centers for Medicare & Medicaid Services. Healthcare Common Procedure Coding System: HCPCS Level II

Policy Title	Policy Type	Summary of Changes
Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes	Medical Policy	• Added A4238 and E2102
Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes (for New Jersey Only)	Medical Policy	• Added A4238 and E2102
Gastrointestinal Pathogen Nucleic Acid Detection Panel Testing for Infectious Diarrhea	Medical Policy	• Removed 0097U
Gastrointestinal Pathogen Nucleic Acid Detection Panel Testing for Infectious Diarrhea (for New Jersey Only)	Medical Policy	• Removed 0097U
Medical Therapies for Enzyme Deficiencies	Medical Benefit Drug Policy	Nexviazyme • Replaced C9085, J3490, and J3590 with J0219
Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions	Medical Policy	• Added 0306U, 0307U, 0313U, 0314U, and 0315U • Revised description for 0022U
Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions (for New Jersey Only)	Medical Policy	• Added 0306U, 0307U, 0313U, 0314U, and 0315U • Revised description for 0022U
Omnibus Codes	Medical Policy	Cardiac Contractility Modulation using an Implantable Device • Added K1030
Ryplazim® (Plasminogen, Human-Tvmh)	Medical Benefit Drug Policy	• Replaced C9399 with C9090
Saphnelo™ (Anifrolumab-Fnia)	Medical Benefit Drug Policy	• Replaced C9086, J3490, and J3590 with J0491

Medical Policy Updates

Updated

Policy Title	Effective Date	Summary of Changes
Cardiovascular Disease Risk Tests	Jun. 1, 2022	**Applicable Codes** • Added CPT code 84999 **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information • Removed *CMS* section
Catheter Ablation for Atrial Fibrillation (for New Jersey Only)	May 1, 2022	**Applicable Codes** • Updated list of applicable CPT codes to reflect annual edits; revised description for 93653 and 93656 **Supporting Information** • Updated *References* section to reflect the most current information
Cognitive Rehabilitation	Apr. 1, 2022	**Coverage Rationale** • Replaced reference to "InterQual® *2021*, *Apr. 2021* Release, LOC: Outpatient Rehabilitation & Chiropractic, *Cerebrovascular Accident (CVA): Rehabilitation (Adult) and Traumatic Brain Injury (TBI): Rehabilitation (Adult)*" with "InterQual® *2022*, *Mar. 2022* Release, LOC: Outpatient Rehabilitation & Chiropractic"
Cognitive Rehabilitation (for Nebraska Only)	Apr. 1, 2022	**Coverage Rationale** • Replaced reference to "InterQual® *Client Defined 2021*, LOC: Outpatient Rehabilitation & Chiropractic, *Cerebrovascular Accident (CVA): Rehabilitation (Adult) (Custom) – UHG and Traumatic Brain Injury (TBI): Rehabilitation (Adult) (Custom) - UHG*" with "InterQual® *2022*, *Mar. 2022 Release*, LOC: Outpatient Rehabilitation & Chiropractic"
Corneal Hysteresis and Intraocular Pressure Measurement (for New Jersey Only)	Apr. 1, 2022	**Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information
Deep Brain and Cortical Stimulation	Apr. 1, 2022	**Coverage Rationale** • Updated language to clarify responsive cortical stimulation is proven and medically necessary for treating *refractory* partial or focal seizure disorder **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information

Medical Policy Updates

Updated

Policy Title	Effective Date	Summary of Changes

Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal Conditions and Soft Tissue Wounds (for New Jersey Only)	May 1, 2022	**Title Change**
		• Previously titled *Extracorporeal Shock Wave Therapy (ESWT) (for New Jersey Only)*
		Coverage Rationale
		• Updated language to clarify:
		  ○ Extracorporeal shock wave therapy (ESWT), whether low energy, high energy or radial wave, is unproven and not medically necessary for *any musculoskeletal or soft tissue* indications
		  ○ This policy does not address extracorporeal shock wave lithotripsy (ESWL) *used for the treatment of:*
		  ▪ *Gallstones*
		  ▪ *Kidney stones*
		  ▪ *Pancreatic stones*
		  ▪ *Salivary stones*
		Supporting Information
		• Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information

Prolotherapy and Platelet Rich Plasma Therapies (for New Jersey Only)	May 1, 2022	**Applicable Codes** • Removed CPT/HCPCS codes 0481T and S9055 **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information

Transcatheter Heart Valve Procedures	Apr. 1, 2022	**Application**
		• Added language to indicate this Medical Policy does not apply to the states of Mississippi and Pennsylvania; refer to the state specific policy version
		Coverage Rationale
		• Added instruction to refer to the following sources for additional information pertaining to Volume Requirements consistent with the Centers for Medicare and Medicaid Services (CMS):
		  ○ CMS National Coverage Determination 20.32: *Transcatheter Aortic Valve Replacement (TAVR)*
		  ○ Society of Thoracic Surgeons/American College of Cardiology (STS/ACC) *Transcatheter Valve Therapy (TVT) Registry*
		Definitions
		• Updated definition of "CMS Volume Requirements for Transcatheter Aortic Heart Valve Replacement (TAVR)"
		Supporting Information
		• Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information

Medical Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale

Apheresis (for New Jersey Only)	May 1, 2022	**Coverage Rationale**
		• Revised list of conditions/diagnoses for which therapeutic apheresis is proven and medically necessary:
		  ○ Added:
		  ▪ Cryoglobulinemia (second line therapy)
		  ▪ Hypertriglyceridemic pancreatitis, severe
		  ▪ Major hematopoietic stem cell transplant, ABO incompatible, second line therapy
		  – HPC(M)
		  – HPC(A)
		  ▪ Myeloma cast nephropathy (second line therapy)
		  ▪ Neuromyelitis optica spectrum disorders (Devic's syndrome), relapse (second line therapy)
		  ▪ Renal transplantation, ABO incompatible (second line therapy)
		  – Antibody mediated rejection
		  ▪ Voltage gated potassium channel antibodies-related conditions
		  ○ Removed:
			Therapeutic apheresis is proven and medically necessary for treating or managing the following conditions/diagnoses:
			• Acute inflammatory demyelinating polyneuropathy (Guillain-Barré syndrome), primary treatment
			• Acute liver failure (requiring High Volume Plasma Exchange)
			• ANCA-associated rapidly progressive glomerulonephritis (Granulomatosis with polyangiitis; and Microscopic Polyangiitis)
			  ○ Dialysis dependent
			  ○ Diffuse alveolar hemorrhage (DAH)
			• Anti-glomerular basement membrane disease (Goodpasture's syndrome)
			  ○ Dialysis dependent
			  ○ DAH
			• Cardiac transplantation (second line therapy)
			  ○ Recurrent rejection
			  ○ Desensitization
			• Chronic inflammatory demyelinating polyneuropathy
			• Cryoglobulinemia, (second line therapy)
			• Cutaneous T-cell lymphoma; mycosis fungoides; Sezary syndrome, erythrodermic
			• Familial hypercholesterolemia
			  ○ Homozygous
			  ○ Heterozygous (second line therapy)
			• Focal segmental glomerulosclerosis, recurrent in transplanted kidney (second line therapy)
			• Graft-versus-host disease
			  ○ Acute
			  ○ Chronic, second line therapy
			• Hereditary hemochromatosis
			• Hypertriglyceridemic pancreatitis, severe
			• Hyperlipoproteinemia
			• Hyperviscosity in hypergammaglobulinemia
			• Idiopathic dilated cardiomyopathy, NYHA class II-IV, via IA
			• Inflammatory bowel disease, via adsorptive cytapheresis

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Apheresis (for New Jersey Only) (continued)	May 1, 2022	▪ ABO incompatible heart transplantation in children less than 40 months of age (only as second line therapy) ▪ ABO incompatible major hematopoietic stem cell/bone marrow transplant (only as second line therapy) ▪ ABO incompatible kidney transplantation (only as second line therapy) – Antibody mediated rejection, living donor (LD) desensitization – A^2/A^2B into B, deceased donor ▪ Age-related macular degeneration, dry ▪ Coagulation factor inhibitors, autoantibody via immunoadsorption (IA) ▪ Hyperleukocytosis, symptomatic ▪ Systemic lupus erythematosus nephritis ○ Replaced: ▪ "ABO incompatible liver transplantation, desensitized ABOi, *deceased* donor" with "liver transplantation, ABO incompatible: desensitized	• Liver transplantation, ABO incompatible ○ Desensitized ABOi ○ Living donor • Lung transplantation, bronchiolitis obliterans syndrome • Major hematopoietic stem cell transplant, ABO incompatible, second line therapy ○ HPC(M) ○ HPC(A) • Multiple sclerosis, second line therapy ○ Acute CNS inflammatory, demyelinating ○ Relapsing form with steroid resistant exacerbations • Myasthenia gravis, acute • Myeloma cast nephropathy, (second line therapy) • Neuromyelitis optica spectrum disorders, (Devic's syndrome), acute or relapse, second line therapy • *N*-methyl D-aspartate receptor antibody encephalitis • Paraproteinemic polyneuropathies via Therapeutic Plasma Exchange (TPE) ○ Anti-MAG ○ Multifocal motor ○ IgG/IgA ○ IgM • Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS exacerbation) • Peripheral vascular diseases • Polycythemia vera; erythrocytosis • Progressive multifocal leukoencephalopathy associated with natalizumab • Pruritus due to hepatobiliary diseases • Renal transplantation, ABO compatible ○ Antibody mediated rejection ○ Desensitization, living donor • Renal transplantation, ABO incompatible, second line therapy ○ Antibody mediated rejection • Rheumatoid arthritis, refractory second line therapy • Sickle cell disease

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Apheresis (for New Jersey Only) (continued)	May 1, 2022	ABOi, *living* donor" ▪ "Graft-versus-host disease: acute or chronic, *skin and non-skin*" with "graft-versus-host disease: acute or chronic" ▪ "Hyperviscosity in *monoclonal gammopathies*" with "hyperviscosity in *hypergammaglobulinemia*" ▪ "Myasthenia gravis" with "myasthenia gravis, *acute*" ▪ "Sickle cell disease: *primary or secondary* stroke prevention" with "sickle cell disease: stroke prevention" ▪ "Vasculitis: Behçet's disease (*adsorption granulo*cytapheresis), *EGPA (TPE)*" with "Vasculitis: Behçet's disease (*adsorptive* cytapheresis)" ○ Added language to indicate therapeutic apheresis is proven and medically necessary for the following only as *second line therapy*. ▪ Cardiac transplantation ▪ Multiple sclerosis: acute CNS inflammatory,	○ Acute stroke or multi-organ failure ○ Acute chest syndrome, severe, second line therapy ○ Stroke prevention ○ Prevention of transfusional iron overload ● Thrombotic microangiopathy, complement mediated ○ MCP mutations ● Thrombotic microangiopathy, Shiga toxin mediated ○ Absence of severe neurological symptoms ● Thrombotic thrombocytopenic purpura ● Vasculitis ○ Behcet's disease (adsorptive cytapheresis) ○ Idiopathic PAN (TPE) ● Voltage gated potassium channel antibodies-related conditions ● Wilson's disease, fulminant Due to insufficient evidence of efficacy, therapeutic apheresis including plasma exchange, plasmapheresis, or photopheresis is unproven and not medically necessary for treating or managing the following conditions/diagnoses, including but not limited to: ● Acute disseminated encephalomyelitis ● Acute inflammatory demyelinating polyneuropathy (Guillain-Barré syndrome), after IVIG ● Age related macular degeneration ● Amyloidosis, systemic ● Amyotrophic lateral sclerosis ● ANCA-associated rapidly progressive glomerulonephritis, dialysis independent (Granulomatosis with polyangiitis; and Microscopic Polyangiitis) ● Anti-glomerular basement membrane disease, dialysis dependent, without DAH (Goodpasture's syndrome) ● Aplastic anemia; pure red cell aplasia ● Atopic (neuro-) dermatitis (atopic eczema), recalcitrant ● Autoimmune hemolytic anemia: warm autoimmune hemolytic anemia; cold agglutinin disease

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Apheresis (for New Jersey Only) (continued)	May 1, 2022	demyelinating • Revised list of conditions/ diagnoses for which therapeutic apheresis is unproven and not medically necessary: ○ Added: ▪ Age related macular degeneration ▪ Liver transplantation – ABO incompatible – Antibody mediated rejection ○ Removed: ▪ ABO incompatible liver transplantation, antibody mediated rejection ▪ Cryoglobulinemia ▪ Myeloma cast nephropathy ▪ Prevention of RhD alloimmunization after RBC exposure ▪ Voltage gated potassium channel antibodies ○ Replaced: ▪ "Coagulation factor inhibitors, *alloantibody (via IA), autoantibody (via TPE or IA)*" with "coagulation factor inhibitors" ▪ "Hematopoietic stem cell transplantation, major/minor HPC(A)" with "hematopoietic stem cell	• Babesiosis • Burn shock resuscitation • Cardiac neonatal lupus • Cardiac transplantation ○ Antibody mediated rejection ○ Rejection prophylaxis • Catastrophic antiphospholipid syndrome • Chronic focal encephalitis (Rasmussen's encephalitis) • Coagulation factor inhibitors • Complex regional pain syndrome • Cutaneous T-cell lymphoma; mycosis fungoides; Sézary syndrome, non-erythrodermic • Dermatomyositis/polymyositis • Erythropoietic porphyria, liver disease • Focal segmental glomerulosclerosis, native kidney, steroid resistant • Hashimoto's encephalopathy • HELLP syndrome • Hematopoietic stem cell transplantation, ○ HLA desensitized ○ Major ABO incompatibility with pure RBD aplasia ○ Minor HPC(A) • Hemolytic uremic syndrome • Hemophagocytic lymphohistiocytosis • Henoch-Schonlein purpura • Heparin induced thrombocytopenia and thrombosis • Hyperleukocytosis • Hypertriglyceridemic pancreatitis, prevention • Immune thrombocytopenia • IgA nephropathy (Berger's Disease) • Inflammatory bowel disease, via Extracorporeal Photopheresis • Lambert-Eaton myasthenic syndrome • Liver transplantation ○ ABO incompatible ○ Antibody mediated rejection

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

Apheresis (for New Jersey Only) (continued)	May 1, 2022	transplantation, major/minor *ABO incompatibility with pure RBD aplasia*, *minor* HPC(A)"
		▪ "Hyperleukocytosis, *prophylaxis*" with "hyperleukocytosis"
		▪ "Hypertriglyceridemic pancreatitis" with "hypertriglyceridemic pancreatitis, *prevention*"
		▪ "*Immunoglobulin* nephropathy" with "*IgA* nephropathy *(Berger's Disease)*"
		▪ "Multiple sclerosis (unless noted [in the policy] as proven)" with "multiple sclerosis, *chronic* (unless noted [in the policy] as proven)"
		▪ "Red cell alloimmunization, *in pregnancy*" with "red cell alloimmunization, *prevention and treatment*"
		▪ "Sickle cell disease, *non-acute* (unless noted [in the policy] as proven)" with "sickle cell disease (unless noted [in the policy] as proven)"
			• Lung transplantation
			  ○ Antibody mediated rejection
			  ○ Desensitization
			• Malaria
			• Multiple sclerosis, chronic (unless noted above as proven)
			• Nephrogenic systemic fibrosis
			• Neuromyelitis optica spectrum disorders, maintenance
			• Overdose, venoms, and poisoning
			• Paraneoplastic neurologic syndromes
			• Paraproteinemic polyneuropathy, multiple indications (unless noted above as proven)
			• Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (Sydenham's chorea, severe)
			• Pemphigus vulgaris
			• Phytanic acid storage disease (Refsum's disease)
			• Post transfusion purpura
			• Psoriasis
			• Red cell alloimmunization, prevention and treatment
			• Renal transplantation, ABO compatible, desensitized, deceased donor
			• Scleroderma (systemic sclerosis)
			• Sepsis with multiorgan failure
			• Sickle cell disease, (unless noted above as proven)
			• Stiff-person syndrome
			• Sudden sensorineural hearing loss
			• Systemic lupus erythematosus, severe
			• Thrombocytosis
			• Thrombotic microangiopathy (unless noted above as proven)
			• Thyroid storm
			• Toxic epidermal necrolysis
			• Vasculitis (unless noted above as proven)
			
			Note: Refer to the *Description of Services* section of the policy for information regarding all apheresis-based procedures.

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Apheresis (for New Jersey Only) (continued)	May 1, 2022	Supporting Information • Updated *Clinical Evidence* and *References* sections to reflect the most current information	
Articular Cartilage Defect Repairs (for New Jersey Only)	May 1, 2022	Title Change • Previously titled *Autologous Chondrocyte Transplantation in the Knee (for New Jersey Only)* Related Policies • Added reference link to the Medical Policy titled *Surgery of the Knee (for New Jersey Only)* Coverage Rationale *Autologous Chondrocyte Transplantation (ACT)* • Revised coverage statement; replaced language indicating "ACT is proven and medically necessary for treating individuals with a *single* symptomatic full-thickness articular cartilage defect when all of [the listed] criteria are met" with "ACT is proven and medically necessary for treating individuals with a symptomatic full-thickness articular cartilage defect when all of [the listed] criteria are met" • Revised coverage criteria for proven and medically necessary treatment: ○ Added criterion requiring: ▪ Knee is stable with intact menisci and ligaments	**ACT and Microfracture** Autologous chondrocyte transplantation (ACT) is proven and medically necessary for treating patients with symptomatic full-thickness articular cartilage defects when all of the following criteria are met: • The lesion is: ○ Greater than or equal to 2 squared centimeters ○ A result of acute or repetitive trauma ○ Single or multiple full thickness (Outerbridge Classification of grade III or IV) articular cartilage defect of the femoral condyle (medial, lateral or trochlea) and/or patella • Knee is stable with intact menisci and ligaments • Normal joint space and alignment confirmed by X-ray • No active inflammatory or other arthritis, clinically and by X-ray • Failed non-surgical conservative management (e.g., physical therapy, braces, and/or nonsteroidal anti-inflammatory drugs) • Inadequate response to a prior arthroscopic or other surgical repair procedure (e.g., debridement, microfracture, drilling/abrasion arthroplasty, or osteochondral allograft/autograft) • Individual is less than 55 years of age ACT is unproven and not medically necessary for treating patients with the following indications due to insufficient evidence of efficacy: • Treatment of joints other than the knee • Growth plates have not closed • History of partial-thickness defects • Osteochondritis dissecans (OCD) • Malignancy in the bone, cartilage, fat or muscle of the treated limb • Active infection in the affected knee • Instability of the knee

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Articular Cartilage Defect Repairs (for New Jersey Only) (continued)	May 1, 2022	▪ Normal joint space and alignment confirmed by x-ray ▪ No active inflammatory or other arthritis, clinically and by x-ray ○ Replaced criterion requiring: ▪ "*Defect is caused by* acute or repetitive trauma" with "*the lesion is a result of* acute or repetitive trauma" ▪ "*Defect* is greater than 2 squared cm" with "*the lesion* is greater than *or equal to* 2 squared cm *in size*" ▪ "*Individual has* defect *in the* articular cartilage of the femoral condyle (medial, lateral, or trochlea)" with "*the lesion is a single or multiple full thickness (Outerbridge Classification of grade III or IV)* articular cartilage defect of the femoral condyle (medial, lateral or trochlea) *and/or patella*" ● Revised list of unproven and not medically necessary indications: ○ Added: ▪ Active infection in the affected knee	● History of total meniscectomy ● Repeat ACT ● Active inflammatory degenerative, rheumatoid or osteoarthritis ● As initial or first line of surgical therapy Microfracture repair to treat full and partial thickness chondral defects of the knee is proven and medically necessary when all of the following criteria are met. ● Symptomatic focal cartilage defects of the weight-bearing femoral condyles, tibial plateau, trochlea, and patella ● Defect has been identified by Magnetic resonance imaging (*MRI), arthrogram or arthroscopy ● Outerbridge Grade 3-4 cartilage lesions ● Measure less than or equal to 4 square centimeters **Osteochondral Autograft and Allograft Transplantation** Osteochondral Autograft and Allograft transplantation is proven and medically necessary for treating individuals with cartilage defects of the knee. For medical necessity clinical coverage criteria for Osteochondral Autograft and Allograft Transplantation, refer to the InterQual® 2021, Apr. 2021 Release, CP: Procedures: ● Arthrotomy, Knee ● Arthroscopy or Arthroscopically Assisted Surgery, Knee ● Arthroscopy or Arthroscopically Assisted Surgery, Knee (Pediatric) Click here to view the InterQual® criteria. **Focal Articular Cartilage Repair** Focal articular cartilage repair is unproven and not medically necessary for treating individuals with any of the following due to insufficient evidence of efficacy: ● Osteochondral Autograft and Allograft transplantation for all other indications than those listed above

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Articular Cartilage Defect Repairs (for New Jersey Only) (continued)	May 1, 2022	▪ Repeat ACT ▪ As initial or first line of surgical therapy ○ Removed: ▪ Cartilage defects ▪ History of multiple defects ▪ History of defects of the patella ▪ Osteoarthritis ○ Replaced: ▪ "*In locations* other than *the femoral condyle of* the knee" with "*treatment of a joint* other than the knee" ▪ "*Previous history of cancer* in the bones, cartilage, fat, or muscle of the treated limb" with "*malignancy* in the bone, cartilage, fat, or muscle of the treated limb" ▪ "Total meniscectomy" with "*history of* total meniscectomy" ▪ "Inflammatory *diseases of the joint*" with "*active* inflammatory *degenerative, rheumatoid, or osteoarthritis*" *Microfracture Repair* ● Revised coverage guidelines to indicate Microfracture repair to treat full and partial thickness chondral defects of the knee is	● Use of minced articular cartilage repair (whether synthetic, allograft or autograft) for treating osteochondral defects of the knee ● Use of cryopreserved viable Osteochondral Allograft products (e.g., Cartiform) ● Microfracture repair of the knee with any of the following indications: ○ Misalignment of the knee ○ Osteoarthritis ○ Systemic immune-mediated disease, disease-induced arthritis, or cartilage disease ○ Unwilling or unable to participate in post-operative physical rehabilitation program

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Articular Cartilage Defect Repairs (for New Jersey Only) (continued)	May 1, 2022	proven and medically necessary when all of the following criteria are met: ○ Symptomatic focal cartilage defects of the weight-bearing femoral condyles, tibial plateau, trochlea, and patella ○ Defect has been identified by Magnetic resonance imaging (*MRI), arthrogram or arthroscopy ○ Outerbridge Grade 3-4 cartilage lesions ○ Measure less than or equal to 4 square centimeters *Osteochondral Autograft and Allograft Transplantation* ● Added language to indicate Osteochondral Autograft and Allograft transplantation is proven and medically necessary for treating individuals with cartilage defects of the knee; for medical necessity clinical coverage criteria for Osteochondral Autograft and Allograft Transplantation, refer to the InterQual® 2021, Apr. 2021 Release, CP: Procedures: ○ Arthrotomy, Knee ○ Arthroscopy or Arthroscopically Assisted Surgery, Knee ○ Arthroscopy or	

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Articular Cartilage Defect Repairs (for New Jersey Only) (continued)	May 1, 2022	Arthroscopically Assisted Surgery, Knee (Pediatric) *Focal Articular Cartilage Repair* • Added language to indicate focal articular cartilage repair is unproven and not medically necessary for treating individuals with any of the following due to insufficient evidence of efficacy: ○ Osteochondral Autograft and Allograft transplantation for all other indications than those listed above ○ Use of minced articular cartilage repair (whether synthetic, allograft or autograft) for treating osteochondral defects of the knee ○ Use of cryopreserved viable Osteochondral Allograft products (e.g., Cartiform) ○ Microfracture repair of the knee with any of the following indications: ▪ Misalignment of the knee ▪ Osteoarthritis ▪ Systemic immune-mediated disease, disease-induced arthritis, or cartilage disease ▪ Unwilling or unable to participate in post-operative physical	

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Articular Cartilage Defect Repairs (for New Jersey Only) (continued)	May 1, 2022	rehabilitation program Definitions • Added definition of: ○ Allograft ○ Allograft Discs (e.g., Cartiform, ProChondrix CR) ○ Allografts ○ Autografts ○ Autologous Chondrocyte Transplantation (ACT) ○ Femoral Condyles ○ Focal Defect ○ Juvenile Cartilage Allograft Tissue Implantation (e.g., DeNovo® NT Natural Tissue Graft) ○ Matrix-Induced Autologous Chondrocyte Implantation (MACI) Procedure ○ Microfracture ○ Minced Cartilage Repair ○ Mosaicplasty ○ Osteochondral Allograft (OCA) ○ Osteochondral Autograft Transfer System (OATS) ○ Osteochondral Autologous Transplant (OAT) ○ Outerbridge Classification of Articular Lesions by Severity Applicable Codes • Added CPT codes 27415, 27416, 28446, 29866, 29867, and 29879 Supporting Information	

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Articular Cartilage Defect Repairs (for New Jersey Only) (continued)	May 1, 2022	• Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	
Balloon Sinus Ostial Dilation (for New Jersey Only)	May 1, 2022	Coverage Rationale • Added language to indicate self-expanding absorptive sinus ostial dilation is unproven and not medically necessary for evaluating or treating sinusitis and all other conditions due to insufficient evidence of efficacy • Revised coverage criteria: *Chronic Rhinosinusitis* ○ Added criterion requiring: ▪ Computed tomography (CT) images are obtained after completion of medical management ▪ Documentation of which sinus has the disease and the extent of disease including the percent of opacification or the use of a scale such as the Modified Lund-Mackay Scoring system ▪ Sinonasal symptoms such as pain, pressure, or drainage are present on the same side as CT scan findings of rhinosinusitis ○ Replaced criterion requiring:	Balloon sinus ostial dilation is proven and medically necessary for either of the following conditions: • Chronic Rhinosinusitis which has all of the following: ○ Lasted longer than 12 weeks ○ Persistence of symptoms despite administration of full courses of all of the following treatments: ▪ Antibiotic therapy if bacterial infection is suspected; and ▪ Intranasal corticosteroids; and ▪ Nasal lavage ○ Confirmation of Chronic Rhinosinusitis on a computed tomography (CT) scan for each sinus to be dilated meeting all of the following criteria: ▪ CT images are obtained after completion of medical management; and ▪ Documentation of which sinus has the disease and the extent of disease including the percent of opacification or the use of a scale such as the Modified Lund-Mackay Scoring system; and ▪ CT findings include one or more of the following: – Bony remodeling – Bony thickening – Opacified sinus – Ostial obstruction (outflow tract obstruction) and mucosal thickening ○ Sinonasal symptoms such as pain, pressure, or drainage are present on the same side as CT scan findings of rhinosinusitis ○ The balloon sinus ostial dilation limited to the frontal, maxillary, or sphenoid sinuses ○ The balloon sinus ostial dilation performed as either a stand-alone procedure or part of Functional Endoscopic Sinus Surgery (FESS) • Recurrent Acute Rhinosinusitis with all of the following:

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Balloon Sinus Ostial Dilation (for New Jersey Only) (continued)	May 1, 2022	▪ "Chronic Rhinosinusitis *of the* sinus to be dilated *is confirmed* on a computed tomography (CT) scan *with findings of one or more* of the [listed criteria]" with "c*onfirmation of* Chronic Rhinosinusitis on a computed tomography (CT) scan *for each* sinus to be dilated *meeting all* of the [listed] criteria" ▪ "CT findings include mucosal thickening *or* obstruction *of the ostiomeatal complex*" with "CT findings include *ostial* obstruction *(outflow tract obstruction) and* mucosal thickening" *Recurrent Acute Rhinosinusitis* ○ Replaced criterion requiring: ▪ "CT evidence of ostial occlusion and*/or* mucosal thickening in the sinus to be dilated" with "CT *scan* evidence of ostial *obstruction (outflow tract obstruction)* and mucosal thickening in the sinus to be dilated" ▪ "Sinonasal symptoms" with "sinonasal symptoms	○ Four or more episodes per year with distinct symptom free intervals between episodes; and ○ CT scan evidence of ostial obstruction (outflow tract obstruction) and mucosal thickening in the sinus to be dilated; and ○ Sinonasal symptoms such as pain, pressure, or drainage are present on the same side as CT scan findings of rhinosinusitis Balloon sinus ostial dilation is unproven and not medically necessary for treating the following due to insufficient evidence of efficacy: • Nasal polyps or tumors • All other conditions that do not meet the above criteria Self-expanding absorptive sinus ostial dilation is unproven and not medically necessary for evaluating or treating sinusitis and all other conditions due to insufficient evidence of efficacy. **Documentation Requirements** Provide medical notes documenting the following: • History of illness • Recent physical exam • One of the following: ○ Chronic Rhinosinusitis including all of the following: ▪ Treatments tried and failed including duration of treatments/medical therapies ▪ Post medical management CT scan image(s): – That shows the abnormality for which surgery is being requested – Is the optimal image to show the abnormality of the affected area – With use of the Modified Lund-Mackay Scoring System to define the severity of Chronic Rhinosinusitis – Note: Upon request, CT images may be required and must be labeled with the: • Date taken

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Balloon Sinus Ostial Dilation (for New Jersey Only) (continued)	May 1, 2022	*such as pain, pressure, or drainage are present on the same side as CT scan findings of rhinosinusitis*" *Documentation Requirements (new to policy)* • Added language to indicate medical notes documenting the following are required, when applicable: ○ History of illness ○ Recent physical exam ○ One of the following: ▪ Chronic Rhinosinusitis including all of the following: – Treatments tried and failed including duration of treatments/medical therapies – Post medical management CT scan image(s): • That shows the abnormality for which surgery is being requested • Is the optimal image to show the abnormality of the affected area • With use of the	• Applicable case number obtained at time of notification, or the member's name and ID number on the image(s) • Whether the image(s) was taken pre- or post-medical therapy – Submission of diagnostic imaging is required via the external portal at www.uhcprovider.com/paan; faxes will not be accepted ▪ CT scan report documents all of the following: – Which sinus has the disease – The extent of the disease including the percent of opacification or the use of a scale such as the Modified Lund-Mackay Scoring System ▪ Evidence that the sinusitis involves frontal, maxillary, or sphenoid sinuses ▪ Planned procedure, including if the procedure will be part of a functional endoscopic sinus surgery (FESS) ○ Recurrent Acute Rhinosinusitis including all of the following: ▪ Number of episodes per year of acute rhinosinusitis ▪ Signs and symptoms ▪ CT scan image(s): – That shows the abnormality for which surgery is being requested – Is the optimal image to show the abnormality of the affected area – Note: Upon request, CT images may be required and must be labeled with the: • Date taken • Applicable case number obtained at time of notification, or the member's name and ID number on the image(s) • Whether the image(s) was taken pre- or post-medical therapy – Submission of diagnostic imaging is required via the external portal at www.uhcprovider.com/paan; faxes will not be accepted

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Balloon Sinus Ostial Dilation (for New Jersey Only) (continued)	May 1, 2022	Modified Lund-Mackay Scoring System to define the severity of Chronic Rhinosinusitis • Note: Upon request, CT images are required and must be labeled with the: ○ Date taken ○ Applicable case number obtained at time of notification, or the member's name and ID number on the image(s) ○ Whether the image(s) was taken pre- or post-medical therapy • Submission of diagnostic imaging is required via the external portal at www.uhcprovider.com/paan; faxes	▪ CT scan report documents all of the following: – Which sinus has the disease – The extent of the disease including the percent of opacification or the use of a scale such as the Modified Lund-Mackay Scoring System

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Balloon Sinus Ostial Dilation (for New Jersey Only) (continued)	May 1, 2022	will not be accepted – CT scan report documents all of the following: • Which sinus has the disease • The extent of the disease including the percent of opacification or the use of a scale such as the Modified Lund Mackay Scoring System – Evidence that the sinusitis involves frontal, maxillary, or sphenoid sinuses – Planned procedure, including if the procedure will be part of a functional endoscopic sinus surgery (FESS) ▪ Recurrent Acute Rhinosinusitis including all of the following: – Number of episodes per year of acute rhinosinusitis – Signs and symptoms – CT scan image(s):	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Balloon Sinus Ostial Dilation (for New Jersey Only) (continued)	May 1, 2022	• That shows the abnormality for which surgery is being requested • Is the optimal image to show the abnormality of the affected area • Note: Upon request, CT images are required and must be labeled with the: ○ Date taken ○ Applicable case number obtained at time of notification, or the member's name and ID number on the image(s) ○ Whether the image(s) was taken pre- or post-medical therapy • Submission of diagnostic imaging is required via the external portal at	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Balloon Sinus Ostial Dilation (for New Jersey Only) (continued)	May 1, 2022	www.uhcprovider.com/paan; faxes will not be accepted ▪ CT scan report documents all of the following: – Which sinus has the disease – The extent of the disease including the percent of opacification or the use of a scale such as the Modified Lund Mackay Scoring System **Definitions** • Added definition of "Modified Lund-Mackay Scoring System" **Applicable Codes** • Added CPT code 31299 **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	
Cell-Free Fetal DNA Testing (for New Jersey Only)	May 1, 2022	**Coverage Rationale** • Replaced language indicating "*nonamplified or sequenced cell-free* DNA-based noninvasive prenatal *tests (e.g.,* Vanadis*) are* unproven and not medically necessary" with "*the following*	DNA-based noninvasive prenatal tests of fetal aneuploidy are proven and medically necessary as screening tools for trisomy 21 (Down syndrome), trisomy 18 (Edwards syndrome) or trisomy 13 (Patau syndrome) for individuals with a singleton pregnancy in any one of the following circumstances: • Maternal age or oocyte age of 35 years or older at delivery; or • Fetal ultrasound findings indicating an increased risk of aneuploidy; or

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Cell-Free Fetal DNA Testing (for New Jersey Only) (continued)	May 1, 2022	DNA-based noninvasive prenatal *test is* unproven and not medically necessary: Vanadis"
		Supporting Information
		• Updated *Clinical Evidence* section to reflect the most current information
			• History of a prior pregnancy with a trisomy; or
			• Positive first- or second-trimester screening test results for aneuploidy; or
			• Parental balanced Robertsonian translocation with an increased risk of fetal trisomy 13 or trisomy 21; or
			• Screening after pre-test counseling from a board-certified genetic counselor or from the prenatal care physician or healthcare professional using Shared Decision-Making (SDM)
			
			Due to insufficient evidence of efficacy, DNA-based noninvasive prenatal tests are unproven and not medically necessary for any of the following:
			• Conditions including, but not limited to, the following:
			  ○ Multiple gestation pregnancies
			  ○ Twin zygosity
			  ○ Repeat testing due to low fetal fraction
			  ○ Screening for the following:
			  ▪ Aneuploidy other than trisomies 21, 18, or 13
			  ▪ Microdeletions
			  ▪ Single gene disorders
			  ▪ Fetal RhD status
			
			Due to insufficient evidence of efficacy, the following DNA-based noninvasive prenatal test is unproven and not medically necessary:
			• Vanadis
			
			Genetic Counseling
			Genetic counseling is strongly recommended prior to fetal screening or prenatal diagnosis in order to inform persons being tested about the advantages and limitations of the test as applied to a unique person.

Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes (for New Jersey Only)	May 1, 2022	Coverage Rationale *Insulin Delivery* • Revised language pertaining to medical necessity clinical coverage criteria for external insulin pumps	**Insulin Delivery** External insulin pumps that deliver insulin by continuous subcutaneous infusion are proven and medically necessary for managing individuals with type 1 or insulin-requiring type 2 diabetes.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes (for New Jersey Only) (continued)	May 1, 2022	that deliver insulin by continuous subcutaneous infusion; replaced reference to the "InterQual® 2021, *Apr. 2021 Release* CP: Durable Medical Equipment, Insulin Pump, Ambulatory" with "InterQual® *Client Defined 2021*, CP: Durable Medical Equipment, Insulin Pump, Ambulatory *(Custom) - UHG*" *Continuous Glucose Monitoring* • Revised list of proven and medically necessary indications; replaced: ○ "Short-term use (3-*7* days) by a healthcare provider for diagnostic purposes" with "short-term use (3-*14* days) by a healthcare provider for diagnostic purposes" ○ "Long-term use for personal use at home for managing individuals with type 1 diabetes who meet all of the [listed] criteria" with "long-term use for personal use at home for managing individuals with: ▪ Diabetes during pregnancy when certain criteria are met; for medical necessity clinical coverage criteria, refer to the InterQual® Client Defined 2021, CP: Durable Medical	Note: Programmable disposable external insulin pumps (e.g., Omnipod) are considered clinically equivalent to standard insulin pumps. For medical necessity clinical coverage criteria, refer to the InterQual® Client Defined 2021, CP: Durable Medical Equipment, Insulin Pump, Ambulatory (Custom) – UnitedHealth Group. Click here to view the InterQual® criteria. Due to insufficient evidence of efficacy, the following devices are unproven and not medically necessary for managing individuals with diabetes: • Implantable insulin pumps • Insulin infuser ports • Nonprogrammable transdermal insulin delivery systems (e.g., V-Go) **Continuous Glucose Monitoring (CGM)** CGM is proven and medically necessary for managing individuals with diabetes in the following circumstances: • Short-term use (3-14 days) by a healthcare provider for diagnostic purposes • Long-term use for personal use at home for managing individuals with diabetes during pregnancy when certain criteria are met. For medical necessity clinical coverage criteria, refer to the InterQual® Client Defined 2021, CP: Durable Medical Equipment, Continuous Glucose Monitors (Custom) – UHG. • Long-term use for personal use at home for managing individuals with type 1 or type 2 diabetes when certain criteria are met. For medical necessity clinical coverage criteria, refer to the InterQual® Client Defined 2021, CP: Durable Medical Equipment, Continuous Glucose Monitors (Custom) - UHG. Click here to view the InterQual® criteria. Due to insufficient evidence of efficacy, the following services and/or devices are unproven and not medically necessary for managing individuals with diabetes:

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes (for New Jersey Only) (continued)	May 1, 2022	Equipment, Continuous Glucose Monitors (Custom) – UHG ▪ Type 1 or type 2 diabetes when certain criteria are met; for medical necessity clinical coverage criteria, refer to the InterQual® Client Defined 2021, CP: Durable Medical Equipment, Continuous Glucose Monitors (Custom) - UHG" • Removed language indicating long-term CGM for managing individuals with type 2 or gestational diabetes is unproven and not medically necessary **Applicable Codes** • Removed notation indicating: ○ The i-Port device does not have a listed code; E1399 can apply to other unspecified DME devices ○ Procedure codes for continuous glucose monitoring (CGM) are unproven and not medically necessary when reported with diagnosis codes for type 2 diabetes or gestational diabetes • Added HCPCS code A4211 • Removed ICD-10 diagnosis codes	• CGM using an implantable glucose sensor (e.g., Eversense) • CGM using a noninvasive device

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes (for New Jersey Only) (continued)	May 1, 2022	O24.414 and O24.434 **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	
Epiduroscopy, Epidural Lysis of Adhesions and Discography (for New Jersey Only)	May 1, 2022	**Title Change** • Previously titled *Epiduroscopy, Epidural Lysis of Adhesions and Functional Anesthetic Discography (for New Jersey Only)* **Coverage Rationale** • Added language to indicate chemonucleolysis is unproven and not medically necessary for the diagnosis or treatment of any type of neck, back, or spinal disorder **Applicable Codes** • Added CPT codes 62291, 62292, and 72285 **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information	The following are unproven and not medically necessary for the diagnosis or treatment of any type of neck, back, or spinal disorder due to insufficient evidence of efficacy: • Discography ○ Functional anesthetic discography ○ Provocative discography ○ Chemonucleolysis • Epiduroscopy (including spinal myeloscopy) • Percutaneous and endoscopic epidural lysis of adhesions
Functional Endoscopic Sinus Surgery (FESS) (for New Jersey Only)	May 1, 2022	**Coverage Rationale** • Revised coverage criteria for: *Chronic Rhinosinusitis* ○ Replaced criterion requiring "symptoms persist despite *medical therapy with one or more* of the following: nasal	Functional Endoscopic Sinus Surgery (FESS) is proven and medically necessary when one or more of the following conditions are present: • Chronic Rhinosinusitis (CRS) lasted longer than 12 weeks, with all of the following: ○ Persistence of symptoms despite administration of full courses of all of the following treatments: ▪ Antibiotic therapy if bacterial infection is suspected;

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Functional Endoscopic Sinus Surgery (FESS) (for New Jersey Only) (continued)	May 1, 2022	lavage, antibiotic therapy (if bacterial infection is suspected), *or* intranasal corticosteroids" with "persistence of symptoms despite *administration of full courses of all* of the following *treatments*: antibiotic therapy (if bacterial infection is suspected), nasal lavage, *and* intranasal corticosteroids" *Recurrent Acute Rhinosinusitis* ○ Added criterion requiring "four or more episodes per year with distinct symptom free intervals between episodes and all of the following: sinonasal symptoms and computed tomography (CT) evidence of ostial occlusion and/or mucosal thickening in the sinus to be treated" Supporting Information • Updated *Clinical Evidence* and *References* sections to reflect the most current information	▪ Nasal lavage; and ▪ Intranasal corticosteroids; ○ CRS is confirmed on a computed tomography (CT) scan with findings of one or more of the following: ▪ Mucosal thickening ▪ Bony remodeling ▪ Bony thickening ▪ Obstruction of the ostiomeatal complex ▪ Opacified sinus • Recurrent Acute Rhinosinusitis with four or more episodes per year with distinct symptom free intervals between episodes and all of the following: ○ Sinonasal symptoms; and ○ CT evidence of ostial occlusion and/or mucosal thickening in the sinus to be treated • Any of the following conditions confirmed on CT scan: ○ Concha bullosa ○ Complications of sinusitis such as abscess ○ Mucocele ○ Tumor confirmed (such as polyposis or malignancy)
Intensity-Modulated Radiation Therapy (for New Jersey Only)	May 1, 2022	Coverage Rationale • Replaced language indicating "intensity-modulated radiation therapy (IMRT) for Definitive Therapy of the primary site of breast cancer is proven and medically necessary for partial	Note: This policy applies to persons 19 years of age and older. Intensity-modulated radiation therapy (IMRT) is covered without further review for persons 18 years and younger. The following are proven and medically necessary: • IMRT for Definitive Therapy of the primary site of the following conditions: ○ Anal cancer ○ Breast cancer in the following circumstances:

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Intensity-Modulated Radiation Therapy (for New Jersey Only) (continued)	May 1, 2022	breast irradiation *when dose is at least 3Gy/fraction*" with "IMRT for Definitive Therapy of the primary site of breast cancer is proven and medically necessary for partial breast irradiation *of up to 5 fractions*"	▪ When the left-sided internal mammary nodes are being treated ▪ Partial breast irradiation when dose is at least 3Gy/fraction ○ Central nervous system (CNS) tumors (primary or benign) including the brain, brainstem and spinal cord ○ Cervical cancer ○ Endometrial cancer ○ Esophageal cancer ○ Head and neck cancers, including lymphoma and solitary plasmacytomas, when treatment includes the following areas: pharynx (nasopharynx, oropharynx and hypopharynx), larynx, salivary glands, oral cavity (includes the tongue), nasal cavity, paranasal sinuses ○ Mediastinal tumors (e.g., lymphomas, thymomas), including tracheal cancer ○ Pancreatic cancer ○ Prostate cancer ● Compensator based beam modulation treatment when done in combination with an IMRT indication that is listed above as proven ● IMRT may be covered for a condition that is not listed above as proven, including recurrences or metastases in selected cases. Requests for exceptions will be evaluated on a case-by-case basis when at least one of the following conditions is present: ○ A non-IMRT technique would increase the probability of clinically meaningful normal tissue (e.g., as specified by the Radiation Therapy Oncology Group (RTOG) or QUANTEC guidelines) and demonstrated on a comparison of treatment plans for the IMRT and non-IMRT technique (e.g., three-dimensional conformal treatment plan) ○ The same or an immediately adjacent area has been previously irradiated, and the dose distribution within the individual must be sculpted to avoid exceeding the cumulative tolerance dose of nearby normal tissue The following is unproven and not medically necessary due to insufficient evidence of efficacy: ● IMRT used in conjunction with proton beam radiation therapy

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Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions (for New Jersey Only)	May 1, 2022	Coverage Rationale
		• Updated list of examples of liquid biopsy tumor tests for genetic analysis or tumor screening:
		  ○ Added "Foundation One Liquid CDx"
		  ○ Replaced "Guardant" with "Guardant*360*"
		• Added language to indicate multi-cancer early detection tests (e.g., Galleri) are unproven and not medically necessary
		• Replaced language indicating "molecular *profiling using* gene expression profiling, Chromosome Microarray multi-gene cancer panels are unproven and not medically necessary for all other indications [not listed as proven in the policy]" with "molecular *testing such as* gene expression profiling, Chromosome Microarray *Analysis, and* multi-gene cancer panels are unproven and not medically necessary for all other indications [not listed as proven in the policy]"
		• Revised list of indications for which molecular testing is unproven and not medically necessary:
		  ○ Added:
		  ▪ Pancreatic cancer (e.g., PancraGen)
		  ▪ Tumor-informed assays
			Breast Cancer
			The use of one of the following Gene Expression Tests – MammaPrint, Oncotype Dx Breast, Prosigna PAM-50 Breast Cancer Prognostic Gene Signature Assay, Breast Cancer Index (BCI) and EndoPredict – is proven and medically necessary to make a treatment decision regarding adjuvant chemotherapy in females or males with invasive breast cancer in the following situations:
			• Newly diagnosed (within the last 6 months) when all of the following criteria are met:
			  ○ Lymph node negative or 1-3 positive ipsilateral axillary lymph nodes; and
			  ○ No distant metastases; and
			  ○ Hormone receptor-positive (estrogen receptor positive, progesterone receptor positive or both); and
			  ○ HER2 receptor negative; and
			  ○ Adjuvant chemotherapy is not precluded due to any other factor (e.g., advanced age and/or significant co-morbidities)
			or
			• Currently receiving adjuvant hormonal therapy (e.g., Tamoxifen or an aromatase inhibitor) for a breast cancer when all of the following criteria are met:
			  ○ Hormone receptor-positive (estrogen receptor positive, progesterone receptor positive or both); and
			  ○ HER2 receptor negative; and
			  ○ Individual and treating physician have had a discussion prior to testing regarding the potential results of the test and determined to use the results to guide a decision regarding extended adjuvant hormonal therapy
			
			Use of more than one predictive Gene Expression Test for the same tumor in an individual with breast cancer is unproven and not medically necessary due to insufficient evidence of efficacy.
			*Note: This does not apply to BCI testing.

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions (for New Jersey Only) (continued)	May 1, 2022	(Signatera) ○ Replaced "Leukemia other than Chromosome Microarray" with "Leukemia other than Chromosome Microarray *Analysis*" ○ Updated list of examples of molecular tests for: ▪ Cancers of unknown primary site: Removed "Pathfinder TG" ▪ Colorectal cancer: Added "ColoPrint®" and "ColDx" ▪ Melanoma: Removed "Decision Dx-UM" ▪ Prostate cancer; Added "ExoDX Prostate IntelliScore (EPI)" *Breast Cancer* • Replaced language indicating: ○ "[The listed] Gene Expression Tests are proven and medically necessary to make a treatment decision regarding adjuvant chemotherapy in females or males with breast cancer in the [listed] situations" with "[the listed] Gene Expression Tests are proven and medically necessary to make a treatment decision regarding adjuvant chemotherapy in females or males with *invasive* breast	Gene Expression Tests for breast cancer are unproven and not medically necessary for all other indications, including ductal carcinoma in situ (DCIS), due to insufficient evidence of efficacy. Due to insufficient evidence of efficacy, gene expression profiling assays for breast cancer treatment other than those previously described as covered are unproven and not medically necessary, including but not limited to: • BluePrint (also referred to as "80-gene profile") • Breast Cancer Gene Expression Ratio (also known as Theros H/I) • DCISionRT • Oncotype DX DCIS • The 41-gene signature assay • The 76-gene "Rotterdam signature" assay **Thyroid Cancer** Molecular profiling of thyroid nodules with indeterminate cytology (e.g., Afirma GSC, ThyroSeq V3, ThyGeNEXT/ThyraMIR is proven and medically necessary when all the following criteria are met: • Follicular pathology on fine needle aspiration is indeterminate (Bethesda III/IV) • The results of the test will be used for making decisions about further surgery Molecular profiling of confirmed thyroid cancer (except anaplastic thyroid cancer) with genes or gene panels (NTRK, ALK, MMR, MSI, RAS, HRAS, NRAS, RET/PTC1, RET/PTC3, PAX8/PPARγ) is unproven and not medically necessary for all indications due to insufficient evidence of efficacy. Use of more than one molecular profile test in an individual with a thyroid nodule is unproven and not medically necessary due to insufficient evidence of efficacy.

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions (for New Jersey Only) (continued)	May 1, 2022	cancer in the [listed] situations" ○ "Use of more than one Gene Expression Test for the same tumor in an individual with breast cancer is unproven and not medically necessary" with "use of more than one *predictive* Gene Expression Test for the same tumor in an individual with breast cancer is unproven and not medically necessary *(this does not apply to BCI testing)*" • Revised coverage criteria: ○ Added criterion for newly diagnosed breast cancer requiring "no distant metastases" ○ Replaced criterion requiring: ▪ "Lymph node negative or 1-3 positive axillary lymph nodes" with "lymph node negative or 1-3 positive *ipsilateral* axillary lymph nodes" ▪ "[Individual is] currently receiving adjuvant hormonal therapy for a breast cancer *diagnosed within the prior six years* when criteria are met" with "[Individual is] currently receiving adjuvant	**Hematological Cancer** Molecular profiling using chromosomal microarray Analysis (e.g., Oncoscan, Reveal SNP-Oncology, CGH or SNP array) is proven and medically necessary for individuals with acute leukemia. Use of a Next Generation Sequencing profile test to assess minimal residual disease (e.g., ClonoSeq, MyMRD) is proven and medically necessary when the following criteria are met: • Individual has acute myeloid leukemia (AML) or acute lymphoblastic leukemia (ALL) and testing is being performed within 3 months of completing a course of therapy and there is no clinical evidence of disease; or • Individual has multiple myeloma and testing is being performed within three months of an allogenic or autologous bone marrow transplant; and there is no clinical evidence of disease All other multigene, gene expression or microarray molecular profiling for hematological malignancies is unproven and not medically necessary due to insufficient evidence of efficacy. This includes, but is not limited to the following: • Assessment of minimal residual disease by Next Generation Sequencing for acute myeloid leukemia • Use of multi-gene Next Generation Sequencing gene panels for predicting prognosis **Lung Cancer** Multigene molecular profiling of metastatic non-small cell lung cancer is proven and medically necessary when all of the following criteria are met: • The panel selected has no more than 50 genes; and • No prior molecular profiling has been performed on the same tumor Liquid biopsy (circulating tumor cell free DNA) molecular profiling tests of non-small cell lung cancer are proven and medically necessary when the

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions (for New Jersey Only) (continued)	May 1, 2022	hormonal therapy for a breast cancer when criteria are met" ○ Removed criterion requiring: ▪ The individual [with newly diagnosed breast cancer] and treating physician have had a discussion prior to testing regarding the potential results of the test and determined to use the results to guide therapy ▪ The individual [is currently receiving adjuvant hormonal therapy and] has not had prior Gene Expression Testing ● Revised list of unproven and not medically necessary gene expression profiling assays for breast cancer treatment; added "DCISionRT" *Thyroid Cancer* ● Replaced language indicating "molecular profiling of thyroid nodules (e.g., Afirma GSC, ThyroSeq V3, ThyGeNEXT/ThyraMIR, *or the gene and gene fusion panel BRAF V600E, RET fusions, NTRK, ALK, MMR,* MSI*RAS, HRAS, NRAS, RET/PTC1, RET/PTC3,*	following criteria is met: ● The test selected has no more than 50 genes; and ● No prior molecular profiling has been performed on the same tumor; and ● The individual is not medically fit for invasive biopsy; or ● Non-small cell lung cancer has been pathologically confirmed, but there is insufficient material available for molecular testing; and ● Individual and treating physician have had a discussion prior to testing regarding the potential results of the test and determined to use the results to guide therapy **Uveal Melanoma** Gene expression profile testing (e.g., DecisionDx-UM) is considered proven and medically necessary when used to assist with predicting disease severity and making treatment decisions in the following situations: ● Individual has primary, localized uveal melanoma; and ● There is no evidence of metastatic disease; and ● Has not previously had DecisionDx-UM testing for current diagnosis Liquid biopsy (circulating tumor cell free DNA or circulating tumor cells) for any other tumor genetic analysis or tumor screening (e.g., Guardant360, ColoSentry, epi ProColon, OncoCEE CTC, Foundation One Liquid CDx) or multi-cancer early detection tests (e.g., Galleri) are unproven and not medically necessary due to insufficient evidence of efficacy. Due to insufficient evidence of efficacy, molecular testing such as gene expression profiling, Chromosome Microarray Analysis and multi-gene cancer panels are unproven and not medically necessary for all other indications, including but not limited to: ● Bladder Cancer (e.g., Decipher Bladder) (NCCN, Bladder 2021) ● Cancers of unknown primary site (e.g., Response Dx, CancerTYPE ID, Rosetta Cancer Origin, ProOnc, SourceDX,) ● Pancreatic Cancer (e.g., PancraGen) ● Colorectal Cancer (e.g., Oncotype DX® Colon Cancer Assay, Colorectal

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions (for New Jersey Only) (continued)	May 1, 2022	*PAX8/PPARγ*) is proven and medically necessary when all of the [listed] criteria are met" with "molecular profiling of thyroid nodules *with indeterminate cytology* (e.g., Afirma GSC, ThyroSeq V3, ThyGeNEXT/ ThyraMIR) is proven and medically necessary when all of the [listed] criteria are met" • Updated coverage criteria; replaced criterion requiring "follicular pathology on fine needle aspiration is indeterminate" with "follicular pathology on fine needle aspiration is indeterminate *(Bethesda III/IV)*" • Removed language indicating molecular profiling of thyroid nodules or thyroid cancers is unproven and not medically necessary for all other indications [not listed as proven in the policy] • Added language to indicate molecular profiling of confirmed thyroid cancer (except anaplastic thyroid cancer) with genes or gene panels (NTRK, ALK, MMR, MSI, RAS, HRAS, NRAS, RET/PTC1, RET/PTC3, PAX8/PPARγ) is unproven and not medically necessary for *all indications* due to insufficient evidence of efficacy	Cancer DSA™, Genefx Colon® (also known as ColDx), OncoDefender™, CRC, ColoPrint®, ColDx) • Gene panels of >50 genes • Leukemia other than Chromosome Microarray Analysis (e.g., *FoundationOne*® Heme) • Melanoma (e.g., DecisionDx–Melanoma, DermTech PLA) • Multiple myeloma (e.g., MyPRS/MyPRS Plus) • Prostate cancer [e.g., Oncotype DX Prostate Cancer Assay, TMPRSS2 fusion gene, Prolaris Prostate Cancer Test, Decipher Prostate Cancer Classifier, ExoDX Prostate IntelliScore (EPI)] • Tumor-informed assays (Signatera) • Whole Exome Sequencing (WES) and Whole Genome Sequencing (WGS) of tumors

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions (for New Jersey Only) (continued)	May 1, 2022	*Hematological Cancer* • Revised language pertaining to Next Generation Sequencing to indicate the use of a Next Generation Sequencing profile test to assess minimal residual disease (e.g., ClonoSeq, MyMRD) is proven and medically necessary when the following criteria are met: ○ Individual has acute myeloid leukemia (AML) or acute lymphoblastic leukemia (ALL) and testing is being performed within 3 months of completing a course of therapy and there is no clinical evidence of disease; or ○ Individual has multiple myeloma and testing is being performed within three months of an allogenic or autologous bone marrow transplant; and there is no clinical evidence of disease *Lung Cancer* • Replaced language indicating "multigene molecular profiling of non-small cell lung cancer is proven and medically necessary when all of the [listed] criteria are met" with "multigene molecular profiling of *metastatic* non-small cell lung cancer is proven and	

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions (for New Jersey Only) (continued)	May 1, 2022	medically necessary when all of the [listed] criteria are met" • Revised coverage criteria for multigene molecular profiling of metastatic non-small cell lung cancer; removed criterion requiring "the individual and treating physician have had a discussion prior to testing regarding the potential results of the test and determined to use the results to guide therapy" *Uveal Melanoma* • Added language to indicate gene expression profile testing (e.g., DecisionDx-UM) is considered proven and medically necessary when used to assist with predicting disease severity and making treatment decisions in the following situations: ○ Individual has primary, localized uveal melanoma; and ○ There is no evidence of metastatic disease; and ○ Has not previously had DecisionDx-UM testing for current diagnosis • Removed language indicating molecular profiling using gene expression profiling, Chromosome Microarray, and multi-gene cancer panels is unproven and not	

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale

Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions (for New Jersey Only) (continued)	May 1, 2022	medically necessary for uveal melanoma (e.g., Decision Dx-UM)
		Definitions
		• Added definition of:
		  ○ Predictive Molecular Markers
		  ○ Prognostic Molecular Markers
		• Updated definition of:
		  ○ Comparative Genome Hybridization (CGH)
		  ○ Chromosome Microarray Analysis
		Applicable Codes
		• Updated list of applicable CPT codes to reflect annual edits:
		  ○ Added 0017M, 0120U, 0239U, 0242U, 0244U, 0245U, 0250U, 81529, and 81546
		  ○ Removed 81545
		• Removed ICD-10 diagnosis codes C91.40, C91.41, and C91.42
		Supporting Information
		• Updated *Clinical Evidence* and *References* sections to reflect the most current information	

Negative Pressure Wound Therapy	Jun. 1, 2022	**Coverage Rationale**
		• Revised list of indications and devices that are unproven and not medically necessary:
		  ○ Added "negative pressure wound therapy (NPWT) systems with instillation"
		  ○ Replaced "NPWT for treating closed surgical *wounds*" with
			Notes:
			• The proven and medically necessary coverage statements in this policy apply to the use of negative pressure wound therapy (NPWT) in the outpatient setting.
			• The unproven and not medically necessary coverage statements in this policy apply to all settings.
			
			NPWT, in an outpatient setting or upon discharge from an inpatient setting, is proven and medically necessary for treating individuals who have

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Negative Pressure Wound Therapy (continued)	Jun. 1, 2022	"NPWT for treating closed surgical *incisions*" **Definitions** • Updated definition of "National Pressure Injury Advisory Panel (NPIAP) Staging System" **Applicable Codes** • Removed instruction to refer to the Coverage Determination Guideline titled *Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/Replacements* for use of HCPCS codes K0743 and K0746 **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information	undergone a complete wound therapy program and meet indication-specific criteria as noted below. A complete wound therapy program, meeting the following criteria, must have been tried or considered and ruled out prior to initiation of NPWT: • Documentation of evaluation, care and wound measurements; and • Application of dressings to maintain a moist wound environment; and • Debridement of necrotic tissue, if present; and • Evaluation of and provision for adequate nutritional status; and • Documentation, by provider, of indication for NPWT; and • Documentation that an open wound has not responded to conventional treatment after 30 days **Indications** • Pressure ulcer (Stage III or IV) with documentation of the following: ○ Complete wound therapy program, as outlined above; and ○ Appropriate turning and positioning; and ○ Use of a pressure-reducing support surface; and ○ Moisture and incontinence management • Neuropathic ulcer (e.g., Diabetic ulcer) with documentation of the following: ○ Complete wound therapy program, as outlined above; and ○ Comprehensive diabetic management program; and ○ Reduction in pressure on ulcer • Venous insufficiency ulcer with documentation of the following: ○ Complete wound therapy program, as outlined above; and ○ Compression bandages and/or garments have been used consistently, for at least 30 days; and ○ Leg elevation and ambulation • Open surgical wound with documentation of the following: ○ Post-operative dehiscence (separation of a previously closed surgical incision) with documentation of a complete wound therapy program, as outlined above; or ○ Open, non-healing amputation site in diabetics; or

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Negative Pressure Wound Therapy (continued)	Jun. 1, 2022		○ Post-sternotomy infection (mediastinitis); or ○ Delayed healing or non-healing of skin graft is likely due to irregularly contoured or inadequate blood flow of the graft bed ● High-risk open fracture (Gustilo Grade III) The following indications and devices are unproven and not medically necessary due to insufficient evidence of efficacy: ● NPWT for treating all other indications, including but not limited to: ○ Closed surgical incisions ○ Pilonidal disease ● Disposable/single-use NPWT systems ● NPWT systems with instillation **Contraindications to NPWT** ● Active bleeding or exposed vasculature in wound ● Eschar or necrotic tissue present in wound ● Exposed bone, nerves or organs in vicinity of wound ● Malignancy present in wound ● Uncontrolled soft tissue infection or osteomyelitis within vicinity of wound ● Presence of an open fistula to body organs or cavities within vicinity of wound NPWT should be discontinued when any of the following criteria are present: ● Documentation of weekly assessment of the wound's dimensions and characteristics by the provider indicate failure of progressive wound healing (i.e., wound is not diminishing in size [either surface area or depth] within 30 days); or ● The depth of the wound is 1 mm or less; or ● Uniform granulation tissue has been obtained
Obstructive and Central Sleep Apnea Treatment	Jun. 1, 2022	Coverage Rationale *Nonsurgical Treatment* ● Revised list of services/devices that are unproven and not	**Nonsurgical Treatment** Removable Oral Appliances are proven and medically necessary for treating Obstructive Sleep Apnea (OSA) as documented by a sleep study (e.g., polysomnography or Home Sleep Apnea Testing). Refer to the Medical Policy

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Obstructive and Central Sleep Apnea Treatment (continued)	Jun. 1, 2022	medically necessary for treating Obstructive Sleep Apnea (OSA); added: ○ Non-surgical electrical muscular training ○ Morning repositioning devices *Surgical Treatment* ● Revised coverage criteria for implantable hypoglossal nerve stimulation: ○ Added criterion requiring total AHI < 25% for central + mixed apneas ○ Replaced reference to "polysomnography" with "Polysomnography *(Attended)*" ● Revised list of surgical procedures that are unproven and not medically necessary for treating Obstructive Sleep Apnea (OSA); added "distraction osteogenesis for maxillary expansion (DOME)" Definitions ● Added definition of "Polysomnogram (Attended)" Applicable Codes ● Added CPT/HCPCS codes 21142, E1399, K1028, and K1029 ● Added notation to indicate: ○ HCPCS code E0486 applies to the custom fabricated oral device/appliance used to reduce upper airway	titled Attended Polysomnography for Evaluation of Sleep Disorders for further information. For many individuals, oral appliance therapy (OAT) may be an effective alternative to failed continuous positive airway pressure (CPAP) therapy. Documentation of the following is required: ● A patient presenting with symptoms of OSA be seen in a face-to-face evaluation with a qualified physician (MD or DO) trained in sleep medicine or with an Advanced Practice Provider working under the direct supervision of a sleep medicine physician prior to beginning treatment for OAT (AASM and AADSM, December 2012, AAO-HNS, November 2019) ● A treating physician (MD or DO) or an Advanced Practice Provider must diagnose OSA and recommend course of treatment (AAO-HNS, November 2019) ● If the patient refuses CPAP therapy, documentation of the refusal from the patient's treating physician (MD or DO) or an Advanced Practice Provider must be supplied For information on snoring and Oral Appliances, refer to the Coverage Determination Guideline titled Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/Replacements. For medical necessity clinical coverage criteria for removable oral appliances, refer to the InterQual® 2021, Oct. 2021 Release, CP: Durable Medical Equipment, Noninvasive Airway Assistive Devices. Click here to view the InterQual® criteria. The following are unproven and not medically necessary due to insufficient evidence of efficacy: ● Devices for treating Positional OSA ● Nasal dilator devices for treating OSA ● Removable Oral Appliances for treating Central Sleep Apnea ● Prefabricated Oral Appliance/Device ● Non-surgical electrical muscular training

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Obstructive and Central Sleep Apnea Treatment (continued)	Jun. 1, 2022	collapsibility, adjustable or nonadjustable and includes fitting and adjustment ○ Dental services (e.g., D9947, D9948, and D9949) are excluded from coverage under the medical plan; the member specific benefit plan document must be referenced prior to determining any coverage decision **Supporting Information** ● Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	● Morning repositioning devices **Surgical Treatment** The following surgical procedures are proven and medically necessary for treating OSA as documented by polysomnography. For medical necessity clinical coverage criteria, InterQual® Client Defined 2021, CP: Procedures: ● Mandibular Osteotomy (Custom) – UnitedHealth Group ● Maxillomandibular Osteotomy and Advancement (Custom) - UnitedHealth Group ● Uvulopalatopharyngoplasty (UPPP) (Custom) - UnitedHealth Group Click here to view the InterQual® criteria. Implantable hypoglossal nerve stimulation is proven and medically necessary in an adult patient with moderate to severe OSA when all of the following criteria are met: ● Body Mass Index of (BMI) less than or equal to 32kg/m2; and ● Apnea hypopnea Index (AHI) of ≥ 20 and ≤ 65 as determined with Polysomnography (Attended); and ● Total AHI < 25% for central + mixed apneas; and ● Absence of complete concentric collapse at the soft palate level; and ● Failure or intolerance of Positive Airway Pressure (PAP) treatments (such as continuous positive airway pressure [CPAP] or bi-level positive airway pressure [BPAP] machines) ○ PAP failure is defined as an inability to eliminate OSA (AHI of greater than 20 despite PAP usage) and PAP intolerance is defined as: ▪ Inability to use PAP (greater than 5 nights per week of usage; usage defined as greater than 4 hours of use per night); or ▪ Unwillingness to use PAP (for example, a patient returns the PAP system after attempting to use it) Implantable neurostimulation devices for the treatment of Central Sleep Apnea (CSA) are unproven and not medically necessary due to insufficient evidence of safety and/or efficacy.

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Obstructive and Central Sleep Apnea Treatment (continued)	Jun. 1, 2022		The following surgical procedures are unproven and not medically necessary for treating OSA due to insufficient evidence of efficacy: • Laser-assisted uvulopalatoplasty (LAUP) • Lingual suspension - Also referred to as tongue stabilization, tongue stitch or tongue fixation • Palatal implants • Radiofrequency ablation of the soft palate and/or tongue base • Transoral robotic surgery (TORS) • Distraction osteogenesis for maxillary expansion (DOME)
Obstructive and Central Sleep Apnea Treatment (for New Jersey Only)	May 1, 2022	Title Change • Previously titled *Obstructive Sleep Apnea Treatment (for New Jersey Only)* Coverage Rationale *Nonsurgical Treatment* • Revised coverage criteria for oral appliance therapy (OAT) as an effective alternative to failed continuous positive airway pressure (CPAP) therapy to reflect/include: ○ A patient presenting with symptoms of OSA be seen in a face-to-face evaluation with a qualified physician (MD or DO) trained in sleep medicine *or with an Advanced Practice Provider working under the direct supervision of a sleep medicine physician* prior to beginning treatment for OAT ○ A treating physician (MD or DO) *or an Advanced Practice*	**Nonsurgical Treatment** Removable Oral Appliances are proven and medically necessary for treating Obstructive Sleep Apnea (OSA) as documented by a sleep study (e.g., polysomnography or Home Sleep Apnea Testing). Refer to the Medical Policy titled Attended Polysomnography for Evaluation of Sleep Disorders (for New Jersey Only) for further information. For many individuals, oral appliance therapy (OAT) may be an effective alternative to failed continuous positive airway pressure (CPAP) therapy. Documentation of the following is required: • A patient presenting with symptoms of OSA be seen in a face-to-face evaluation with a qualified physician (MD or DO) trained in sleep medicine or with an Advanced Practice Provider working under the direct supervision of a sleep medicine physicianprior to beginning treatment for OAT (AASM and AADSM, December 2012, AAO-HNS, November 2019) • A treating physician (MD or DO) or an Advanced Practice Provider must diagnose OSA and recommend course of treatment (AAO-HNS, November 2019) • If the patient refuses CPAP therapy, documentation of the refusal from the patient's treating physician (MD or DO) or an Advanced Practice Provider must be supplied For information on snoring and Oral Appliances, see the Coverage Determination Guideline titled Durable Medical Equipment, Orthotics, Medical

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Obstructive and Central Sleep Apnea Treatment (for New Jersey Only) (continued)	May 1, 2022	*Provider* must diagnose OSA and recommend course of treatment ○ If the patient refuses CPAP therapy, documentation of the refusal from the patient's treating physician (MD or DO) *or an Advanced Practice Provider* must be supplied • Revised list of unproven and not medically necessary devices; added: ○ Devices for treating Positional Obstructive Sleep Apnea (OSA) ○ Prefabricated Oral Appliance/device *Surgical Treatment* • Revised coverage criteria for implantable hypoglossal nerve stimulation; replaced criterion requiring "apnea hypopnea Index (AHI) of *15 or greater* and less than or equal to 65 as determined with polysomnography" with "apnea hypopnea Index (AHI) of *≥ 20* and ≤ 65 as determined with polysomnography" • Added language to indicate implantable neurostimulation devices for the treatment of Central Sleep Apnea (CSA) are unproven and not medically necessary due to	Supplies and Repairs/Replacements (for New Jersey Only). For medical necessity clinical coverage criteria, refer to the InterQual® 2021, Dec. 2021 Release, Medicare: Durable Medical Equipment, Oral Appliances for Obstructive Sleep Apnea. Click here to view the InterQual® criteria. The following are unproven and not medically necessary due to insufficient evidence of efficacy: • Devices for treating Positional OSA • Nasal dilator devices for treating OSA • Removable Oral Appliances for treating Central Sleep Apnea • Prefabricated Oral Appliance/Device **Surgical Treatment** The following surgical procedures are proven and medically necessary for treating OSA as documented by polysomnography. For medical necessity clinical coverage criteria, refer to the refer to the InterQual® 2021: • Apr. 2021 Release, CP: Procedures: ○ Osteotomy, LeFort I ○ Osteotomy, Sagittal Split, Mandible Ramus ○ Uvulopalatopharyngoplasty (UPPP) • July 2021 Release, CP: Procedures, Osteotomy, Anterior Segment, Mandible • Oct. 2021 Release, CP: Procedures, Maxillomandibular Advancement Click here to view the InterQual® criteria. Implantable hypoglossal nerve stimulation is proven and medically necessary in an adult patient with moderate to severe OSA when all of the following criteria are met: • Body Mass Index of (BMI) less than or equal to 32kg/m^2; and • Apnea Hypopnea Index (AHI) of ≥ 20 and ≤65 as determined with

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Obstructive and Central Sleep Apnea Treatment (for New Jersey Only) (continued)	May 1, 2022	insufficient evidence of safety and/or efficacy **Definitions** • Added definition of: ○ Advanced Practice Providers (APPs) ○ Central Sleep Apnea (CSA) ○ Oral Appliance ○ Positional Obstructive Sleep Apnea • Updated definition of: ○ Apnea Hypopnea Index (AHI) ○ Home Sleep Apnea Testing (HSAT) ○ Hypopnea ○ Physician or Practitioner ○ Respiratory Disturbance Index (RDI) ○ Respiratory Event Index (REI) **Applicable Codes** • Added CPT/HCPCS codes 0424T, 0425T, 0426T, 0427T, 0428T, 0429T, 0430T, 0431T, 0432T, 0433T, 0434T, 0435T, 0436T, K1001, and S2900 • Removed HCPCS code K1027 **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	polysomnography; and • Absence of complete concentric collapse at the soft palate level; and • Failure or intolerance of Positive Airway Pressure (PAP) treatments (such as continuous positive airway pressure [CPAP] or bi-level positive airway pressure [BPAP] machines) ○ PAP failure is defined as an inability to eliminate OSA (AHI of greater than 20 despite PAP usage) and PAP intolerance is defined as: ▪ Inability to use PAP (greater than 5 nights per week of usage; usage defined as greater than 4 hours of use per night); or ▪ Unwillingness to use PAP (for example, a patient returns the PAP system after attempting to use it) Implantable neurostimulation devices for the treatment of Central Sleep Apnea (CSA) are unproven and not medically necessary due to insuffiicent evidence of safety and/or efficacy. The following surgical procedures are unproven and not medically necessary for treating OSA due to insufficient evidence of efficacy: • Laser-assisted uvulopalatoplasty (LAUP) • Palatal implants • Lingual suspension – Also referred to as tongue stabilization, tongue stitch or tongue fixation • Transoral robotic surgery (TORS) • Radiofrequency ablation of the soft palate and/or tongue base

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale

Skin and Soft Tissue Substitutes	Jun. 1, 2022	**Coverage Rationale**
		• Revised list of skin and soft tissue substitutes that are unproven and not medically necessary for any indication; added:
		  ○ Apis
		  ○ Cygnus matrix
		  ○ InnovaMatrix AC
		  ○ Microlyte Matrix
		  ○ Mirragen Advanced Wound Matrix
		  ○ NovoSorb SynPath
		  ○ Restrata
		  ○ Symphony
		  ○ TheraGenesis
		  ○ XCelliStem
		Applicable Codes
		• Added HCPCS codes A2001, A2002, A2004, A2005, A2006, A2007, A2008, A2009, A2010, and Q4199
		Supporting Information
		• Updated *Clinical Evidence* and *References* sections to reflect the most current information
			• Refer to the policy for complete details.

Surgery of the Elbow (for New Jersey Only)	May 1, 2022	**Title Change** • Previously titled *Elbow Replacement Surgery (Arthroplasty) (for New Jersey Only)* **Coverage Rationale** • Replaced language indicating "elbow *replacement surgery* is	Surgery of the elbow is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® 2021, Apr. 2021 Release, CP: Procedures: • Arthroscopy, Diagnostic, +/- Synovial Biopsy, Elbow • Arthroscopy, Surgical, Elbow • Joint Replacement, Elbow • Removal or Revision, Arthroplasty, Elbow Click here to view the InterQual® criteria.

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Surgery of the Elbow (for New Jersey Only) (continued)	May 1, 2022	proven and medically necessary in certain circumstances" with "*surgery of the* elbow is proven and medically necessary in certain circumstances" • Revised language pertaining to medical necessity clinical coverage criteria: added reference to the InterQual® 2021, Apr. 2021 Release, CP: Procedures: ○ Arthroscopy, Diagnostic, +/- Synovial Biopsy, Elbow ○ Arthroscopy, Surgical, Elbow ○ Removal or Revision, Arthroplasty, Elbow *Documentation Requirements* • Added language to indicate medical notes documenting the following are required, when applicable: ○ Upon request, we may require the specific diagnostic image(s) that show the abnormality for which surgery is being requested, which may include MRI, CT scan, X-ray, and/or bone scan; consultation with requesting surgeon may be of benefit to select the optimal images ▪ Diagnostic images must be labeled with: – The date taken	**Documentation Requirements** Medical notes documenting the following, when applicable: • Upon request, we may require the specific diagnostic image(s) that show the abnormality for which surgery is being requested, which may include MRI, CT scan, X-ray, and/or bone scan; consultation with requesting surgeon may be of benefit to select the optimal images ○ Note: Diagnostic images must be labeled with: ▪ The date taken ▪ Applicable case number obtained at time of notification, or member's name and ID number on the image(s) ○ Submission of diagnostic imaging is required via the external portal at www.uhcprovider.com/paan; faxes will not be accepted • Reports of all recent imaging studies and applicable diagnostic tests) ○ Microbiological findings ○ Synovial fluid exam ○ Erythrocyte sedimentation rate (ESR) ○ C-reactive protein (CRP) • Condition requiring procedure • Pertinent physical examination of the relevant joint • Pain severity, circadian patterns of pain, location of pain, and details of functional disability(ies) interfering with activities of daily living (preparing meals, dressing, driving) • Prior therapies/ treatments tried, failed, or contraindicated. Include the dates and reason for discontinuation • Date of previous failed surgery to the same joint, if applicable • Physician's treatment plan, including pre-op discussion • For revision surgery, also include: ○ Details of complication ○ Complete (staged) surgical plan

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Surgery of the Elbow (for New Jersey Only) (continued)	May 1, 2022	– Applicable case number obtained at time of notification, or member's name and ID number on the image(s) ▪ Submission of diagnostic imaging is required via the external portal at uhcprovider.com/paan; faxes will not be accepted o Reports of all recent imaging studies and applicable diagnostic tests) ▪ Microbiological findings ▪ Synovial fluid exam ▪ Erythrocyte sedimentation rate (ESR) ▪ C-reactive protein (CRP) o Condition requiring procedure o Pertinent physical examination of the relevant joint o Pain severity, circadian patterns of pain, location of pain, and details of functional disability(ies) interfering with activities of daily living (preparing meals, dressing, driving) o Prior therapies/ treatments tried, failed, or contraindicated. Include the dates and reason for discontinuation	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Surgery of the Elbow (for New Jersey Only) (continued)	May 1, 2022	○ Date of previous failed surgery to the same joint, if applicable ○ Physician's treatment plan, including pre-op discussion ○ For revision surgery, also include: ▪ Details of complication ▪ Complete (staged) surgical plan **Applicable Codes** ● Added CPT codes 24365, 24366, 29830, 29834, 29837, and 29838 **Supporting Information** ● Updated *FDA* section to reflect the most current information	
Surgery of the Shoulder (for New Jersey Only)	May 1, 2022	**Coverage Rationale** ● Revised language pertaining to medical necessity clinical coverage criteria: added reference to the InterQual® 2021: ○ July 2021 Release, CP: Procedures, Arthroscopy, Diagnostic, +/- Synovial Biopsy, Shoulder ○ Jan. 2022 Release, CP: Procedures, Arthroscopy or Arthroscopically Assisted Surgery, Shoulder (Adolescent) **Applicable Codes** ● Added CPT code 29820	Surgery of the shoulder is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the: ● InterQual® 2021, Apr. 2021 Release, CP: Procedures, Joint Replacement, Shoulder ● InterQual® 2021, July 2021 Release, CP: Procedures, Arthroscopy, Diagnostic, +/- Synovial Biopsy, Shoulder ● InterQual® 2021, Jan. 2022 Release, CP: Procedures: ○ Arthroscopy or Arthroscopically Assisted Surgery, Shoulder ○ Arthroscopy or Arthroscopically Assisted Surgery, Shoulder (Adolescent) ○ Arthrotomy, Shoulder ● InterQual® Client Defined 2021, CP: Procedures, Arthroplasty, Removal or Revision, Shoulder (Custom) - UHG Click here to view the InterQual® criteria. **Documentation Requirements** Provide medical notes documenting the following:

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Surgery of the Shoulder (for New Jersey Only) (continued)	May 1, 2022		• Pertinent physical examination of the relevant joint • Severity of pain as documented on a validated pain scale • Functional disability(ies) as documented on a validated functional disability scale or described as interfering with activities of daily living (preparing meals, dressing, driving, walking) • Specific diagnostic image(s) that documents the severity of joint disease using a validated scale (e.g., Walch classification of primary glenohumeral osteoarthritis) and shows the abnormality for which surgery is being requested, which may include MRI, CT scan, X-ray, and/or bone scan; consultation with requesting surgeon may be of benefit to select the optimal image(s) ○ Note: Diagnostic images: ▪ May include MRI, CT scan, X-ray, and/or bone scan, and ▪ Must be labeled with the: – Date taken – Applicable case number obtained at time of notification, or the member's name and ID number on the image(s) ○ Submission of diagnostic imaging is required via the external portal at www.uhcprovider.com/paan; faxes will not be accepted • Advanced joint disease using a validated scale (e.g., Walch classification of primary glenohumeral osteoarthritis) • Diagnostic image(s) report(s) • Condition requiring procedure • Physician's treatment plan including pre-op discussion • Co-morbid medical condition(s) • Therapies tried (including dates) and failed as documented by a lack of clinically significant improvement between at least two measurements concurrent to the therapy, on validated pain or functional disability scale(s) or quantifiable symptoms; these therapies could include: ○ Nonoperative Therapy (i.e., orthotics, medications/injections, physical therapy, other pain management procedures, etc.) ○ Surgery

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale

Temporomandibular Joint Disorders (for New Jersey Only)	May 1, 2022	**Coverage Rationale**
		• Revised language pertaining to medical necessity clinical coverage criteria:
		  ○ Added reference to the InterQual® Client Defined 2021, CP: Procedures, Arthroplasty, Temporomandibular Joint (TMJ) (Custom) - UHG
		  ○ Removed reference to the InterQual® 2021, Apr. 2021 Release, CP: Procedures, Arthroplasty, Temporomandibular Joint (TMJ)
		• Added language to indicate multiple occlusal splints (i.e., daytime and nighttime splints, maxillary and mandibular splints) are unproven and not medically necessary for treating disorders of the temporomandibular joint (TMJ)
		• Added reference link to the Medical Benefit Drug Policy titled *Botulinum Toxins A and B* for information regarding botulinum toxin injections for temporomandibular joint disorders
		Supporting Information
		• Updated *Clinical Evidence* and *References* sections to reflect the most current information
		• Removed *CMS* section
			The following services are proven and medically necessary for treating disorders of the temporomandibular joint (TMJ):
			• Arthrocentesis
			• Arthroscopy
			• Intra-articular Injections of corticosteroids
			• Trigger point injections
			• Physical therapy
			• Occlusal splints (stabilization and repositioning splints)
			• Partial or total joint replacement
			
			For medical necessity clinical coverage criteria for the following services, see the InterQual® 2021, Apr. 2021 Release, CP Procedures:
			• Arthroscopy, Temporomandibular Joint (TMJ)
			• Discectomy, Temporomandibular Joint (TMJ)
			• Reconstruction, Temporomandibular Joint (TMJ)
			
			Click here to view the InterQual® criteria.
			
			For medical necessity clinical coverage criteria, refer to the InterQual® Client Defined 2021, CP: Procedures
			• Arthroplasty, Temporomandibular Joint (TMJ) (Custom) – UHG
			
			Click here to view the InterQual® criteria.
			
			The following services are unproven and not medically necessary for treating disorders of the temporomandibular joint (TMJ) due to insufficient evidence of efficacy (this list is not all-inclusive):
			• Biofeedback
			• Craniosacral manipulation/therapy
			• Passive rehabilitation therapy
			• Low-load prolonged-duration stretch (LLPS) devices
			• Multiple occlusal splints (i.e., daytime, and nighttime splints; maxillary and mandibular splints)

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Temporomandibular Joint Disorders (for New Jersey Only) (continued)	May 1, 2022		For information regarding intra-articular injections of sodium hyaluronate for temporomandibular joint disorders, refer to the Medical Benefit Drug Policy titled *Sodium Hyaluronate*. For information regarding botulinum toxin injections for temporomandibular joint disorders, refer to the Medical Benefit Drug Policy titled *Botulinum Toxins A and B*.
Vagus and External Trigeminal Nerve Stimulation (for New Jersey Only)	May 1, 2022	**Title Change** • Previously titled *Vagus Nerve Stimulation (for New Jersey only)* **Coverage Rationale** • Revised coverage criteria for proven and medically necessary use of implantable vagus nerve stimulators for treating epilepsy; replaced criterion requiring "the individual is not a *surgical* candidate or has failed *a surgical intervention*" with "the individual is not a candidate *for epilepsy surgery*, has failed *epilepsy surgery, or refuses epilepsy surgery after Shared Decision Making discussion*" • Revised list of unproven and not medically necessary indications: ○ Added external or transcutaneous (non-implantable) trigeminal nerve stimulation devices (e.g., Monarch® eTNS System, Cefaly®) for preventing or treating all conditions,	Implantable vagus nerve stimulators are proven and medically necessary for treating epilepsy in individuals with all of the following (see below for implants that allow detection and stimulation of increased heart rate): • Medically refractory epileptic seizures with failure of two or more trials of single or combination antiepileptic drug therapy or intolerable side effects of antiepileptic drug therapy; and • The individual is not a candidate for epilepsy surgery or has failed epilepsy surgery, or refuses epilepsy surgery after Shared Decision Making discussion; and • No history of left or bilateral cervical vagotomy. The U.S. Food and Drug Administration (FDA) identifies a history of left or bilateral cervical vagotomy as a contraindication to vagus nerve stimulation. Implantable vagus nerve stimulators are unproven and not medically necessary for treating all other conditions due to insufficient evidence of efficacy. These conditions include but not limited to: • Alzheimer's disease • Anxiety disorder • Autism spectrum disorder • Back and neck pain • Bipolar disorder • Bulimia • Cerebral palsy • Chronic pain syndrome • Cluster headaches • Depression

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Vagus and External Trigeminal Nerve Stimulation (for New Jersey Only) (continued)	May 1, 2022	including but not limited to: ▪ Attention deficit hyperactivity disorder (ADHD) ▪ Depression ▪ Epilepsy ▪ Headache ○ Updated list of examples of vagus nerve stimulation implants that allow detection and stimulation of increased heart rate; added "SenTiva™ Model 1000" **Definitions** ● Added definition of "Shared Decision Making" **Supporting Information** ● Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	● Fibromyalgia ● Heart failure ● Migraines ● Morbid obesity ● Narcolepsy ● Obsessive-compulsive disorder ● Paralysis agitans ● Sleep disorders ● Tourette's syndrome The following are unproven and not medically necessary due to insufficient evidence of efficacy: ● Vagus nerve stimulation implants that allow detection and stimulation of increased heart rate (e.g., AspireSR™ Model 106, SenTiva™ Model 1000) for treating epilepsy ● Transcutaneous (nonimplantable) vagus nerve stimulation (e.g., gammaCore® for headaches) for preventing or treating all indications ● External or transcutaneous (nonimplantable) trigeminal nerve stimulation devices (e.g., Monarch® eTNS System, Cefaly®) for preventing or treating all conditions including but not limited to: ○ Attention deficit hyperactivity disorder (ADHD) ○ Depression ○ Epilepsy ○ Headache Note: For vagus nerve blocking for the treatment of obesity, refer to the Medical Policy titled Bariatric Surgery (for New Jersey Only).
Video Electro-encephalographic (vEEG) Monitoring and Recording (for New Jersey Only)	May 1, 2022	**Title Change** ● Previously titled *Electroencephalographic (EEG) Monitoring and Video Recording (for New Jersey Only)* **Coverage Rationale**	Video electroencephalographic (vEEG) monitoring and recording is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® 2021, Apr. 2021 Release, CP: Procedures: ● Video Electroencephalographic (EEG) Monitoring ● Video Electroencephalographic (EEG) Monitoring (Pediatric)

Medical Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Video Electro-encephalographic (vEEG) Monitoring and Recording (for New Jersey Only) (continued)	May 1, 2022	• Replaced language indicating "*electroencephalographic (EEG) monitoring and video recording* is proven and medically necessary in certain circumstances" with "*video electroencephalographic (vEEG) monitoring and recording* is proven and medically necessary in certain circumstances" • Added language to indicate inpatient admission is proven and medically necessary for any of the following circumstances when the [listed] InterQual® criteria for video EEG are met: ○ Individual is not expected to have a seizure or seizure-like diagnostic event within a timeframe that is reasonable for an ambulatory vEEG recording (Note: Most individuals will have an event within 48 hours) ○ Individual is undergoing preoperative evaluation for epilepsy surgery ○ Seizure provocation maneuvers are required that warrant direct observation in an inpatient setting ○ Seizure medication is being adjusted in such a way as to risk provoking an event that	Click here to view the InterQual® criteria. If the InterQual® criteria for video EEG monitoring referred to above are met, then inpatient admission is proven and medically necessary for any of the following circumstances: • Individual is not expected to have a seizure or seizure-like diagnostic event within a timeframe that is reasonable for an ambulatory vEEG recording* • Individual is undergoing preoperative evaluation for epilepsy surgery • Seizure provocation maneuvers are required that warrant direct observation in an inpatient setting • Seizure medication is being adjusted in such a way as to risk provoking an event that would require inpatient management • Seizure medication discontinuation is required to provoke seizure for diagnostic purposes *Note: Most individuals will have an event within 48 hours

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Video Electro-encephalographic (vEEG) Monitoring and Recording (for New Jersey Only) (continued)	May 1, 2022	would require inpatient management ○ Seizure medication discontinuation is required to provoke seizure for diagnostic purposes **Supporting Information** ● Added *Description of Services*, *Clinical Evidence*, and *References* sections	

Replaced		
Policy Title	**Effective Date**	**Summary of Changes**
Osteochondral Grafting (for New Jersey Only)	May 1, 2022	● Policy replaced; refer to the Medical Policy titled Articular Cartilage Defect Repairs (for New Jersey Only)

Medical Benefit Drug Policy Updates

Updated		
Policy Title	**Effective Date**	**Summary of Changes**
Adakveo® (Crizanlizumab-Tmca)	May 1, 2022	**Application** • Added language to indicate this Medical Benefit Drug Policy does not apply to the state of Texas; refer to the state's Medicaid clinical policy **Applicable Codes** • Added ICD-10 diagnosis codes D57.0, D57.2, D57.21, D57.3, D57.4, D57.41, D57.43, D57.45, D57.8, D57.81, D57.813, and D57.818 • Revised description for ICD-10 diagnosis code D57.819 **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information
Amondys 45™ (Casimersen)	Apr. 1, 2022	**Application** • Added language to indicate this Medical Benefit Drug Policy does not apply to the state of Texas; refer to the state's Medicaid clinical policy **Supporting Information** • Updated *References* section to reflect the most current information
Antiemetics for Oncology	Apr. 1, 2022	**Application** • Added language to indicate this Medical Benefit Drug Policy does not apply to the state of Hawaii
Exondys 51® (Eteplirsen)	Apr. 1, 2022	**Application** • Added language to indicate this Medical Benefit Drug Policy does not apply to the state of Texas; refer to the state's Medicaid clinical policy **Supporting Information** • Updated *References* section to reflect the most current information
Radicava® (Edaravone)	Apr. 1, 2022	**Application** • Added language to indicate this Medical Benefit Drug Policy does not apply to the state of Texas; refer to the state's Medicaid clinical policy **Supporting Information** • Updated *References* section to reflect the most current information

Review at Launch for New to Market Medications	Apr. 1, 2022	**Related Document**
		• Updated *Review at Launch Medication List*:
		  ○ Added Korsuva™ (difelikefalin)
		  ○ Removed Nexviazyme™ (avalglucosidase alfa-ngpt)
		Application
		• Updated language to indicate this Medical Benefit Drug Policy applies to the state of Kentucky

Medical Benefit Drug Policy Updates

Updated

Policy Title	Effective Date	Summary of Changes

Somatostatin Analogs	Apr. 1, 2022	**Application**
		• Added language to indicate this Medical Benefit Drug Policy does not apply to the states of:
		  ○ Florida; refer to the state's Medicaid clinical policy
		  ○ Pennsylvania; refer to the state-specific policy version

Synagis® (Palivizumab)	Apr. 1, 2022	**Application** • Added language to indicate this Medical Benefit Drug Policy does not apply to the states of Arizona, Florida, Hawaii, Louisiana, Maryland, Michigan, Mississippi, Nebraska, New Jersey, Ohio, Pennsylvania, Rhode Island, Texas, Virginia, and Washington; refer to the Medical Benefit Drug Policy titled *Denied Drug Codes – Pharmacy Benefit Drugs*
Tepezza® (Teprotumumab-Trbw)	Apr. 1, 2022	**Application** • Added language to indicate this Medical Benefit Drug Policy does not apply to the state of Texas; refer to the state's Medicaid clinical policy **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information
Trogarzo® (Ibalizumab-Uiyk)	Apr. 1, 2022	**Application** • Removed language indicating this Medical Benefit Drug Policy does not apply to the state of Florida
Vyondys 53™ (Golodirsen)	Apr. 1, 2022	**Application** • Added language to indicate this Medical Benefit Drug Policy does not apply to the state of Texas; refer to the state's Medicaid clinical policy **Supporting Information** • Updated *References* section to reflect the most current information

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale

Lemtrada® (Alemtuzumab)	May 1, 2022	**Coverage Rationale**
		• Revised list of drug products (at least two required) the patient has a history of failure following a trial for at least 4 weeks or history of intolerance; added cladribine (Mavenclad)
		Supporting Information
		• Updated *References* section to
			Lemtrada (alemtuzumab) is proven and medically necessary for treatment of relapsing forms of multiple sclerosis when all of the following criteria are met:
			• Diagnosis of relapsing forms of multiple sclerosis (MS) (e.g., relapsing-remitting MS, active secondary-progressive MS); and
			• One of the following:
			  ○ Treatment-naïve to alemtuzumab:
			  ▪ Patient has history of failure following a trial for at least 4 weeks or history of intolerance to at least two of the following:
			  – Interferon β-1a (Avonex® or Rebif®)

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Lemtrada® (Alemtuzumab) (continued)	May 1, 2022	reflect the most current information	– Interferon β-1b (Betaseron® or Extavia®) – Glatiramer acetate (Copaxone® or Glatopa®) – Dimethyl fumarate (Tecfidera®) – Teriflunomide (Aubagio®) – Fingolimod (Gilenya®) – Peginterferon beta-1a (Plegridy™) – Natalizumab (Tysabri®) – Ocrelizumab (Ocrevus®) – Rituximab (Rituxan®, Riabni™, Truxima®, Ruxience™) – Siponimod (Mayzent®) – Ozanimod (Zeposia®) – Ofatumumab (Kesimpta®) – Monomethyl fumarate (Bafiertam) – Cladribine (Mavenclad) and ▪ Patient has not been previously treated with alemtuzumab; and ▪ Patient is not receiving alemtuzumab in combination with another disease modifying agent for multiple sclerosis (e.g., interferon beta preparations, glatiramer acetate, natalizumab, fingolimod, teriflunomide, ocrelizumab, etc.); and ▪ Initial dosing is administered: 12 mg intravenously daily for 5 consecutive days; and ▪ Regimen is administered only once within 12 months; and ▪ Initial authorization is for no more than 12 months or ○ Treatment-experienced with alemtuzumab: ▪ Patient has previously received treatment with alemtuzumab; and ▪ Documentation of positive clinical response to alemtuzumab therapy; and ▪ Patient is not receiving alemtuzumab in combination with another disease modifying agent for multiple sclerosis (e.g., interferon beta preparations, glatiramer acetate, natalizumab, fingolimod, teriflunomide, ocrelizumab, etc.); and

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Lemtrada® (Alemtuzumab) (continued)	May 1, 2022		▪ Retreatment dosing is administered: 12 mg intravenously daily for 3 consecutive days; and ▪ Regimen is administered only once within 12 months; and ▪ Authorization is for no more than 12 months Alemtuzumab is unproven and not medically necessary for the treatment of: ● Rheumatoid arthritis ● Autoimmune neutropenia ● Autoimmune hemolytic anemia ● Pure red cell aplasia ● Immune thrombocytopenic purpura ● Evans syndrome ● Autoimmune pancytopenia
Long-Acting Injectable Antiretroviral Agents for HIV	May 1, 2022	Coverage Rationale ● Revised list of applicable long-acting injectable antiretroviral products; added Apretude (cabotegravir) ● Added language to indicate: ○ Apretude (cabotegravir) has been added to the Review at Launch program and some members may not be eligible for coverage of this medication at this time; refer to the Medical Benefit Drug Policy titled *Review at Launch for New to Market Medications* for additional details ○ Apretude (cabotegravir) is proven to reduce the risk of sexually acquired HIV-1 infection in at-risk adults and	This policy refers to the following long-acting injectable antiretroviral products: ● Apretude (cabotegravir) ● Cabenuva (cabotegravir/rilpivirine) Apretude (cabotegravir) is proven to reduce the risk of sexually acquired HIV-1 infection in at-risk adults and adolescents weighing at least 35kg. Apretude is medically necessary when the following additional criteria are met: ● For initial therapy, all of the following: ○ Used for HIV-1 pre-exposure prophylaxis (PrEP); and ○ Patient has a negative HIV-1 test; and ○ Provider confirms that the patient will be tested for HIV-1 infection with each subsequent injection; and ○ Patient is not an appropriate candidate for oral PrEP (e.g., difficulty with adherence to prior oral PrEP, significant renal disease); and ○ Provider attests that patient demonstrates treatment readiness by both of the following: ▪ Patient understands the risks of missed doses of Apretude ▪ Patient has the ability to adhere to the required every 2 months injection and testing appointments; and

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Long-Acting Injectable Antiretroviral Agents for HIV (continued)	May 1, 2022	adolescents weighing at least 35kg ○ Apretude is medically necessary when the following additional criteria are met: *Initial Therapy* ▪ Used for HIV-1 pre-exposure prophylaxis (PrEP) ▪ Patient has a negative HIV-1 test ▪ Provider confirms that the patient will be tested for HIV-1 infection with each subsequent injection ▪ Patient is not an appropriate candidate for oral PrEP (e.g., difficulty with adherence to prior oral PrEP, significant renal disease) ▪ Provider attests that patient demonstrates treatment readiness by both of the following: – Patient understands the risks of missed doses of Apretude – Patient has the ability to adhere to the required every 2 months injection and testing appointments	○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Initial authorization is for no more than 12 months. • For continuation therapy, all of the following: ○ Patient has previously received treatment with Apretude; and ○ Patient has a negative HIV-1 test; and ○ Provider confirms that the patient will be tested for HIV-1 infection with each subsequent injection; and ○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Authorization is for no more than 12 months. Apretude is unproven and not medically necessary for the treatment of human immunodeficiency virus type-1 (HIV-1). Cabenuva (cabotegravir/rilpivirine) is proven for the treatment of a human immunodeficiency virus type-1 (HIV-1) in patients who are virologically suppressed (HIV-1 RNA less than 50 copies per mL). Cabenuva is medically necessary when the following additional criteria are met: • For initial therapy, all of the following: ○ Diagnosis of HIV-1 infection; and ○ Patient has no prior virologic failures or baseline resistance to either cabotegravir or rilpivirine; and ○ Patient is currently on a stable antiretroviral regimen; and ○ Submission of medical records (e.g., chart notes, laboratory results) showing viral suppression (HIV-1 RNA less than 50 copies per mL) for at least 6 months prior to initiation of Cabenuva; and ○ Provider attests that patient demonstrates treatment readiness by both of the following: ▪ Patient understands the risks of missed doses of Cabenuva ▪ Patient has the ability to adhere to the required monthly or every 2 months injection appointments and

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Long-Acting Injectable Antiretroviral Agents for HIV (continued)	May 1, 2022	▪ Dosing is in accordance with the United States Food and Drug Administration approved labeling ▪ Initial authorization is for no more than 12 months *Continuation Therapy* ▪ Patient has previously received treatment with Apretude ▪ Patient has a negative HIV-1 test ▪ Provider confirms that the patient will be tested for HIV-1 infection with each subsequent injection ▪ Dosing is in accordance with the United States Food and Drug Administration approved labeling ▪ Authorization is for no more than 12 months ○ Apretude is unproven and not medically necessary for the treatment of human immunodeficiency virus type-1 (HIV-1) Applicable Codes ● Added HCPCS codes C9399 and J3490 ● Added ICD-10 diagnosis codes	○ Provider confirms that tolerability will be assessed using a 28-day oral lead-in of Vocabria (cabotegravir) and Edurant® (rilpivirine) tablets prior to the first injection of Cabenuva; and ○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Initial authorization is for no more than 12 months ● For continuation therapy, all of the following: ○ Patient has previously received treatment with Cabenuva; and ○ Provider confirms that the patient has achieved and maintained viral suppression (HIV-1 RNA less than 50 copies per mL) while on Cabenuva therapy; and ○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Authorization is for no more than 12 months Cabenuva is unproven and not medically necessary for the treatment of: ● Human immunodeficiency virus type-1 (HIV-1) in patients who are not currently virally suppressed (HIV-1 RNA less than 50 copies per mL)

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Long-Acting Injectable Antiretroviral Agents for HIV (continued)	May 1, 2022	Z11.3, Z11.4, Z20, Z20.2, Z20.6, Z72.5, Z72.51, Z72.52, and Z72.53 **Supporting Information** • Updated *Background*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	
Repository Corticotropin Injections	May 1, 2022	**Title Change** • Previously titled *Repository Corticotropin Injection (Acthar® Gel)* **Coverage Rationale** • Revised list of applicable drug products; added "Purified Cortrophin Gel™ (repository corticotropin injection USP)" • Added language to indicate: ○ Purified Cortrophin Gel is proven and medically necessary for the treatment of infantile spasm (i.e., West Syndrome) and opsoclonus-myoclonus syndrome (i.e., OMS, Kinsbourne Syndrome) when all of the criteria [listed in the policy] are met ○ Purified Cortrophin Gel is not medically necessary for treatment of acute exacerbations of multiple sclerosis ○ Purified Cortrophin Gel is unproven and not medically necessary for treatment of the	This policy refers to the following drug products: • Acthar® Gel (repository corticotropin injection) • Purified Cortrophin Gel™ (repository corticotropin injection USP) Acthar Gel (repository corticotropin injection) and Purified Cortrophin Gel (repository corticotropin injection USP) are proven and medically necessary for the treatment of: • Infantile spasm (i.e., West Syndrome) for up to 4 weeks when all of the following criteria are met: ○ Diagnosis of infantile spasms (i.e., West Syndrome); and ○ Patient is less than 2 years old; and ○ Physician attestation that the caregiver is not able to be trained or are physically unable to administer the drug. Physician must submit explanation; and ○ Dosing for infantile spasm is as follows: ▪ Initial dose: 75 U/m^2 intramuscular (IM) twice daily for 2 weeks ▪ After 2 weeks, dose should be tapered according to the following schedule: 30 U/m^2 IM in the morning for 3 days; 15 U/m^2 IM in the morning for 3 days; 10 U/m^2 IM in the morning for 3 days; and 10 U/m^2 IM every other morning for 6 days (3 doses) • Opsoclonus-myoclonus syndrome (i.e., OMS, Kinsbourne Syndrome) when both of the following criteria are met: ○ Diagnosis of Opsoclonus-myoclonus syndrome (i.e., OMS, Kinsbourne Syndrome); and ○ Physician attestation that the caregiver is not able to be trained or are physically unable to administer the drug; physician must submit

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Repository Corticotropin Injections (continued)	May 1, 2022	following disorders and diseases: ▪ Allergic States: Serum sickness ▪ Collagen Diseases: Systemic lupus erythematosus, systemic dermatomyositis (polymyositis) ▪ Dermatologic Diseases: Severe erythema multiforme, Stevens-Johnson syndrome ▪ Edematous State: To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus ▪ Ophthalmic Diseases: Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation ▪ Respiratory Diseases: Symptomatic sarcoidosis	explanation. Acthar Gel and Purified Cortrophin Gel are not medically necessary for treatment of acute exacerbations of multiple sclerosis. Acthar Gel and Purified Cortrophin Gel are unproven and not medically necessary for treatment of the following disorders and diseases: • Allergic States: Serum sickness • Collagen Diseases: Systemic lupus erythematosus, systemic dermatomyositis (polymyositis) • Dermatologic Diseases: Severe erythema multiforme, Stevens-Johnson syndrome • Edematous State: To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus • Ophthalmic Diseases: Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis, optic neuritis, chorioretinitis, anterior segment inflammation • Respiratory Diseases: Symptomatic sarcoidosis • Rheumatic Disorders: Psoriatic arthritis, rheumatoid arthritis, including juvenile rheumatoid arthritis, ankylosing spondylitis • Any indication outside of the proven indications above

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Repository Corticotropin Injections (continued)	May 1, 2022	▪ Rheumatic Disorders: Psoriatic arthritis, rheumatoid arthritis, including juvenile rheumatoid arthritis, ankylosing spondylitis ▪ Any indication outside of the proven indications [listed in the policy] • Revised coverage criteria for: *Infantile Spasm* ○ Added criterion requiring physician attestation that the caregiver is not able to be trained or are physically unable to administer the drug; the physician must submit an explanation *Opsoclonus-Myoclonus Syndrome* ○ Added criterion requiring: ▪ Diagnosis of opsoclonus-myoclonus syndrome (i.e., OMS, Kinsbourne Syndrome) ▪ Physician attestation that the caregiver is not able to be trained or are physically unable to administer the drug; the physician must submit an explanation Supporting Information • Updated *Background*, *Clinical*	

Medical Benefit Drug Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Repository Corticotropin Injections (continued)	May 1, 2022	*Evidence*, *FDA*, and *References* sections to reflect the most current information	
Stelara® (Ustekinumab)	May 1, 2022	Coverage Rationale *Crohn's Disease* • Revised coverage criteria for initial therapy; added criterion requiring history of failure, contraindication, or intolerance to two biologic DMARDs FDA-approved for the treatment of Crohn's disease (document drug, date, and duration of trial) *Plaque Psoriasis* • Revised coverage criteria for initial therapy; added criterion requiring history of failure, contraindication, or intolerance to two biologic or targeted synthetic DMARDs FDA-approved for the treatment of plaque psoriasis (document drug, date, and duration of trial) *Psoriatic Arthritis* • Revised coverage criteria for initial therapy; added criterion requiring one of the following: ○ History of failure, contraindication, or intolerance to two biologic or targeted synthetic DMARDs FDA-approved for the treatment of	This policy refers to Stelara (ustekinumab) injection. Stelara (ustekinumab) for self-administered subcutaneous injection is obtained under the pharmacy benefit. Refer to the policy for complete details.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Stelara® (Ustekinumab) (continued)	May 1, 2022	psoriatic arthritis (document drug, date, and duration of trial); or ○ Patient is currently on Stelara *Ulcerative Colitis* ● Revised coverage criteria; added criterion requiring history of failure, contraindication, or intolerance to one biologic or targeted synthetic DMARD FDA-approved for the treatment of ulcerative colitis (document drug, date, and duration of trial)	

Coverage Determination Guideline Updates

Updated

Policy Title	Effective Date	Summary of Changes

Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/Replacements (for New Jersey Only)	May 1, 2022	**Title Change**
		• Previously titled *Durable Medical Equipment, Orthotics, Ostomy Supplies, Medical Supplies and Repairs/Replacements (for New Jersey Only)*
		Coverage Rationale
		• Removed content/language pertaining to:
		  ○ Safety enclosure with beds; refer to the Coverage Determination Guideline titled *Beds and Mattresses*
		  ○ Speech Generating Devices; refer to the Coverage Determination Guideline titled *Speech Generating Devices*
		Breast Pumps
		• Revised coverage guidelines to indicate:
		  ○ Double electric and manual breast pumps (HCPCS codes E0603 and E0602) are provided to individuals at any time during pregnancy, the adoption of an infant, and the postpartum period; the member may receive one breast pump per birth event
		  ○ Multiuser, hospital grade electrical breast pumps (E0604) are covered with an order from a qualified healthcare professional and when any one of the following conditions are met:
		  ▪ Separation or hospitalization of either the infant or mother which prevents direct breastfeeding, or
		  ▪ An infant with a congenital anomaly or medical condition (i.e., cleft palate/lip), that may prevent effective breastfeeding, or
		  ▪ A mother with a medical condition that prevents effective breastfeeding, and a healthcare provider has determined a standard electric breast pump would not be beneficial
		  ○ Breast pump supply HCPCS codes A4281, A4282, A4283, A4284, A4285, A4286 and K1005 are covered
		  ○ The following are considered comfort and convenience items:
		  ▪ Hands free breast pumps (HCPCS code E0603, modifier SC)
		  ▪ Hands free bras (HCPCS code A9900)
		Implanted Devices
		• Replaced notation pertaining to the cochlear implant benefit indicating "*if benefits exist for a cochlear implant,* the external components (i.e., speech processor, microphone, and transmitter coil) are considered under the DME benefit, and the implantable components are considered under the medical-surgical benefit" with "the external components (i.e., speech processor, microphone, and transmitter coil) are considered under the DME benefit, and the implantable components are considered under the medical-surgical benefit"
		Insulin Pumps
		• Replaced language indicating "insulin pumps *are considered DME*" with "insulin pumps, *disposable and durable, are covered*"
		• Added reference link to the Medical Policy titled *Continuous Glucose Monitoring and Insulin Delivery for Managing*

Coverage Determination Guideline Updates

Updated

Policy Title	Effective Date	Summary of Changes
Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/Replacements (for New Jersey Only) (continued)	May 1, 2022	*Diabetes (for New Jersey Only)9* *Lymphedema Stockings for the Arm* • Updated language to clarify *post-mastectomy* lymphedema stockings for the arm are considered DME *Mobility Devices* • Replaced language indicating "Mobility Devices include manual wheelchairs, electric wheelchairs, transfer chair, *or* scooters/power-operated vehicles (POV)" with "Mobility Devices include manual wheelchairs, electric wheelchairs, transfer chairs, scooters/power-operated vehicles (POV), *canes, and walkers*" *Oral Appliances* • Removed language indicating *coverage may be provided* for oral appliances *(prefabricated or custom fabricated)* for sleep apnea *Repair, Replacement, and Upgrade* • Replaced language indicating: ○ "Replacement of DME is for the same or similar type of equipment" with "replacement of DME is for the same or similar type of equipment *which is beyond its reasonable useful life span and has become irreparable*" ○ "Pediatric *equipment should* allow room for growth *with* 3 inches of depth and width *available for adjustments*" with "pediatric *DME must* allow room for growth *adjustments to a minimum of 2 inches in seat* width and 3 inches of *seat* depth" • Added notation to indicate: ○ Growth method may not mean ordering equipment that it is too large for current needs ○ A new prescription isn't needed if the needs of the patient are the same *Ventilators and Respiratory Assist Devices* • Added language to indicate: ○ The coverage guidelines in this section of the policy apply to individuals 2 years of age and older ○ Ventilators are covered to treat neuromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure consequent to chronic obstructive pulmonary disease ○ Ventilators are not covered when used only to deliver continuous or intermittent positive airway pressure for adults and children 2 years of age and older Definitions • Added definition of: ○ Customized ○ Multi-User, Hospital Grade Breast Pump Supporting Information • Updated *References* section to reflect the most current information

Coverage Determination Guideline Updates

Updated

Policy Title	Effective Date	Summary of Changes
Outpatient Physical and Occupational Therapy	Apr. 1, 2022	Coverage Rationale • Replaced reference to: *Medical Necessity Clinical Coverage Criteria* ○ "InterQual® *2021*, LOC: Outpatient Rehabilitation & Chiropractic" with "InterQual® *2022*, *Mar. 2022 Release*, LOC: Outpatient Rehabilitation & Chiropractic" *Visit Guidelines* ○ "InterQual® *2021*" with "InterQual® *2022*"
Outpatient Physical and Occupational Therapy (for Nebraska Only)	Apr. 1, 2022	Coverage Rationale • Replaced reference to: *Medical Necessity Clinical Coverage Criteria* ○ "InterQual® *2021*, LOC: Outpatient Rehabilitation & Chiropractic" with "InterQual® *2022*, *Mar. 2022 Release*, LOC: Outpatient Rehabilitation & Chiropractic" *Visit Guidelines* ○ "InterQual® *2021*" with "InterQual® *2022*"
Outpatient Physical and Occupational Therapy (for New Jersey Only)	Apr. 1, 2022	Coverage Rationale • Replaced reference to "InterQual® *2021*" with "InterQual® *2022*"
Speech Language Pathology Services	Apr. 1, 2022	Coverage Rationale • Replaced reference to: *Medical Necessity Clinical Coverage Criteria* ○ "InterQual® *2021*, LOC: Outpatient Rehabilitation & Chiropractic" with "InterQual® *2022*, *Mar. 2022 Release*, LOC: Outpatient Rehabilitation & Chiropractic" *Visit Guidelines* ○ "InterQual® *2021*" with "InterQual® *2022*"
Speech Language Pathology Services (for Nebraska Only)	Apr. 1, 2022	Coverage Rationale • Replaced reference to: *Medical Necessity Clinical Coverage Criteria* ○ "InterQual® *2021*, LOC: Outpatient Rehabilitation & Chiropractic" with "InterQual® *2022*, *Mar. 2022 Release*, LOC: Outpatient Rehabilitation & Chiropractic" *Visit Guidelines* ○ "InterQual® *2021*" with "InterQual® *2022*"

Coverage Determination Guideline Updates

Updated

Policy Title	Effective Date	Summary of Changes
Speech Language Pathology Services (for New Jersey Only)	Apr 1, 2022	Coverage Rationale • Replaced reference to "InterQual® *2021*" with "InterQual® *2022*"

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Outpatient Physical and Occupational Therapy (for New Jersey Only)	May 1, 2022	Coverage Rationale *Required Documentation* Initial Therapy Evaluation/Initial Therapy Visit Requests • Updated list of items to be documented in the therapy evaluation report; added language to clarify alternatives for members with conditions that prevent them from them from completing Standardized Assessment(s) could include: ○ The therapist provides in-depth objective clinical information using task analysis to describe the member's deficit area(s) in lieu of Standardized Assessments ○ The therapist should include checklists, caregiver reports or interviews, and clinical observation Requests for Continuation of Therapy Visits/Progress Reports • Added language to indicate intermittent progress reports must demonstrate that the member is	Refer to the policy for complete details.

Coverage Determination Guideline Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Outpatient Physical and Occupational Therapy (for New Jersey Only) (continued)	May 1, 2022	making functional progress *related to the treatment goals* to reflect that continued services are Medically Necessary • Updated list of items to be documented in the progress report; added language to clarify: ○ *If the member is not making the progress expected,* the progress report must describe any changes in prognosis, POC, and goals and why **Re-Evaluations** • Revised language pertaining to the documentation needed prior to completion of a Physical Therapy or Occupational Therapy re-evaluation; replaced "a signed and dated physician order, less than *30* days old" with "a signed and dated physician order, less than *45* days old" **Visit Guidelines** • Added *Standard Functional Outcome Measures (FOM) used in PT/OT OP-Rehab* **Additional Considerations** • Removed reference to the member benefit plan document; added instruction to check the *federal, state, or contractual requirements* that may supersede the *Additional Considerations* and *Coverage*	

Coverage Determination Guideline Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Outpatient Physical and Occupational Therapy (for New Jersey Only) (continued)	May 1, 2022	*Limitations and Exclusions* [listed in the policy] Definitions • Removed reference to the member benefit plan document; added instruction to check *the federal, state, or contractual definitions* that supersede the definitions [listed in the policy] • Added definition of "Work Hardening" Supporting Information • Updated *References* section to reflect the most current information	
Speech Language Pathology Services (for New Jersey Only)	May 1, 2022	Coverage Rationale *Restorative Therapy/Rehabilitation Services* • Replaced language indicating "evaluation results must address one or more of the [listed] *deficits*" with "*clinical feeding and swallowing* evaluation results must address one or more of the [listed] *clinical findings*" • Revised list of clinical findings to be addressed in the clinical feeding and swallowing evaluation results; updated language pertaining to *known or suspected aspiration* to indicate one or more of the following imaging studies should be performed to confirm aspiration: ○ Video fluoroscopic swallowing	The coverage rationale for this policy contains the following sections: • Indications for Coverage • Restorative Therapy/Rehabilitation Services • Early Childhood Intervention (ECI) and State/School-Based Services • Required Documentation • Visit Guidelines • Discharge Criteria • Additional Considerations • Coverage Limitations and Exclusions • Refer to the policy for complete details.

Coverage Determination Guideline Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Speech Language Pathology Services (for New Jersey Only) (continued)	May 1, 2022	exam (VFSE), also sometimes called a modified barium swallow exam (MBS) ○ Fiber optic endoscopic evaluation of swallowing (FEES) *Aural Rehabilitation (includes Speech and Language Therapy)* ● Removed coverage guidelines for Aural Rehabilitation therapy provided by a Speech-Language Pathologist *Required Documentation* Initial Therapy Evaluation/Initial Therapy Visit Requests ● Updated list of items to be documented in the therapy evaluation report; added language to clarify *alternatives* for members with conditions that prevent them from them from completing Standardized Assessment(s) could include: ○ The therapist provides in-depth objective clinical information using task analysis to describe the member's deficit area(s) in lieu of Standardized Assessments ○ The therapist should include checklists, caregiver reports or interviews, and clinical observation	

Coverage Determination Guideline Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Speech Language Pathology Services (for New Jersey Only) (continued)	May 1, 2022	**Bilingual and Multilingual Speakers** • Replaced references to "member with exposure to more than 1 language/member who is a minority language speaker" with "member with limited English proficiency" **Aural Rehabilitation Evaluations** • Removed clinical documentation requirements **Requests for Continuation of Therapy Visits/Progress Reports** • Updated list of items to be documented in the progress report; added language to clarify: ○ *If the member is not making the progress expected,* the progress report must describe any changes in prognosis, POC, and goals and why **Re-Evaluations** • Revised language pertaining to the documentation needed prior to completion of a Physical Therapy or Occupational Therapy re-evaluation; replaced "a signed and dated physician order, less than *30* days old" with "a signed and dated physician order, less than *45* days old" ***Additional Considerations*** • Removed reference to the member	

Coverage Determination Guideline Updates

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

Speech Language Pathology Services (for New Jersey Only) (continued)	May 1, 2022	benefit plan document; added instruction to check the *federal, state, or contractual requirements* that may supersede the *Additional Considerations* and *Coverage Limitations and Exclusions* [listed in the policy]
		Coverage Limitations and Exclusions
		• Removed language indicating benefits for cognitive rehabilitation therapy are covered only when Medically Necessary following a post-traumatic brain Injury or cerebral vascular accident
		Definitions
		• Removed reference to the member benefit plan document; added instruction to check *the federal, state, or contractual definitions* that supersede the definitions [listed in the policy]
		• Removed definition of:
		  ○ Aural Rehabilitation
		  ○ Comprehensive Care Management
		Supporting Information
		• Updated *References* section to reflect the most current information	

Utilization Review Guideline Updates

Updated

Policy Title	Effective Date	Summary of Changes
Observation Services (for Nebraska Only)	Jul. 1, 2022	Notice of Revision: The following summary of changes has been modified and the effective date has been changed to Jul. 1, 2022. Please take note of the additional update noted in red below. **Coverage Rationale** • Added instruction to refer to the Nebraska Department of Health and Human Services, Behavioral Health Observation Room for behavioral health conditions **Supporting Information** • Updated *References* section to reflect the most current information
Outpatient Speech, Occupational and Physical Therapy Services (for Florida Only)	Apr. 1, 2022	**Coverage Rationale** • Replaced reference to "InterQual® *2021*, LOC: Outpatient Rehabilitation & Chiropractic" with "InterQual® *2022*, *Mar. 2022 Release*, LOC: Outpatient Rehabilitation & Chiropractic"
Outpatient Speech, Occupational and Physical Therapy – Site of Service (for Florida Only)	Apr. 1, 2022	**Coverage Rationale** • Replaced reference to "InterQual® *2021*, LOC: Outpatient Rehabilitation & Chiropractic" with "InterQual® *2022*, *Mar. 2022 Release*, LOC: Outpatient Rehabilitation & Chiropractic"

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Provider Administered Drugs – Site of Care (for New Jersey Only)	May 1, 2022	**Application** • Added language to indicate this policy only applies to the following medications: ○ Actemra® (Tocilizumab) ○ Avsola™ (Infliximab-axxq) ○ Entyvio® (Vedolizumab) ○ Ilumya™ (Tildrakizumab-asmn) ○ Inflectra™ (Infliximab-dyyb) ○ Orencia® (Abatacept) ○ Remicade® (Infliximab) ○ Renflexis™ (Infliximab-abda)	This guideline addresses the criteria for consideration of allowing hospital outpatient facility medication infusion services. This includes claim submissions for hospital-based services with the following CMS/AMA Place of Service codes: • 22 On Campus-Outpatient Hospital; and • 19 Off Campus-Outpatient Hospital Alternative sites of care, such as non-hospital outpatient infusion, physician office, ambulatory infusion or home infusion services are well accepted places of service for medication infusion therapy. If a patient does not meet criteria for outpatient hospital facility infusion, alternative sites of care may be used. Outpatient hospital facility-based intravenous medication infusion is

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Provider Administered Drugs – Site of Care (for New Jersey Only) (continued)	May 1, 2022	○ Simponi Aria® (Golimumab) **Coverage Rationale** • Revised list of specialty medications requiring healthcare provider administration; added Avsola™ (infliximab-axxq) **Applicable Codes** • Added HCPCS codes J0129, J1602, J1745, J3245, J3262, J3380, Q5103, Q5104, and Q5121	medically necessary for individuals who meet at least one of the following criteria (submission of medical records is required): • Documentation that the individual is medically unstable for administration of the prescribed medication at the alternative sites of care as determined by any of the following: ○ The individual's complex medical status or therapy requires enhanced monitoring and potential intervention above and beyond the capabilities of the office or home infusion setting; or ○ The individual's documented history of a significant comorbidity (e.g., cardiopulmonary disorder) or fluid overload status that precludes treatment at an alternative Site of Care; or ○ Outpatient treatment in the home or office setting presents a health risk due to a clinically significant physical or cognitive impairment; or ○ Difficulty establishing and maintaining patent vascular access; or ○ To initiate or re-initiate products for a short duration (e.g., 4 weeks) or • Documentation (e.g., infusion records, medical records) of episodes of severe or potentially life-threatening adverse events (e.g., anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure) that have not been responsive to acetaminophen, steroids, diphenhydramine, fluids, infusion rate reductions, or other pre-medications, thereby increasing risk to the individual when administration is in the home or office setting; or • Initial infusion or re-initiation of therapy after more than 6 months; or • Homecare or infusion provider has deemed that the individual, home caregiver, or home environment is not suitable for home infusion therapy (if the prescriber cannot infuse in the office setting) Ongoing outpatient hospital facility-based infusion duration of therapy will be no more than 6 months to allow for reassessment of the individual's ability to receive therapy at an alternative Site of Care. This policy applies to these medications that require healthcare provider administration:

Utilization Review Guideline Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Provider Administered Drugs – Site of Care (for New Jersey Only) (continued)	May 1, 2022		• Actemra® (Tocilizumab) • Avsola™ (infliximab-axxq) • Entyvio® (Vedolizumab) • Ilumya™ (Tildrakizumab-asmn) • Inflectra™ (Infliximab-dyyb) • Orencia® (Abatacept) • Remicade® (Infliximab) • Renflexis™ (Infliximab-abda) • Simponi Aria® (Golimumab)

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 Medical Policy, Medical Benefit Drug Policy, Coverage Determination Guideline, and Utilization Review Guideline updates. When information in this bulletin conflicts with applicable state and/or federal law, UnitedHealthcare follows such applicable federal and/or state law.

Policy Update Classifications

New

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

Updated

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

Revised

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

Replaced

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

Retired

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

The complete library of UnitedHealthcare Community Plan Medical Policies, Medical Benefit Drug Policies, Coverage Determination Guidelines, and Utilization Review Guidelines is available at UHCprovider.com > Policies and Protocols > Community Plan Policies > Medical & Drug Policies and Coverage Determination Guidelines for Community Plan.