United Healthcare Community Plan

UnitedHealthcare Community Plan of Tennessee
Medical Policy Update Bulletin: May 2022

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Take Note

InterQual® 2022 Clinical Criteria: Apr. 2022 Release

Effective May 1, 2022, the following Medical Policies, Coverage Determination Guidelines, and Utilization Review Guidelines have been updated to reflect the applicable InterQual® clinical criteria reference(s) associated with the Apr. 2022 Release:

Policy Title	Policy Type
Abnormal Uterine Bleeding and Uterine Fibroids (for Tennessee Only)	Medical Policy
Airway Clearance Devices (for Tennessee Only)	Medical Policy
Articular Cartilage Defect Repairs (for Tennessee Only)	Medical Policy
Beds and Mattresses (for Tennessee Only)	Coverage Determination Guideline
Catheter Ablation for Atrial Fibrillation (for Tennessee Only)	Medical Policy
Chemotherapy Observation or Inpatient Hospitalization (for Tennessee Only)	Utilization Review Guideline
Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes (for Tennessee Only)	Medical Policy
Cosmetic and Reconstructive Procedures (for Tennessee Only)	Coverage Determination Guideline
Deep Brain and Cortical Stimulation (for Tennessee Only)	Medical Policy
Electroencephalographic (EEG) Monitoring and Video Recording (for Tennessee Only)	Medical Policy
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Minimally Invasive Procedures for Gastroesophageal Reflux Disease (GERD) and Achalasia (for Tennessee Only)	Medical Policy
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Pediatric Gait Trainers, Standing Systems, and Walkers (for Tennessee Only)	Coverage Determination Guideline
Plagiocephaly and Craniosynostosis Treatment (for Tennessee Only)	Medical Policy
Pneumatic Compression Devices (for Tennessee Only)	Medical Policy
Rhinoplasty and Other Nasal Surgeries (for Tennessee Only)	Coverage Determination Guideline
Speech Generating Devices (for Tennessee Only)	Coverage Determination Guideline
Surgery of the Elbow (for Tennessee Only)	Medical Policy

Take Note

Policy Title	Policy Type
Surgery of the Hip (for Tennessee Only)	Medical Policy
Surgery of the Knee (for Tennessee Only)	Medical Policy
Surgery of the Shoulder (for Tennessee Only)	Medical Policy
Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins (for Tennessee Only)	Medical Policy
Surgical Treatment for Spine Pain (for Tennessee Only)	Medical Policy
Temporomandibular Joint Disorders (for Tennessee Only)	Medical Policy
Wheelchair Options and Accessories (for Tennessee Only)	Coverage Determination Guideline
Wheelchair Seating (for Tennessee Only)	Coverage Determination Guideline

Medical Policy Updates

Updated		
Policy Title	**Effective Date**	**Summary of Changes**

Computer Assisted Surgical Navigation for Musculoskeletal Procedures (for Tennessee Only)	Jun. 1, 2022	Application
		• Added language to indicate this Medical Policy applies to CoverKids
		Definitions
		• Added definition of:
		  ○ Appendicular Skeleton System
		  ○ Musculoskeletal System
		Supporting Information
		• Updated *Clinical Evidence*, *FDA*, and References sections to reflect the most current information
		• Removed *CMS* section

Core Decompression for Avascular Necrosis (for Tennessee Only)	May 1, 2022	Application • Added language to indicate this Medical Policy applies to CoverKids Supporting Information • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Removed *CMS* section
Electrical Bioimpedance for Cardiac Output Measurement (for Tennessee Only)	May 1, 2022	Application • Added language to indicate this Medical Policy applies to CoverKids Supporting Information • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Removed *CMS* section
Light and Laser Therapy (for Tennessee Only)	May 1, 2022	Application • Added language to indicate this Medical Policy applies to CoverKids Applicable Codes • Added notation to indicate viral warts or plantar warts are not considered to be vascular proliferative lesions; therefore, laser therapy used to treat warts should not be reported with CPT codes 17106, 17107, or 17108 Supporting Information • Updated *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information • Removed *CMS* section
Lithotripsy for Salivary Stones (for Tennessee Only)	May 1, 2022	Application • Added language to indicate this Medical Policy applies to CoverKids Supporting Information • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Removed *CMS* section

Medical Policy Updates

Updated		
Policy Title	**Effective Date**	**Summary of Changes**
Meniscus Implant and Allograft (for Tennessee Only)	May 1, 2022	Application • Added language to indicate this Medical Policy applies to CoverKids Coverage Rationale • Replaced language indicating "Collagen Meniscus Implants (CMI) are unproven and not medically necessary for treating *or evaluating and managing* meniscus injuries or tears due to insufficient evidence of efficacy" with "Collagen Meniscus Implants (CMI) are unproven and not medically necessary for treating meniscus injuries or tears due to insufficient evidence of efficacy" Supporting Information • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information • Removed *CMS* section
Nerve Graft to Restore Erectile Function During Radical Prostatectomy (for Tennessee Only)	May 1, 2022	Application • Added language to indicate this Medical Policy applies to CoverKids Supporting Information • Updated *Clinical Evide*nce and References sections to reflect the most current information • Removed *CMS* section
Neurophysiologic Testing and Monitoring (for Tennessee Only)	May 1, 2022	Application • Added language to indicate this Medical Policy applies to CoverKids Supporting Information • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Removed *CMS* section
Neuropsychological Testing Under the Medical Benefit (for Tennessee Only)	May 1, 2022	Application • Added language to indicate this Medical Policy applies to CoverKids Coverage Rationale • Replaced language indicating "neuropsychological testing is proven and medically necessary for evaluating individuals with the [listed] conditions when the results of testing will be *useful in determining* a diagnosis, prognosis, or *influence treatment planning*" with "neuropsychological testing is proven and medically necessary for evaluating individuals with the [listed} conditions when the results of testing will be *used to support* a diagnosis, prognosis, or *treatment plan*" • Updated list of conditions for which neuropsychological testing is proven and medically necessary; replaced "dementia, or symptoms of dementia such as memory impairment or memory loss (including extrapyramidal disorders such as Parkinson's disease) that is associated with a new onset or progressive memory loss and a decline in at least one of the [listed] cognitive domains" with "*neurocognitive disorders including mild cognitive impairment (MCI)*,

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Policy Title	**Effective Date**	**Summary of Changes**
Neuropsychological Testing Under the Medical Benefit (for Tennessee Only) (continued)		dementia, or symptoms of dementia such as memory impairment or memory loss (including *Alzheimer's and* extrapyramidal disorders such as Parkinson's disease) that is associated with a new onset or progressive memory loss and a decline in at least one of the [listed] cognitive domains" **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information • Removed *CMS* section

Percutaneous Vertebroplasty and Kyphoplasty (for Tennessee Only)	May 1, 2022	**Related Policies**
		• Removed list of related policies
		Application
		• Added language to indicate this Medical Policy applies to CoverKids
		Definitions
		• Added definition of:
		  ○ Osteonecrosis
		  ○ Vertebral Hemangiomas
		Supporting Information
		• Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information

Prolotherapy and Platelet Rich Plasma Therapies (for Tennessee Only)	May 1, 2022	**Application** • Added language to indicate this Medical Policy applies to CoverKids **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 • Removed *CMS* section
Sensory Integration Therapy and Auditory Integration Training (for Tennessee Only)	May 1, 2022	**Application** • Added language to indicate this Medical Policy applies to CoverKids **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information • Removed *CMS* section

Medical Policy Updates

Updated

Policy Title	Effective Date	Summary of Changes
Total Artificial Heart and Ventricular Assist Devices (for Tennessee)	May 1, 2022	**Application** • Added language to indicate this Medical Policy applies to CoverKids **Coverage Rationale** • Updated coverage criteria; replaced criterion requiring "members have sufficient space in the chest cavity to accommodate the device (generally, this includes *patients* who have a body surface area ≥ 1.7m^2)" with "members have sufficient space in the chest cavity to accommodate the device (generally, this includes *individuals* who have a body surface area ≥ 1.7m^2 *for the 70cc device and a body surface area of ≤ 1.85m^2 for the 50cc device*)" **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information
Virtual Upper Gastrointestinal Endoscopy (for Tennessee Only)	May 1, 2022	**Application** • Added language to indicate this Medical Policy applies to CoverKids **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Removed *CMS* section

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Airway Clearance Devices (for Tennessee Only)	Jun. 1, 2022	**Coverage Rationale** • Added language to indicate a two-month rental trial of a high-frequency chest wall oscillation system is proven and medically necessary in the management of neuromuscular diseases, when all of the following criteria have been met: ○ A confirmed diagnosis of one of the following neuromuscular diseases: ▪ Quadriplegia ▪ Muscular dystrophy ▪ Multiple sclerosis ▪ Polio or post-polio syndrome	A two-month rental trial of a high-frequency chest wall oscillation system is proven and medically necessary in the management of neuromuscular diseases, when all of the following criteria have been met: • A confirmed diagnosis of one of the following neuromuscular diseases: ○ Quadriplegia ○ Muscular dystrophy ○ Multiple sclerosis ○ Polio or post-polio syndrome ○ Other anterior horn cell disease ○ Myotonic disorder or other myopathy ○ Paralysis of the diaphragm ○ Acid maltase deficiency ○ Amyotrophic lateral sclerosis (ALS) ○ Spinal muscular atrophy (SMA) and

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Airway Clearance Devices (for Tennessee Only) (continued)	Jun. 1, 2022	▪ Other anterior horn cell disease ▪ Myotonic disorder or other myopathy ▪ Paralysis of the diaphragm ▪ Acid maltase deficiency ▪ Amyotrophic lateral sclerosis (ALS) ▪ Spinal muscular atrophy (SMA) and ○ Frequent pulmonary symptom exacerbations requiring antibiotic therapy (> 2 per year); and ○ Failure of standard treatments to adequately mobilize retained secretions ● Replaced reference to "pulmonary conditions" with "bronchiectasis and cystic fibrosis" ● Revised language pertaining to medical necessity clinical coverage criteria for high-frequency chest wall oscillation systems used in the management of bronchiectasis and cystic fibrosis; replaced "InterQual® *Client Defined* 2022, CP: Durable Medical Equipment, Secretion Clearance Devices *(Custom) - UHG*" with "InterQual® 2022, *Apr. 2022 Release*, CP: Durable Medical Equipment, Secretion Clearance Devices"	● Frequent pulmonary symptom exacerbations requiring antibiotic therapy (> 2 per year); and ● Failure of standard treatments to adequately mobilize retained secretions A two-month rental trial of a high-frequency chest wall oscillation system is proven and Medically Necessary in the management of bronchiectasis and, cystic fibrosis, which are characterized by the production of excessive airway secretions, infection and inadequate airway clearance when criteria have been met. For additional medical necessity clinical coverage criteria, refer to the InterQual® 2022, Apr. 2022 Release, CP: Durable Medical Equipment, Secretion Clearance Devices. Click here to view the InterQual® criteria. For all indications for a high-frequency chest wall oscillation system, an initial two-month rental trial must confirm individual tolerance and efficacy in using the device before ongoing medical necessity can be determined. For Medical Necessity determination to address ongoing use, refer to the InterQual Criteria. Intrapulmonary percussive ventilation (IPV) device for home use is considered unproven and not Medically Necessary.

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Airway Clearance Devices (for Tennessee Only) (continued)	Jun. 1, 2022	• Replaced language indicating "an initial two-month rental trial must confirm individual tolerance and efficacy in using the device" with "*for all indications for a high-frequency chest wall oscillation system*, an initial two-month rental trial must confirm individual tolerance and efficacy in using the device *before ongoing medical necessity can be determined; for medical necessity determination to address ongoing use, refer to the InterQual Criteria*" • Removed language indicating an acoustical or mechanical percussor, positive expiratory pressure and aerosol drug delivery system combination device (e.g., Vibralung®) is considered Medically Necessary to provide airway clearance in the management of bronchiectasis, cystic fibrosis, and neuromuscular diseases; for medical necessity clinical coverage criteria, refer to the InterQual® Client Defined 2022, CP: Durable Medical Equipment, Secretion Clearance Devices (Custom) – UHG **Definitions** • Added definition of "Bronchiectasis" **Applicable Codes** • Removed HCPCS code E1399 • Added ICD-10 diagnosis codes: G71.8, G72.41, G72.89, G73.1, G73.3,	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Airway Clearance Devices (for Tennessee Only) (continued)	Jun. 1, 2022	G73.7, J98.6, M33.02, M33.12, M33.22, M33.92, M34.82, and M35.03 ● Removed ICD-10 diagnosis codes G12.9 **Supporting Information** ● Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	
Apheresis (for Tennessee Only)	Jun. 1, 2022	**Application** ● Added language to indicate this Medical Policy applies to CoverKids **Coverage Rationale** ● Revised list of conditions/diagnoses for which therapeutic apheresis is proven and medically necessary; replaced: ○ "Hyperlipoproteinemia" with "*lipoprotein(a)* hyperlipoproteinemia" ○ "Inflammatory bowel disease via adsorptive cytapheresis" with "inflammatory bowel disease, *ulcerative colitis/Crohn's Disease* via adsorptive cytapheresis" ○ "Paraproteinemic *polyneuropathies* via TPE" with "paraproteinemic *demyelinating neuropathies* via TPE" ○ "Sickle cell disease *prevention of transfusional iron overload* for individuals requiring chronic transfusion" with "sickle cell	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 Therapeutic Plasma Exchange (TPE-HV)) ● Anti-glomerular basement membrane disease (Goodpasture's syndrome) ○ Dialysis independent ○ Diffuse alveolar hemorrhage (DAH) ● Chronic inflammatory demyelinating polyneuropathy (CIDP) ● Cryoglobulinemia, second line therapy ● Cutaneous T-cell lymphoma (CTCL); mycosis fungoides; Sézary syndrome, erythrodermic ● Dilated cardiomyopathy, idiopathic, New York Heart Association Class II-IV, via Immunoadsorption ● Familial hypercholesterolemia ○ Heterozygous, second line therapy ○ Homozygous ● Focal segmental glomerulosclerosis, recurrent in transplanted kidney, second line therapy ● Graft-versus-host disease ○ Acute ○ Chronic, second line therapy ● Hereditary hemochromatosis

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Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Apheresis (for Tennessee Only) (continued)	Jun. 1, 2022	disease for individuals requiring chronic transfusion *(receiving transfusions once every 5 weeks or more frequently)*" ○ "Thrombotic microangiopathy, *complement mediated (MCP mutations) and Shiga toxin mediated with absence of severe neurological symptoms*" with "thrombotic microangiopathy" ○ "Cardiac transplantation, second line therapy, recurrent rejection" with "transplantation, cardiac, second line therapy, *cellular/* recurrent rejection" ○ "*Major* hematopoietic stem cell transplant, ABO incompatible, second line therapy" with "transplantation, hematopoietic stem cell, ABO incompatible (ABOi), second line therapy" ○ "ANCA-associated *rapidly progressive glomerulonephritis (granulomatosis with polyangiitis and microscopic polyangiitis)*" with "*vasculitis*, antineutrophil cytoplasmic antibodies (ANCA)-associated" ● Revised list of conditions/diagnoses for which therapeutic apheresis is unproven and not medically necessary: ○ Added:	● Hypertriglyceridemic pancreatitis, severe ● Hyperviscosity in hypergammaglobulinemia ● Inflammatory bowel disease, ulcerative colitis/Crohn's Disease via adsorptive cytapheresis ● Lipoprotein(a) hyperlipoproteinemia, ● Multiple sclerosis, second line therapy ○ Acute central nervous system (CNS) inflammatory, demyelinating ○ Relapsing form with steroid resistant exacerbations ● Myasthenia gravis, acute ● Myeloma cast nephropathy, second line therapy ● Neuromyelitis optica spectrum disorders (NMOSD/Devic's syndrome), acute or relapse, second line therapy ● *N*-methyl D-aspartate receptor antibody encephalitis ● Paraproteinemic demyelinating neuropathies via Therapeutic Plasma Exchange (TPE) ○ Anti- myelin-associated glycoprotein (MAG) ○ Multifocal motor neuropathy ○ IgG/IgA ○ IgM ● Pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections (PANDAS) exacerbation ● Peripheral vascular diseases ● Polycythemia vera; erythrocytosis ● Progressive multifocal leukoencephalopathy (PML) associated with natalizumab ● Pruritus due to hepatobiliary diseases ● Rheumatoid arthritis, refractory, second line therapy ● Sickle cell disease ○ Acute stroke or multiorgan failure ○ Acute chest syndrome (ACS), severe, second line therapy ○ Individuals requiring chronic transfusion (receiving transfusions once every 5 weeks or more frequently) ○ Stroke prevention

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Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Apheresis (for Tennessee Only) (continued)	Jun. 1, 2022	▪ Acute liver failure (requiring TPE) ▪ Dilated cardiomyopathy, idiopathic, New York Heart Association Class II-IV, via TPE ▪ Myasthenia gravis, long term treatment ▪ Myeloma cast nephropathy ▪ Transplantation, hematopoietic stem cell, HLA desensitization ▪ Vasculitis, ANCA-associated (AAV): – MPA/GPA/RLV: RPGN, Cr < 5.7 – EGPA ○ Removed: ▪ Acute inflammatory demyelinating polyneuropathy (Guillain-Barré syndrome), after IVIG ▪ Dermatomyositis/polymyositis ○ Replaced: ▪ "Age related macular degeneration" with "age related macular degeneration, *dry*" ▪ "Autoimmune hemolytic anemia; warm autoimmune hemolytic anemia (WAIHA); cold agglutinin disease" with "autoimmune hemolytic	● Thrombotic microangiopathy, thrombotic thrombocytopenic purpura (TTP) ● Transplantation, cardiac, second line therapy ○ Cellular/recurrent rejection, ○ Desensitization ○ in children less than 40 months of age, ABO incompatible ● Transplantation, hematopoietic stem cell, ABO incompatible (ABOi), second line therapy ○ haemopoietic progenitor cells collected by apheresis HPC(A) ○ haemopoietic progenitor cells collected from marrow HPC(M) ● Transplantation, Liver, desensitization, ABOi living donor ● Transplantation, Lung, bronchiolitis obliterans syndrome ● Transplantation, Renal, ABO compatible: ○ Antibody mediated rejection ○ Desensitization, living donor ● Transplantation, Renal, ABO incompatible, second line therapy ○ Antibody mediated rejection ● Vasculitis, Antineutrophil cytoplasmic antibodies (ANCA) -associated ○ Dialysis dependent ○ DAH ● Vasculitis ○ Behcet's disease (adsorptive cytapheresis), ○ Idiopathic polyarteritis nodosa (PAN) (TPE) ● Voltage gated potassium channel (VGKC) antibody-related diseases ● 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 (ADEM) ● Acute liver failure (requiring TPE) ● Age related macular degeneration, dry ● Amyloidosis, systemic

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Apheresis (for Tennessee Only) (continued)	Jun. 1, 2022	anemia; *severe* warm autoimmune hemolytic anemia (WAIHA); *severe* cold agglutinin disease" ▪ "Babesiosis" with "babesiosis, *severe*" ▪ "Focal segmental glomerulosclerosis, *native* kidney, steroid resistant" with "focal segmental glomerulosclerosis, *recurrent* kidney *transplant or* steroid resistant *in native kidney via LA or TPE*" ▪ "Hashimoto's encephalopathy" with "*steroid-responsive encephalopathy associated with autoimmune thyroiditis* (Hashimoto's encephalopathy)" ▪ "Hematopoietic stem cell transplantation" with "transplantation, hematopoietic stem cell *ABOi*" ▪ "Hemophagocytic lymphohistiocytosis" with "hemophagocytic lymphohistiocytosis (HLH)/ *hemophagocytic syndrome/macrophage activating syndrome* "	• 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; severe warm autoimmune hemolytic anemia (WAIHA); severe cold agglutinin disease • Babesiosis, severe • Burn shock resuscitation • Cardiac neonatal lupus • Catastrophic antiphospholipid syndrome/Hemolytic uremic syndrome • Chronic focal encephalitis (Rasmussen's encephalitis) • Coagulation factor inhibitors • Complex regional pain syndrome • Cutaneous T-cell lymphoma; mycosis fungoides; Sézary syndrome, non-erythrodermic • Dilated cardiomyopathy, idiopathic, New York Heart Association Class II-IV, via TPE • Erythropoietic porphyria, liver disease • Focal segmental glomerulosclerosis, recurrent kidney transplant or steroid resistant in native kidney via LA or TPE • Hemolysis, Elevated Liver enzymes and Low Platelets (HELLP) syndrome • Hemophagocytic lymphohistiocytosis (HLH) / Hemophagocytic syndrome/Macrophage activating syndrome • Heparin induced thrombocytopenia and thrombosis (HIT/HITT) • Hyperleukocytosis • Hypertriglyceridemic pancreatitis, prevention of relapse • Immune thrombocytopenia • IgA nephropathy (Berger's Disease) • Inflammatory bowel disease, Crohn's Disease, via Extracorporeal

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Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Apheresis (for Tennessee Only) (continued)	Jun. 1, 2022	▪ "Henoch-Schönlein purpura" with "*vasculitis, IgA* (Henoch-Schönlein purpura)" ▪ "Hypertriglyceridemic pancreatitis, prevention" with "hypertriglyceridemic pancreatitis, prevention *of relapse"* ▪ "Inflammatory bowel disease via extracorporeal photopheresis" with "inflammatory bowel disease, *Crohn's disease*, via extracorporeal photopheresis" ▪ "Multiple sclerosis, chronic *(unless noted [in the policy] as proven)*" with "multiple sclerosis, chronic" ▪ "Overdose, *venoms*, and poisoning" with "overdose, *envenomation*, and poisoning" ▪ "Paraproteinemic *polyneuropathy* (unless noted [in the policy] as proven)" with "paraproteinemic *demyelinating* polyneuropathies, *multiple myeloma (2C)*" ▪ "Systemic lupus erythematosus, severe" with "systemic lupus	Photopheresis ● Lambert-Eaton myasthenic syndrome ● Malaria ● Multiple sclerosis, chronic ● Myasthenia Gravis, long term treatment ● Myeloma cast nephropathy ● Nephrogenic systemic fibrosis ● Neuromyelitis optica spectrum disorders (NMOSD), maintenance ● Overdose, envenomation, and poisoning ● Paraneoplastic neurologic syndromes ● Paraproteinemic demyelinating polyneuropathies, multiple myeloma (2C) ● PANDAS; Sydenham's chorea, severe ● Pemphigus vulgaris ● Phytanic acid storage disease (Refsum's disease) ● Post transfusion purpura (PTP) ● Psoriasis ● Red cell alloimmunization, prevention and treatment ● Scleroderma (systemic sclerosis) ● Sepsis with multiorgan failure ● Sickle cell disease (unless noted above as proven) ● Steroid-responsive encephalopathy associated with autoimmune thyroiditis (Hashimoto's encephalopathy) ● Stiff-person syndrome ● Sudden sensorineural hearing loss ● Systemic lupus erythematosus, severe complications ● Thrombocytosis ● Thrombotic microangiopathy: ○ Coagulation mediated (THBD, DGKE and PLG mutations) ○ Complement mediated (Factor H autoantibody and complement factor gene mutations) ○ Drug associated ○ Infection associated (STEC-HUS, severe; pHUS) ○ Transplantation associated

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Apheresis (for Tennessee Only) (continued)	Jun. 1, 2022	erythematosus, severe *complications*" ▪ "Thrombotic microangiopathy *(unless noted [in the policy] as proven)*" with "thrombotic microangiopathy: coagulation mediated (THBD, DGKE and PLG mutations), complement mediated (Factor H autoantibody and complement factor gene mutations), drug associated, infection associated (STEC-HUS, severe; pHUS), transplantation associated" **Supporting Information** ● Updated *Clinical Evidence*, *FDA,* and *References* sections to reflect the most current information ● Removed *CMS* section	● Thyroid storm ● Toxic epidermal necrolysis (TEN) ● Transplantation, cardiac ○ Rejection prophylaxis ○ Antibody mediated rejection ● Transplantation, hematopoietic stem cell ABOi: ○ HLA desensitized ○ Minor ABOi HPC(A) ○ Major/minor ABOi w/ pure RBC aplasia ● Transplantation, hematopoietic stem cell, HLA desensitization ● Transplantation, Liver ○ ABO incompatible ○ Antibody mediated rejection ● Transplantation, Lung, ○ Antibody mediated rejection ○ Desensitization ● Transplantation, Renal, ABO compatible, desensitization, deceased donor ● Vasculitis, ANCA-associated (AAV) ○ MPA/GPA/RLV: RPGN, Cr < 5.7 ○ EGPA ● Vasculitis, IgA (Henoch-Schönlein purpura) ● Vasculitis (unless noted above as proven) Note: Refer to the Description of Services section for information regarding all apheresis-based procedures.
Bariatric Surgery (for Tennessee Only)	Jun. 1, 2022	**Application** ● Added language to indicate this Medical Policy applies to CoverKids **Coverage Rationale** ● Revised list of bariatric surgical procedures that are proven and medically necessary for treating obesity; replaced:	The following bariatric surgical procedures are proven and medically necessary for treating obesity: ● Biliopancreatic diversion/ Biliopancreatic diversion with duodenal switch ● Gastric bypass (includes robotic-assisted gastric bypass) ● Adjustable gastric banding (using open or laparoscopic approaches) for individuals ≥ 18 years of age. Refer to the U.S. Food and Drug Administration (FDA) section for additional information ● Sleeve Gastrectomy (Vertical Sleeve Gastrectomy)

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Bariatric Surgery (for Tennessee Only) (continued)	Jun. 1, 2022	○ "Biliopancreatic *bypass*" with "biliopancreatic *diversion*" ○ "*Laparoscopic* adjustable gastric banding for individuals > 18 years of age" with "adjustable gastric banding *(using open or laparoscopic approaches)* for individuals ≥ 18 years of age" ● Revised coverage criteria for Adolescents: ○ Replaced criterion requiring "*cardiovascular disease [e.g., stroke, myocardial infarction,* poorly controlled hypertension (systolic blood pressure greater than 140 mm Hg or diastolic blood pressure 90 mm Hg or greater, despite pharmacotherapy)]" with "poorly controlled hypertension (systolic blood pressure greater than 140 mm Hg or diastolic blood pressure 90 mm Hg or greater, despite pharmacotherapy)" ○ Removed criterion requiring: ▪ History of coronary artery disease with a surgical intervention such as coronary artery bypass or percutaneous transluminal coronary angioplasty ▪ History of cardiomyopathy	● Vertical banded gastroplasty In adults, bariatric surgery using one of the procedures identified above for treating obesity is proven and medically necessary when all of the following criteria are met: ● Class III Obesity; or ● Class II Obesity in the presence of one or more of the following co-morbidities: ○ Type 2 diabetes; or ○ Cardiovascular disease [e.g., stroke, myocardial infarction, poorly controlled hypertension (systolic blood pressure greater than 140 mm Hg or diastolic blood pressure 90 mm Hg or greater, despite pharmacotherapy)]; or ○ History of coronary artery disease with a surgical intervention such as coronary artery bypass or percutaneous transluminal coronary angioplasty; or ○ History of cardiomyopathy; or ○ Obstructive Sleep Apnea (OSA) confirmed on polysomnography with an AHI or RDI of ≥ 30 and ● The individual must also meet the following criteria: ○ Both of the following: ▪ Completion of a pre-operative evaluation that includes a detailed weight history along with dietary and physical activity patterns; and ▪ Psychosocial-behavioral evaluation by an individual who is professionally recognized as part of a behavioral health discipline to provide screening and identification of risk factors or potential postoperative challenges that may contribute to a poor postoperative outcome or ○ Participation in a multi-disciplinary surgical preparatory regimen

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Bariatric Surgery (for Tennessee Only) (continued)	Jun. 1, 2022	• Revised list of bariatric interventions that are unproven and not medically necessary for treating obesity; replaced "transoral endoscopic surgery (includes TransPyloric Shuttle® (TPS®) Device)" with "transoral endoscopic surgery (includes TransPyloric Shuttle® (TPS®) Device, *endoscopic sleeve gastroplasty*)" **Definitions** • Updated definition of: ○ Body Mass Index (BMI) ○ Revisional Bariatric Surgery ○ Technical Failure or Major Complication **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information • Removed *CMS* section	In Adolescents, the bariatric surgical procedures identified above are proven and medically necessary for treating obesity when all of the following criteria are met: • Class III obesity; or • Class II obesity in the presence of one or more of the following co-morbidities: ○ Type 2 diabetes; or ○ Poorly controlled hypertension (systolic blood pressure-greater than 140 mm Hg or diastolic blood pressure 90 mm Hg or greater, despite pharmacotherapy)]; ○ Obstructive Sleep Apnea confirmed on polysomnography with an AHI or RDI of ≥ 30 and • The individual must also receive an evaluation at, or in consultation with, a multidisciplinary center focused on the surgical treatment of severe childhood obesity. This may include adolescent centers that have received accreditation by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) or can demonstrate similar programmatic components. Revisional Bariatric Surgery using one of the procedures identified above is proven and medically necessary when due to a Technical Failure or Major Complication from the initial bariatric procedure. The following procedures are unproven and not medically necessary for treating obesity due to insufficient evidence of efficacy: • Revisional Bariatric Surgery for any other indication than those listed above • Bariatric surgery as the primary treatment for any condition other than obesity • Bariatric interventions for the treatment of obesity including but not limited to: ○ Bariatric artery embolization (BAE)

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Bariatric Surgery (for Tennessee Only) (continued)	Jun. 1, 2022		○ Gastric electrical stimulation with an implantable gastric stimulator (IGS) ○ Intragastric balloon ○ Laparoscopic greater curvature plication, also known as total gastric vertical plication ○ Mini-gastric bypass (MGB)/Laparoscopic mini-gastric bypass (LMGBP) ○ Single-Anastomosis Duodenal Switch (also known as duodenal switch with single anastomosis, or stomach intestinal pylorus sparing surgery [SIPS]) ○ Stomach aspiration therapy (AspireAssist®) ○ Transoral endoscopic surgery (includes TransPyloric Shuttle® (TPS®) Device, endoscopic sleeve gastroplasty) ○ Vagus Nerve Blocking (VBLOC®) Gastrointestinal liners (EndoBarrier®) are investigational, unproven, and not medically necessary for treating obesity due to lack of U.S. Food and Drug Administration (FDA) approval and insufficient evidence of efficacy.
Deep Brain and Cortical Stimulation (for Tennessee Only)	Jun. 1, 2022	Coverage Rationale ● Revised language to indicate: ○ Deep brain stimulation is proven and medically necessary for treating the following indications: ▪ Dystonia ▪ Essential tremor ▪ Parkinson's disease ▪ Refractory epilepsy ○ Responsive cortical stimulation is proven and medically necessary for treating partial or focal seizure disorder ○ For medical necessity clinical coverage criteria, refer to the	**Deep Brain Stimulation** Deep brain stimulation is proven and medically necessary for treating the following indications: ● Dystonia ● Essential Tremor ● Parkinson's disease ● Refractory Epilepsy Responsive cortical stimulation is proven and medically necessary for treating partial or focal seizure disorder. For medical necessity clinical coverage criteria, refer to the InterQual® 2022, Apr. 2022 Release, CP: Procedures, Stereotactic Introduction, Subcortical or Cortical Electrodes.

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Deep Brain and Cortical Stimulation (for Tennessee Only) (continued)	Jun. 1, 2022	InterQual® 2022, Apr. 2022 Release, CP: Procedures, Stereotactic Introduction, Subcortical or Cortical Electrodes ○ The following are unproven and not medically necessary due to insufficient evidence of efficacy: ▪ Deep brain stimulation and cortical stimulation for treating obsessive-compulsive disorder (OCD) and for all other indications not listed [in the policy as proven and medically necessary] ▪ Responsive cortical stimulation for treating all other indications not listed [in the policy as proven and medically necessary] **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	Click here to view the InterQual® criteria. The following are unproven and not medically necessary due to insufficient evidence of efficacy: • Deep brain stimulation and cortical stimulation for treating obsessive-compulsive disorder (OCD) and for all other indications not listed above. • Responsive cortical stimulation for treating all other indications not listed above.
Diagnostic Spinal Ultrasonography (for Tennessee Only)	Jun. 1, 2022	**Title Change** • Previously titled *Spinal Ultrasonography (for Tennessee Only)* **Application** • Added language to indicate this Medical Policy applies to CoverKids **Coverage Rationale** • Replaced language indicating:	Spinal and paraspinal ultrasonography are proven and medically necessary only in newborns and infants for the following indications: • Evaluation of caudal regression syndrome, including sacral agenesis, anal atresia, or stenosis • Detection of sequelae of injury, such as: ○ Hematoma following injury such as birth injury ○ Infection or hemorrhage secondary to prior instrumentation such as lumbar puncture ○ Post-traumatic leakage of cerebrospinal fluid

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Diagnostic Spinal Ultrasonography (for Tennessee Only) (continued)	Jun. 1, 2022	○ "Spinal and paraspinal ultrasonography is proven and medically necessary in newborns and infants for *evaluating and managing suspected spinal disorders including* [the listed indications]" with "spinal and paraspinal ultrasonography is proven and medically necessary *only* in newborns and infants for the [listed] indications" ○ "Spinal and paraspinal ultrasonography is unproven and not medically necessary *to diagnose and manage spinal pain and radiculopathies and to guide rehabilitation of neuromusculoskeletal disorders and spinal pain* due to insufficient evidence of efficacy" with "spinal and paraspinal ultrasonography is unproven and not medically necessary *for all other indications* [not listed in the policy as proven and medically necessary] due to insufficient evidence of efficacy" ● Updated list of proven and medically necessary indications; replaced: ○ "Evaluation of suspected defects such as cord tethering, diastematomyelia, hydromyelia, or syringomyelia" with "evaluation of suspected *spinal cord* defects	● Evaluation of suspected spinal cord defects such as cord tethering, diastematomyelia, hydromyelia, or syringomyelia ● Guidance for lumbar puncture ● Lumbosacral stigmata known to be associated with spinal dysraphism ● Post-operative assessment for spinal cord retethering ● Visualization of blood products within the spinal canal of newborns and infants with intracranial hemorrhage Spinal and paraspinal ultrasonography is unproven and not medically necessary for all other indications due to insufficient evidence of efficacy.

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Diagnostic Spinal Ultrasonography (for Tennessee Only) (continued)	Jun. 1, 2022	such as cord tethering, diastematomyelia, hydromyelia, or syringomyelia" ○ "Caudal regression syndrome, including sacral agenesis, anal atresia, or stenosis" with "*evaluation of* caudal regression syndrome, including sacral agenesis, anal atresia, or stenosis" **Supporting Information** ● Updated *Clinical Evidence* and *References* sections to reflect the most current information ● Removed *CMS* section	
Electric Tumor Treatment Field Therapy (for Tennessee Only)	Jun. 1, 2022	**Application** ● Added language to indicate this Medical Policy applies to CoverKids **Coverage Rationale** ● Revised coverage criteria for subsequent approval(s) for continuation of electric tumor treatment fields (TTF); added criterion requiring the individual with newly diagnosed glioblastoma (GBM) continues to receive Temozolomide as the only cancer drug or the device is used as the only treatment for an individual with recurrent GBM **Supporting Information** ● Updated *Description of Services, Clinical Evidence*, and *References*	The following is proven and medically necessary for treating newly diagnosed histologically confirmed Supratentorial glioblastoma (GBM): ● The use of U.S. Food and Drug Administration (FDA) approved devices to generate electric tumor treatment fields (TTF) when used according to FDA labeled indications, contraindications, warnings, and precautions, and when all of the following criteria are met: ○ Treatment with radiation therapy has been completed; and ○ Individual is receiving Temozolomide as the only cancer drug; and ○ Individual has a Karnofsky Performance Status (KPS) score of > 60 or Eastern Cooperative Oncology Group (ECOG) Performance Status ≤ 2; and ○ Individual has been counselled that the device must be worn at least 18 hours daily The following is proven and medically necessary for treating radiologically confirmed recurrence of GBM in the Supratentorial region of the brain: ● The use of FDA approved devices to generate electric TTF after initial chemotherapy when used according to FDA labeled indications,

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Electric Tumor Treatment Field Therapy (for Tennessee Only) (continued)	Jun. 1, 2022	sections to reflect the most current information ● Removed *CMS* section	contraindications, warnings, and precautions and when all of the following criteria are met: ○ The device is used as the only treatment; and ○ Individual has a KPS score of ≥ 60 or ECOG Performance Status of ≤ 2; and ○ Individual has been counselled that the device must be worn at least 18 hours daily When all of the above criteria are met for either newly diagnosed or recurrent GBM, an initial 3 months of electric TTF therapy will be approved. Subsequent approval(s) for continuation of electric TTF is based on: ● Magnetic resonance imaging (MRI) scan has been performed ≤ 2-4 months prior to request and documents no evidence of disease progression; and ● Individual with newly diagnosed glioblastoma continues to receive Temozolomide as the only cancer drug or the device is used as the only treatment for an individual with recurrent GBM: and ● KPS score of ≥ 60; or ECOG Performance Status ≤ 2; and ● Documentation that the individual has been using the device at least 18 hours daily Due to insufficient evidence of efficacy, the use of devices to generate electric TTF is unproven and not medically necessary when the criteria above are not met and for all other indications including but not limited to the following: ● Treatment of tumors other than GBM ● Use of electric TTF therapy with concurrent medical therapy (e.g., bevacizumab or chemotherapy) for treatment of recurrent GBM Computer software used for therapeutic radiology clinical treatment planning in conjunction with electric TTF therapy is unproven and not medically necessary due to insufficient evidence of efficacy.

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Electrical and Ultrasound Bone Growth Stimulators (for Tennessee Only)	Jun. 1, 2022	**Application** ● Added language to indicate this Medical Policy applies to CoverKids **Coverage Rationale** ● Replaced language indicating: ○ "The use of invasive or noninvasive spinal electrical bone growth stimulator is *considered* proven and medically necessary as an adjunct to lumbar spinal fusion surgery" with "the use of invasive or noninvasive spinal electrical bone growth stimulator is proven and medically necessary as an adjunct to lumbar spinal fusion surgery" ○ "The use of invasive or noninvasive *spinal* electrical bone growth stimulators is unproven and not medically necessary for the treatment of all other indications [not listed in the policy as proven and medically necessary]" with "the use of invasive or noninvasive electrical bone growth stimulators is unproven and not medically necessary for the treatment of all other indications [not listed in the policy as proven and medically necessary]" **Supporting Information** ● Updated *Clinical Evidence* and	The use of invasive or noninvasive spinal electrical bone growth stimulator is proven and medically necessary as an adjunct to lumbar spinal fusion surgery when the following two criteria are met: ● Radiographic evidence of skeletal maturity and ● Increased risk for fusion failure demonstrated by any of the following: ○ Previously failed fusion at the same site, when minimum of six months has elapsed since the last surgical procedure ○ Spinal fusion performed or to be performed at more than one level as part of a single surgery ○ Comorbid conditions associated with compromised bone healing (e.g., diabetes, obesity, osteoporosis, current tobacco use) ○ Spondylolisthesis grade II or greater The use of invasive or noninvasive electrical bone growth stimulators is unproven and not medically necessary for the treatment of all other indications due to insufficient evidence of efficacy and/or safety. The use of ultrasonic bone growth stimulators is proven and medically necessary for the treatment of nonunion of long bone fractures when all of the following criteria are met: ● Fracture gap is less than or equal to 1 cm ● Radiographic evidence of a persistent fracture line without bridging callus is present for 3 months or more ● Fracture reduced and immobilized ● Less than 6 months have passed since the date of most recent surgical operation ● Fracture that is not pathological or associated with malignancy ● Radiographic evidence of skeletal maturity The use of ultrasonic bone growth stimulators is unproven and not medically necessary for the treatment of all other indications due to insufficient evidence of efficacy and/or safety.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Electrical and Ultrasound Bone Growth Stimulators (for Tennessee Only) (continued)	Jun. 1, 2022	*References* sections to reflect the most current information • Removed *CMS* section	
Facet Joint Injections for Spinal Pain (for Tennessee Only)	Jun. 1, 2022	Coverage Rationale • Added language to indicate Medial Branch injections for diagnostic purposes in excess of four (4) injections in a calendar year are excluded from coverage; refer to the *Rules of Tennessee Department of Finance and Administration, Bureau of TennCare, Chapter 1200-13-13.10 Exclusions* *Proven and Medically Necessary* • Revised coverage criteria for initial diagnostic Facet Joint Injection/ Medial Branch Block; replaced criterion requiring "*the pain is unresponsive to* four weeks of Conservative *Treatment*, including but not limited to pharmacotherapy, exercise, or physical therapy" with "*clinically significant improvement has not occurred (the pain remains at a 3 or more on a 1-10 pain scale) after a minimum of* four weeks of conservative *care* (including but not limited to pharmacotherapy, exercise, or physical therapy)"	Note: This policy addresses Medial Branch Block and intraarticular Facet Joint Injections of the cervical, thoracic, and lumbar spines. The following are proven and medically necessary: • An initial diagnostic Facet Joint Injection/Medial Branch Block to determine facet joint origin when all of the following criteria are met: ○ Pain is exacerbated by facet loading maneuvers on physical examination (e.g., hyperextension, rotation); and ○ Clinically significant improvement has not occurred (the pain remains at a 3 or more on a 1-10 pain scale) after a minimum of four weeks of conservative care (including but not limited to pharmacotherapy, exercise, or physical therapy) ○ Clinical findings and imaging studies suggest no other cause of the pain (e.g., spinal stenosis with neurogenic claudication, disc herniation with radicular pain, infection, tumor, fracture, pain related to prior surgery) ○ The spinal motion segment is not fused ○ A radiofrequency joint denervation/ablation procedure is being considered • A second Facet Joint Injection/Medial Branch Block performed to confirm the validity of the clinical response to the initial Facet Joint Injection, when all of the following criteria are met: ○ Administered at the same level and side as the initial block ○ The initial diagnostic facet join injection produced a positive response as demonstrated when all the following criteria are met: ▪ For at least the expected minimum duration of the effect of the local anesthetic ▪ Functional improvement that is specific to the individual with

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Facet Joint Injections for Spinal Pain (for Tennessee Only) (continued)	Jun. 1, 2022	*Unproven and Not Medically Necessary* • Replaced language indicating "Facet Joint Injections/Medial Branch Blocks are unproven and not medically necessary if injection of volume of local anesthetics *that* exceeds *minimum required to isolate intended target nerve or joint (i.e.,* > 0.5 ml for *cervical and > 0.7 ml for lumbar)*" with "Facet Joint Injections/Medial Branch Blocks are unproven and not medically necessary if injection of volume of local anesthetics exceeds 0.5 ml *for Median Branch Blocks*" Definitions • Added definition of "Facet Joint Syndrome" Applicable Codes • Added ICD-10 diagnosis codes G89.18, G89.28, G97.82, M51.14, M51.15, M51.16, and M51.17 Supporting Information • Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect most current information • Removed *CMS* section	demonstrable improvement in the physical functions previously limited by the facetogenic pain; and ○ A radiofrequency joint denervation/ablation procedure is being considered Medial branch injections for diagnostic purposes in excess of four (4) injections in a calendar year are excluded from coverage. Refer to Tenn. Comp. R. & Regs. 1200-13-13-.10. Facet Joint Injections/Medial Branch Blocks are unproven and not medically necessary due to insufficient evidence of efficacy: • If radiofrequency ablation procedure not considered as treatment option at the requested level(s) • For treating spinal pain, after diagnostic injections have been completed • After two Facet Injections/Medial Branch Blocks at the same level and same side (this is considered therapeutic rather than diagnostic) • Therapeutic Facet Joint Injections and/or facet nerve block (i.e., medial branch block) for treating chronic spinal pain • For a second Facet Joint Injection/Medial Branch Block if the initial injection did not confirm the joint as the source of pain • In the presence of untreated Radiculopathy at the same level as the intended diagnostic injection (with the exception of Radiculopathy caused by a facet joint synovial cyst) • If injection of volume of local anesthetics exceeds 0.5ml for medial branch blocks • When performed under ultrasound guidance
Functional Endoscopic Sinus Surgery (FESS) (for Tennessee Only)	Jun. 1, 2022	Application • Added language to indicate this Medical Policy applies to CoverKids	Functional Endoscopic Sinus Surgery (FESS) is proven and medically necessary when one or more of the following conditions are present: • Chronic Rhinosinusitis (CRS) with or without polyps which has all of the following:

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Functional Endoscopic Sinus Surgery (FESS) (for Tennessee Only) (continued)	Jun. 1, 2022	**Coverage Rationale** • Revised coverage criteria for Chronic Rhinosinusitis (CRS) with or without polyps; replaced criterion requiring: ○ "Intranasal corticosteroids" with "intranasal corticosteroids *(and/or oral corticosteroids when appropriate)*" ○ "Nasal lavage" with "nasal lavage/*irrigation if appropriate*" • Replaced language indicating "Functional Endoscopic Sinus Surgery (FESS) is proven and medically necessary for any of the [listed] conditions confirmed on CT *scan in the sinus to be treated*" with "Functional Endoscopic Sinus Surgery (FESS) is proven and medically necessary for any of the [listed] conditions confirmed on CT scan" • Revised list of proven and medically necessary indications; replaced: ○ "Concha bullosa" with "*symptomatic* concha bullosa" ○ "Mucocele" with "*symptomatic* mucocele" • Added language to indicate Functional Endoscopic Sinus Surgery (FESS) is unproven and not medically necessary for any condition other than those listed [in the policy as proven and medically necessary] due to insufficient evidence of efficacy	○ Lasted longer than 12 weeks ○ Persistence of symptoms despite administration of full courses of all of the following treatments: ▪ Intranasal corticosteroids (and/or oral corticosteroids when appropriate), and ▪ Antibiotic therapy if bacterial infection is suspected; and ▪ Nasal lavage/irrigation if appropriate ○ Confirmation of Chronic Rhinosinusitis on a computed tomography (CT) scan for each sinus to be treated meeting all of the following criteria: ▪ CT images are obtained after completion of medical management; and ▪ Documentation of which sinus 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 • Recurrent Acute Rhinosinusitis (RARS) with all of the following: ○ Four or more episodes per year with distinct symptom free intervals between episodes; and ○ Sinonasal symptoms such as pain, pressure, or drainage are present on the same side as CT scan findings of rhinosinusitis; and ○ CT scan evidence of one of the following: ▪ For the maxillary, frontal, or sphenoid sinuses, both of the following are present: – Ostial obstruction (outflow tract obstruction) in the sinus to be treated

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Functional Endoscopic Sinus Surgery (FESS) (for Tennessee Only) (continued)	Jun. 1, 2022	Supporting Information • Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information • Removed *CMS* section	– Mucosal thickening in the sinus to be treated ▪ For the ethmoid sinus, mucosal thickening is present • Any of the following conditions confirmed on CT: ○ Complications of sinusitis such as abscess ○ Symptomatic concha bullosa ○ Symptomatic mucocele ○ Polyposis with obstructive symptoms (for Chronic Rhinosinusitis with polyps, refer to the above criteria) ○ Sinonasal tumor Functional Endoscopic Sinus Surgery (FESS) is unproven and not medically necessary for any condition other than those listed above due to insufficient evidence of efficacy. **Documentation Requirements** Medical notes documenting the following, as applicable: • Chronic Rhinosinusitis (CRS) with the following: ○ Signs and symptoms ○ Treatments tried and failed including duration of treatments/medical therapies ○ Post medical management CT scan images: ▪ That show the abnormality for which surgery is being requested ▪ Are 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 – Applicable case number obtained at time of notification, or the member's name and ID number on the images – Whether the imaging was taken pre-or post-medical therapy ▪ CT images can be submitted via the external portal at http://www.uhcprovider.com/paan; faxes will not be accepted

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Functional Endoscopic Sinus Surgery (FESS) (for Tennessee Only) (continued)	Jun. 1, 2022		○ CT scan report documents all of the following: ▪ Which sinus has the disease ▪ The extent of disease including the percent of opacification or the use of a scale such as the Modified Lund-Mackay Scoring System ● Recurrent Acute Rhinosinusitis with the following: ○ Number of episodes per year of acute rhinosinusitis ○ Signs and symptoms ○ CT scan images: ▪ That show the abnormality for which surgery is being requested ▪ Are 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 images – Whether the images were taken pre- or post-medical therapy ▪ CT images can be submitted via the external portal at http://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 disease including the percent of opacification or the use of a scale such as the Modified Lund-Mackay Scoring System
Genetic Testing for Hereditary Cancer (for Tennessee Only)	Jun. 1, 2022	Application ● Added language to indicate this Medical Policy applies to CoverKids Coverage Rationale ● Added language to indicate single gene testing and known mutation testing for familial cancer is proven and medically necessary ● Replaced language indicating “genetic testing for BRCA1 and	Genetic counseling is strongly recommended prior to these tests in order to inform persons being tested about the advantages and limitations of the test as applied to a unique person. Single gene testing and known mutation testing for familial cancer is proven and medically necessary.

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Genetic Testing for Hereditary Cancer (for Tennessee Only) (continued)	Jun. 1, 2022	BRCA2 or Multi-Gene hereditary cancer Panels with RNA testing is unproven and not medically necessary for all indications" with "RNA Panel testing for hereditary cancers is unproven and not medically necessary for all indications" *Hereditary Breast and Ovarian Cancer Panel Testing* ● Replaced references to "genetic testing for *BRCA1 and BRCA2*" with "genetic testing *Panels* for *High Penetrance Breast Cancer Susceptibility Genes*" ● Revised list of proven and medically necessary indications for: Individuals With a Personal History of a BRCA-Related Cancer ○ Added "women with a personal history of lobular breast cancer with personal or family history of diffuse gastric cancer" ○ Removed "a known BRCA1/BRCA2 mutation in a Close Blood Relative" ○ Replaced "women with a personal history of Triple-Negative Breast Cancer diagnosed at age *60 or younger*" with "women with a personal history of Triple-Negative Breast Cancer diagnosed at *any* age"	**Hereditary Breast and Ovarian Cancer Panel Testing** Genetic testing Panels for High Penetrance Breast Cancer Susceptibility Genes for individuals with a personal history of a BRCA-Related Cancer are proven and medically necessary in the following situations: ● At least one first- or second-degree relative with a BRCA-Related Cancer; or ● Ashkenazi Jewish ancestry; or ● An unknown or Limited Family History; or ● A BRCA 1/2 pathogenic mutation detected in tumor tissue; or ● A personal history of pancreatic cancer; or ● Men with a personal history of Breast Cancer; or ● Men with a personal history of metastatic prostate cancer; or ● Women with a personal history of Ovarian Cancer; or ● Women with a personal history of Breast Cancer in any of the following situations: ○ Metastatic Breast Cancer; or ○ Breast Cancer diagnosed at age 45 or younger; or ○ An additional Breast Cancer primary (prior diagnosis or bilateral cancer); or ○ Triple-Negative Breast Cancer diagnosed at any age ○ Lobular breast cancer with personal or family history of diffuse gastric cancer ● Individual has a Tyrer-Cuzick, BRCAPro or Penn11 Score of 2.5% or greater for a *BRCA1/2* pathogenic variant. Genetic testing Panels for High Penetrance Breast Cancer Susceptibility Genes for individuals without a personal history of a related cancer are proven and medically necessary in the following situations: ● At least one first- or second-degree relative with a BRCA-Related Cancer; or ● Ashkenazi Jewish ancestry and at least one Close Blood Relative with a BRCA-Related Cancer; or ● Individual has a Tyrer-Cuzick, BRCAPro or Penn11 Score of 5% or greater for a BRCA1/2 pathogenic variant

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Genetic Testing for Hereditary Cancer (for Tennessee Only) (continued)	Jun. 1, 2022	Individuals Without a Personal History of a Related Cancer ○ Removed "a known BRCA1/BRCA2 mutation in a Close Blood Relative" *Other Hereditary Cancer Syndrome Multi-Gene Panel Testing* ● Replaced language indicating: ○ "Genetic testing with a Multi-Gene hereditary cancer Panel in individuals with a personal history of cancer is proven and medically necessary if all the [listed] criteria are met" with "genetic testing with a Multi-Gene hereditary cancer Panel in individuals with a personal history of *a primary solid tumor* cancer is proven and medically necessary if all the [listed] criteria are met" ○ "Genetic testing with a Multi-Gene hereditary cancer Panel in individuals without a personal history of cancer is proven and medically necessary if all the [listed] criteria are met" with "genetic testing with a Multi-Gene hereditary cancer Panel in individuals without a personal history of *a primary solid tumor* cancer is proven and medically necessary if all the [listed] criteria are met"	Genetic testing Panels for High Penetrance Breast Cancer Susceptibility Genes are unproven and not medically necessary for all other indications including: ● Screening for cancer risk for individuals not listed in the proven indications above; or ● Risk assessment of other cancers; or ● Confirmation of direct to consumer genetic testing without meeting any of the proven indications above. **Other Hereditary Cancer Syndrome Multi-Gene Panel Testing** Genetic testing with a Multi-Gene hereditary cancer Panel in individuals with a personal history of a primary solid tumor cancer is proven and medically necessary if all the following criteria are met: ● The suspected hereditary cancer syndromes can be diagnosed by testing two or more genes included in the specific hereditary cancer panel; and ○ A personal history of at least two different primary solid tumor cancers ; or ○ A personal history of BRCA-related cancer diagnosed at age 40 or younger; or ○ A personal history of BRCA-related cancer and at least one Close Blood Relative with a cancer associated with Lynch Syndrome; or ○ At least one Close Blood Relative diagnosed with a BRCA-Related Cancer at age 40 or younger; or ○ At least two Close Blood Relatives (in addition to affected individual) on the same side of the family diagnosed with any primary solid tumor cancer; or ○ A personal history of cancer associated with Lynch Syndrome; or ○ A personal history of cancer where tumor testing results demonstrate that the cancer was MSI-high or had immunohistochemical staining showing the absence of one or more mismatch repair proteins (MLH1, MSH2, MSH6 or PMS2); or

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Genetic Testing for Hereditary Cancer (for Tennessee Only) (continued)	Jun. 1, 2022	• Revised coverage criteria: **Individuals With a Personal History of a Primary Solid Tumor Cancer** ○ Replaced criterion requiring: ▪ "A personal history of at least two different cancers *(e.g., Breast and Ovarian)*" with "a personal history of at least two different *primary solid tumor* cancers" ▪ "At least *two* Close Blood Relatives on the same side of the family diagnosed with any cancer" with "at least *three* Close Blood Relatives *(in addition to affected individual)* on the same side of the family diagnosed with any *primary solid tumor* cancer" **Individuals Without a Personal History of a Primary Solid Tumor Cancer** ○ Added criterion requiring at least one first-degree relative diagnosed with at least two different primary solid tumor cancers ○ Replaced criterion requiring: ▪ "At least three Close Blood Relatives, on the same side of the family, diagnosed with any cancer" with "at least three Close Blood Relatives, on the	○ A personal history of colorectal polyposis with at least 10 adenomatous polyps, at least 2 hamartomatous polyps or at least 5 serrated polyps/lesions proximal to the rectum; or ○ The individual has a PREMM5, MMRpro or MMRpredict Score of 2.5% or greater for having a Lynch syndrome gene mutation. Genetic testing with a Multi-Gene hereditary cancer Panel in individuals without a personal history of a primary solid tumor cancer is proven and medically necessary if all the following criteria are met: • The suspected hereditary cancer syndromes can be diagnosed by testing two or more genes included in the specific hereditary cancer Panel; and ○ At least one first-degree relative diagnosed with at least two different primary solid tumor cancers; or ○ At least one first- or second-degree relative diagnosed with a BRCA-Related Cancer at age 40 or younger; or ○ At least three Close Blood Relatives, on the same side of the family, diagnosed with any primary solid tumor cancer; or ○ At least one first-degree relative with a cancer associated with Lynch Syndrome; or ○ At least one second-degree relative with a cancer associated with Lynch Syndrome diagnosed at age 50 or younger; or ○ At least one second-degree relative with at least two cancers associated with Lynch Syndrome; or ○ Two or more second-degree relatives with a cancer associated with Lynch Syndrome; or ○ At least one first- or second-degree relative with a clinical diagnosis of Familial Adenomatous Polyposis, Attenuated Familial Adenomatous Polyposis, Juvenile Polyposis Syndrome or Peutz-Jeghers Syndrome; or ○ The individual has a PREMM5, MMRpro or MMRpredict Score of 5% or greater for having a Lynch syndrome gene mutation.

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Genetic Testing for Hereditary Cancer (for Tennessee Only) (continued)	Jun. 1, 2022	same side of the family, diagnosed with any *primary solid tumor* cancer" ▪ "At least one *first- or* second-degree relative with a cancer associated with Lynch Syndrome diagnosed at age 50 or younger" with "at least one second-degree relative with a cancer associated with Lynch Syndrome diagnosed at age 50 or younger" ▪ "At least one *first- or* second-degree relative with at least two cancers associated with Lynch Syndrome" with "at least one second-degree relative with at least two cancers associated with Lynch Syndrome" ▪ "Two or more *first- or* second-degree relatives with a cancer associated with Lynch Syndrome" with "two or more second-degree relatives with a cancer associated with Lynch Syndrome" **Definitions** • Added definition of "High Penetrance Breast Cancer Susceptibility Genes" **Applicable Codes** *BRCA1 and BRCA2* • Removed CPT codes 81212, 81215, and 81217	Genetic testing with a Multi-Gene hereditary cancer Panel in individuals diagnosed with cancer at age 18 or younger is proven and medically necessary. Multi-Gene hereditary cancer Panels are unproven and not medically necessary for all other indications. RNA Panel testing for hereditary cancers is unproven and not medically necessary for all indications.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Genetic Testing for Hereditary Cancer (for Tennessee Only) (continued)	Jun. 1, 2022	*Multi-Gene Panel* • Added CPT code 81479 Supporting Information • Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information • Removed *CMS* section	
Hepatitis Screening (for Tennessee Only)	Jun. 1, 2022	Application • Added language to indicate this Medical Policy applies to CoverKids Coverage Rationale • Replaced language indicating: ○ "Hepatitis screening is proven and medically necessary *for hepatitis C virus (HCV) infection* in adults aged 18 to 79 years whether or not risk factors have been identified" with "Hepatitis *C virus (HCV)* screening is proven and medically necessary in adults aged 18 to 79 years whether or not risk factors have been identified" ○ "*Hepatitis* screening is proven and medically necessary *for high risk* individuals with the [listed] indications" with "*Hepatitis B* screening is proven and medically necessary *in* individuals with the [listed] indications"	Hepatitis C virus (HCV) screening is proven and medically necessary in adults aged 18 to 79 years whether or not risk factors have been identified. Hepatitis B screening is proven and medically necessary in individuals with the following indications: • Birth in or travel to regions with high or moderate prevalence of hepatitis B virus (HBV) infection • Blood transfusion prior to 1992 • Clotting-factor disorders, such as hemophilia • Current and past use of injection drug use. This includes those who injected once or a few times many years ago. • Donors of blood, plasma, organs, tissue, or semen • Elevated ALT/AST of unknown etiology • Exposure to blood or body fluids • Following exposure to an individual with HBV infection through household, secondary contacts or needle sharing • Hemodialysis • High-risk sexual behavior • HIV-positive infection, and those who are high risk of HIV acquisition • Immunosuppression due to immunosuppressive therapy for rheumatologic or gastroenterologic disorders, chemotherapy, and organ transplantation • Infants born in the U.S. whose parents were born in regions with high rates of Hepatitis B • Infants born to HBV infected mothers

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Hepatitis Screening (for Tennessee Only) (continued)	Jun. 1, 2022	• Revised list of proven and medically necessary indications for Hepatitis B screening: ○ Added: ▪ Exposure to blood or body fluids ○ Removed: ▪ Health-care workers, emergency medical, and public safety personnel after needle sticks, sharps or mucosal exposures to HCV-positive blood ▪ Those who work with non-human primates ○ Replaced: ▪ "Birth or travel to *high or moderate endemic* regions with prevalence of *hepatitis A virus (HAV) or* hepatitis B virus (HBV) infection" with "birth *in* or travel to regions with *high or moderate* prevalence of hepatitis B virus (HBV) infection" ▪ "*Chronic or long-term liver disease with* elevated *liver enzymes (abnormal* ALT/AST)" with "elevated ALT/AST *of unknown etiology*" ▪ "Exposure to individuals with HBV infection through	• Men who have sexual relations with men (MSM) • Pregnancy • Present sexual partners of HCB-infected • Prior to anti-TNF initiation • Recipient of clotting factor concentrates made before 1987 • Recipients of blood or organs from a donor who later tested HBV positive • Residents and institutional care workers Hepatitis A screening is proven and medically necessary for individuals who were born in or have travelled to regions with high or moderate prevalence of hepatitis A virus (HAV).

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Hepatitis Screening (for Tennessee Only) (continued)	Jun. 1, 2022	household, secondary contacts or needle sharing" with "*following* exposure to *an* individual with HBV infection through household, secondary contacts or needle sharing" ▪ "Hemodialysis *Hepatitis C virus (HCV) positive*" with "hemodialysis" ▪ "High-risk sexual behavior, *multiple partners, intercourse with trauma, and sexually transmitted diseases (STD)*" with "high-risk sexual behavior" ▪ "Infants born to HBV *or HCV* infected mothers" with "infants born to HBV-infected mothers" ▪ "Pregnancy, *except in settings where the prevalence of HCV infection is < 0.1%*" with "pregnancy" ▪ "Present sexual partners of *HCV*-infected" with "present sexual partners of *HBV*-infected" ▪ "Recipients of blood or organs from a donor who later tested *HCV* positive" with "recipients of blood or organs from a donor who later tested *HBV* positive"	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Hepatitis Screening (for Tennessee Only) (continued)	Jun. 1, 2022	• Added language to indicate Hepatitis A screening is proven and medically necessary for individuals who were born in, or have travelled to regions with high or moderate prevalence of hepatitis A virus (HAV) Applicable Codes • Updated list of ICD-10 diagnosis codes: ○ Added B00.81, O35.7XX0, O35.7XX1, O35.7XX2, O35.7XX3, O35.7XX4, O35.7XX5, O35.7XX9, O36.8210, O36.8211, O36.8212, O36.8213, O36.8214, O36.8215, O36.8219, O36.8220, O36.8221, O36.8222, O36.8223, O36.8224, O36.8225, O36.8229, O36.8230, O36.8231, O36.8232, O36.8233, O36.8234, O36.8235, O36.8239, O36.8290, O36.8291, O36.8292, O36.8293, O36.8294, O36.8295, O36.8299, O94, P58.41, P78.81, P78.84, R78.2, T74.21XS, T76.21XS, T76.22XS, Z03.71, Z03.72, Z03.73, Z03.74, Z03.75, Z03.79, Z04.81, Z29.13, Z32.2, Z36.0, Z36.1, Z36.4, Z36.5, Z36.81, Z36.82, Z36.83, Z36.84, Z36.85, Z36.86, Z36.87, Z36.88, Z36.8A, and Z76.82 ○ Removed A34, B15.0, B15.9, B16.0, B16.1, B16.2, B16.9, B17.0, B17.2, B17.8, B17.9,	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Hepatitis Screening (for Tennessee Only) (continued)	Jun. 1, 2022	B18.0, B18.1, B18.8, B18.9, B19.0, B19.10, B19.11, B19.9, F12.10, F12.11, F12.13, F12.120, F12.121, F12.122, F12.129, F12.150, F12.151, F12.159, F12.180, F12.188, F12.19, F12.20, F12.21, F12.220, F12.23, F12.250, F12.251, F12.29, F12.93, F18.10, F18.11, F18.120, F18.121, F18.129, F18.14, F18.150, F18.151, F18.159, F18.17, F18.180, F18.188, F18.19, F18.20, F18.21, F18.220, F18.229, F18.250, F18.251, F18.259, F18.29, N76.0, N76.1, N76.2, N76.3, N77.1, W46.1XXA, W46.1XXD, Z20.821, and Z33.2 ○ Revised description for O32.9XX0, O69.0XX1, and O74.7 **Supporting Information** ● Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information ● Removed *CMS* section	
Pharmacogenetic Testing (for Tennessee Only)	Jun. 1, 2022	**Application** ● Added language to indicate this Medical Policy applies to CoverKids **Coverage Rationale** ● Updated list of examples of unproven and not medically necessary pharmacogenetic Multi-Gene Panels	The use of pharmacogenetic Multi-Gene Panels to guide therapy decisions is proven and medically necessary for antidepressants and antipsychotics medication when all of the following criteria are met: ● The individual has a diagnosis of major depressive disorder or generalized anxiety disorder; and ● The individual has failed at least one prior medication to treat their condition; and ● The Multi-Gene Panel has no more than 15 relevant genes

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Pharmacogenetic Testing (for Tennessee Only) (continued)	Jun. 1, 2022	for genetic polymorphisms; removed "NeurolDgenetix" • Added language to indicate the use of the PrismRA® molecular signature test is unproven and not medically necessary for evaluating likelihood of inadequate response to anti-TNF therapies for rheumatoid arthritis due to insufficient evidence of efficacy **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Removed *CMS* section	The use of pharmacogenetic Multi-Gene Panels for genetic polymorphisms for any other indication, including but not limited to pain management, cardiovascular drugs, anthracyclines, or polypharmacy, is unproven and not medically necessary for evaluating drug-metabolizer status due to insufficient evidence of efficacy. Examples of these Panels include, but are not limited to the following: • GeneSight® Analgesic • GeneSight® ADHD • Pain Medication DNA Insights® • PharmacoDx • SureGene Test The use of the PrismRA® molecular signature test is unproven and not medically necessary for evaluating likelihood of inadequate response to anti-TNF therapies for rheumatoid arthritis due to insufficient evidence of efficacy.
Skin and Soft Tissue Substitutes (for Tennessee Only)	Jun. 1, 2022	**Coverage Rationale** • Added language to indicate: ○ Grafix® (GrafixPL, GrafixPRIME, GrafixPL PRIME) (non-injectable) is proven and medically necessary for treating diabetic foot ulcer when all of the [listed] criteria are met ○ Grafix is limited to one application per week for up to 12 weeks ○ Grafix is unproven and not medically necessary for all other indications including but not limited to application more frequently than once a week or beyond 12 weeks	**EpiFix or Grafix® (GrafixPL, GrafixPRIME and GrafixPL PRIME) (Non-Injectable)** EpiFix or Grafix is proven and medically necessary for treating diabetic foot ulcer when all of the following criteria are met: • Adequate circulation to the affected extremity as indicated by one or more of the following: ○ Pedal pulses palpable ○ Ankle-brachial index (ABI) between 0.7 and 1.2 ○ Dorsum transcutaneous oxygen test (TcPO2) ≥ 30 mm Hg within the last 60 days ○ Triphasic or biphasic Doppler arterial waveforms at the ankle of affected leg • Optimal glucose control Glycated hemoglobin test (HgA1c) < 12% (within the last 90 days) • Individual has a diagnosis of Type 1 or Type 2 diabetes • Ulcer size ≥ 1 cm^2 and < 25 cm^2

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Skin and Soft Tissue Substitutes (for Tennessee Only) (continued)	Jun. 1, 2022	• Revised coverage criteria for EpiFix (non-injectable): ○ Added criterion requiring: ▪ Adequate circulation to the affected extremity as indicated by pedal pulses palpable ○ Removed criterion requiring: ▪ Serum creatinine < 3.0 mg/dL (within the last 6 months) ▪ Individual does not have a diagnosis of autoimmune connective tissue disease ▪ Individual is not receiving radiation therapy or chemotherapy ▪ Individual is not taking medications considered to be immune system modulators ○ Replaced criterion requiring: ▪ "Adequate circulation to the affected extremity as indicated by dorsum transcutaneous oxygen test (TcPO2) ≥ 30 mm Hg" with "adequate circulation to the affected extremity as indicated by dorsum transcutaneous oxygen test (TcPO2) ≥ 30 mm Hg *within the last 60 days*" ▪ "Glycated hemoglobin test (HgA1c) < 12% (within the last	• Ulcer has failed to demonstrate Measurable Signs of Healing with at least 4 weeks of standard wound care which includes all of the following: ○ Application of dressings to maintain a moist wound environment ○ Debridement of necrotic tissue if present ○ Offloading • Individual does not have active Charcot deformity or major structural abnormalities of the affected foot • Individual does not have a known or suspected malignancy of the current ulcer being treated • Standard wound care continues • Ulcer being treated does not extend to tendon, muscle, capsule or bone **EpiFix and Grafix Application Limitations** • EpiFix is limited to one application per week for up to 12 weeks • Grafix is limited to one application per week for up to 12 weeks Due to insufficient evidence of efficacy, EpiFix and/or Grafix are unproven and not medically necessary for all other indications including but not limited to: • EpiFix application more frequently than once a week or beyond 12 weeks • Grafix application more frequently than once a week or beyond 12 weeks **TransCyte™** TransCyte is proven and medically necessary for treating surgically excised Full-Thickness Thermal Burn wounds and deep Partial-Thickness Thermal Burn wounds before autograft placement. TransCyte is unproven and not medically necessary for all other indications due to insufficient evidence of efficacy.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Skin and Soft Tissue Substitutes (for Tennessee Only) (continued)	Jun. 1, 2022	*60* days)" with "*optimal glucose control* glycated hemoglobin test (HgA1c) < 12% (within the last *90* days)" ▪ "*EpiFix is used in conjunction with* standard wound care" with "standard wound care *continues*" ▪ "Individual does not have active Charcot deformity or major structural abnormalities of the foot" with "individual does not have active Charcot deformity or major structural abnormalities of the *affected* foot" ▪ "Individual does not have a known or suspected malignancy of current ulcer" with "individual does not have a known or suspected malignancy of the current ulcer *being treated*" ▪ "*Individual* does not *have an* ulcer extending to tendon, muscle, capsule or bone" with "ulcer *being treated* does not extend to tendon, muscle, capsule or bone" ● Revised list of skin and soft tissue substitutes that are unproven and not medically necessary for any indication:	**Other Skin and Soft Tissue Substitutes** The following skin and soft tissue substitutes are unproven and not medically necessary for any indication* due to insufficient evidence of efficacy: ● Affinity® ● AlloGen™ ● AlloSkin™ ● AlloWrap® ● Altiply® ● Amnio Wound™ ● Amnio Wrap2™ ● AmnioAMP-MP™ ● AmnioArmor™ ● AmnioBand® ● AmnioCore ● Amniocyte Plus™ ● AMNIOEXCEL®, AMNIOEXCEL Plus, or BioDExcel™ ● AmnioFix® ● AMNIOMATRIX® or BioDMatrix™ ● Amnio-Maxx™ or Amnio-Maxx™ Lite ● Amniorepair ● Amniotext ● Amniotext patch ● Amnion Bio™ ● AMNIPLY™ ● Architect® ● Artacent® Cord ● Artacent Wound or Artacent AC ● ArthroFLEX® ● Ascent™ ● AxoBioMembrane™ ● Axolotl™ Ambient or Axolotl Cryo ● Axolotl Graft or Axolotl DualGraft

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Skin and Soft Tissue Substitutes (for Tennessee Only) (continued)	Jun. 1, 2022	○ Added: ▪ Cellesta Flowable Amnion ▪ Grafix Core ▪ Vendaje ▪ Vim ▪ Zenith Amniotic Membrane ○ Removed: ▪ BionextPatch ▪ carePATCH ▪ Grafix® ▪ GrafixPL® ▪ Grafix PRIME® ▪ GrafixPL PRIME® **Definitions** • Added definition of "Xenograft" **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information • Removed *CMS* section	• BellaCell HD™ • bio-ConneKt® • BioDfence™ or BioDFence DryFlex™ • Bioskin™ • Bioskin Flow • Biovance® • BioWound™, BioWound Plus, or BioWound Xplus • Cellesta™ or Cellesta Duo • Cellesta Cord • Cellesta Flowable Amnion • CLARIX® • CLARIX FLO® • Cogenex (amniotic membrane and flowable amnion) • Coll-e-Derm™ • Conexa™ • Corecyte™ • Coretext™ or Protext™ • CorMatrix® • Corplex™ • Corplex p • Cryo-Cord™ • Cygnus™ • Cymetra™ • Cytal™ • DermACELL®*, DermACELL AWM® or DermACELL AWM Porous (*see asterisked note below when DermACELL is used during breast reconstruction*) • Dermacyte® • Derma-Gide™ • DermaPure™ • DermaSpan™ • Dermavest® or Plurivest® • Derm-Maxx

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Skin and Soft Tissue Substitutes (for Tennessee Only) (continued)	Jun. 1, 2022		• EpiCord® • EpiFix®, injectable • Excellagen® • E-Z Derm® • FlowerAmnioFlo™ or FlowerFlo™ • FlowerAmnioPatch™ or FlowerPatch™ • FlowerDerm™ • Fluid Flow™ • Fluid GF™ • GammaGraft™ • Genesis Amniotic Membrane • Grafix Core • Guardian • HelicoII™ • hMatrix® • Hyalomatrix® • Integra® Flowable Wound Matrix • IntéguPly® • Interfy™ • Keramatrix® • Kerasorb® • Kerecis™ Omega3 • Keroxx™ • Matrion™ • MatriStem® • Mediskin™ • Membrane Graft™ • Membrane Wrap™ • MemoDerm™ • MIRODERM™ • MyOwn Skin™ • NeoPatch™ • NEOX®

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Skin and Soft Tissue Substitutes (for Tennessee Only) (continued)	Jun. 1, 2022		• NEOX FLO® • Novachor™ • Novafix™ • Novafix™ DL • NuDYN™ • NuShield® • PalinGen® Amniotic Tissue Allograft and PalinGen Flow products • Polycyte™ • PriMatrix® • Procenta® • ProgenaMatrix™ • ProMatrX™ • PuraPly®, PuraPly AM, or PuraPly XT • REGUaRD™ • Repriza® • Restorigin™ • Revita™ • Revitalon® • SkinTE™ • STRATTICE™ • Stravix™ or StravixPL™ • Surederm™ • Surfactor® • SurGraft™ • SurgiCORD™ • SurgiGRAFT™ • SurgiGRAFT-DUAL • Talymed® • TenSIX® • TheraSkin® • Therion™ • TranZgraft® • TruSkin™

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Skin and Soft Tissue Substitutes (for Tennessee Only) (continued)	Jun. 1, 2022		• Vendaje • Vim • WoundEx® • WoundEx™ Flow • WoundFix™, WoundFix Plus, or WoundFix Xplus • Xcellerate™ • XCM BIOLOGIC® Tissue Matrix • XWRAP™ • Zenith Amniotic Membrane *Refer to the Coverage Determination Guideline titled *Breast Reconstruction Post Mastectomy and Poland Syndrome (for Tennessee Only)* for information about coverage for skin and soft tissue substitutes used during post mastectomy breast reconstruction procedures.

Medical Benefit Drug Policy Updates

New

Policy Title	Effective Date	Coverage Rationale
Enjaymo™ (Sutimlimab-Jome)	Jun. 1, 2022	Enjaymo is medically necessary for the treatment of CAD in patients who meet all of the following criteria: ● For initial therapy, all of the following: ○ Diagnosis of CAD by, or in consultation with, a hematologist with expertise in the diagnosis of CAD; and ○ Confirmation of the CAD diagnosis based on all of the following: ▪ Evidence of chronic hemolysis (e.g., elevated lactated dehydrogenase [LDH], decreased haptoglobin, increased indirect bilirubin, increased reticulocyte count); and ▪ Positive polyspecific direct antiglobin test (DAT); and ▪ Positive monospecific DAT specific for C3d; and ▪ Immunoglubulin G (IgG) DAT ≤ 1+; and ▪ Cold agglutinin titer ≥ 64 at 4°C and ○ Cold agglutinin syndrome secondary to other factors has been ruled out (e.g., infection, rheumatologic disease, systemic lupus erythematosus, overt hematologic malignancy, other autoimmune disorders); and ○ Patient has a baseline hemoglobin level ≤ 10 g/dL; and ○ Enjaymo is prescribed by a hematologist; and ○ Enjaymo dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Patient is not receiving Enjaymo in combination with a complement inhibitor [e.g., Soliris (eculizumab), Ultomiris (ravilizumab-cwzb), Empaveli (pegcetacoplan)]; and ○ Initial authorization will be for no more than 6 months. ● For continuation of therapy, all of the following: ○ Documentation of positive clinical response to therapy (e.g., increase in hemoglobin, decreased transfusion requirements, decreased markers of hemolysis, improvement in anemia-related symptoms); and ○ Enjaymo is prescribed by, or in consultation with, a hematologist; and ○ Enjaymo dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Patient is not receiving Enjaymo in combination with a complement inhibitor [e.g., Soliris (eculizumab), Ultomiris (ravilizumab-cwzb), Empaveli (pegcetacoplan)]; and ○ Reauthorization will be for no more than 12 months.

Updated

Policy Title	Effective Date	Summary of Changes
Rituximab (Riabni™, Rituxan®, Ruxience®, & Truxima®)	Jun. 1, 2022	Applicable Codes ● Revised description for HCPCS code Q5115

Medical Benefit Drug Policy Updates

Updated

Policy Title	Effective Date	Summary of Changes
Zolgensma® (Onasemnogene Abeparvovec-Xioi)	Jun. 1, 2022	**Applicable Codes** ● Added ICD-10 diagnosis code G12.8 **Supporting Information** ● Updated *References* section to reflect the most current information

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Actemra® (Tocilizumab) Injection for Intravenous Infusion	Jun. 1, 2022	**Coverage Rationale** ● Added language to indicate: ○ Actemra is proven and medically necessary for the treatment of giant cell arteritis when all of the following criteria are met: *Initial Therapy* ▪ Diagnosis of giant cell arteritis (GCA) ▪ Actemra is dosed according to U.S. Food and Drug Administration (FDA) labeled dosing for giant cell arteritis ▪ Patient is not receiving Actemra in combination with either of the following: – Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)]	Refer to the Medical Benefit Drug Policy titled Oncology Medication Clinical Coverage for updated information based upon the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium® (NCCN Compendium®) for oncology indications. This policy refers only to Actemra (tocilizumab) injection for intravenous infusion. Actemra (tocilizumab) for self-administered subcutaneous injection is obtained under the pharmacy benefit. Actemra is proven and medically necessary for the treatment of: **Polyarticular Juvenile Idiopathic Arthritis** Actemra is proven and medically necessary for the treatment of polyarticular juvenile idiopathic arthritis when all of the following criteria are met: ● For initial therapy, all of the following: ○ Diagnosis of polyarticular juvenile idiopathic arthritis (PJIA); and ○ Actemra is dosed according to U.S. Food and Drug Administration (FDA) labeled dosing for polyarticular juvenile idiopathic arthritis; and ○ Patient is not receiving Actemra in combination with either of the following: ▪ Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] ▪ Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] and

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Actemra® (Tocilizumab) Injection for Intravenous Infusion (continued)	Jun. 1, 2022	– Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] ▪ Prescribed by or in consultation with a rheumatologist ▪ Initial authorization is for no more than 12 months *Continuation of Therapy* ▪ Patient has previously received Actemra injection for intravenous infusion ▪ Documentation of positive clinical response to Actemra ▪ Actemra is dosed according to FDA labeled dosing for giant cell arteritis ▪ Patient is not receiving Actemra in combination with either of the following: – Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] – Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant	○ Prescribed by or in consultation with a rheumatologist; and ○ Initial authorization is for no more than 12 months ● For continuation of therapy, all of the following: ○ Patient has previously received Actemra injection for intravenous infusion; and ○ Documentation of positive clinical response to Actemra; and ○ Actemra is dosed according to FDA labeled dosing for polyarticular juvenile idiopathic arthritis; and ○ Patient is not receiving Actemra in combination with either of the following: ▪ Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] ▪ Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] and ○ Authorization is for no more than 12 months **Rheumatoid Arthritis** Actemra is proven and medically necessary for the treatment of rheumatoid arthritis when all of the following criteria are met: ● For initial therapy, all of the following: ○ Diagnosis of moderately to severely active rheumatoid arthritis (RA); and ○ One of the following: ▪ History of failure intolerance to a 3-month trial of one non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced; or ▪ Patient has been previously treated with a biologic or targeted synthetic DMARD FDA-approved for the treatment of rheumatoid arthritis [e.g., Humira (adalimumab), Simponi (golimumab), Rinvoq

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Actemra® (Tocilizumab) Injection for Intravenous Infusion (continued)	Jun. 1, 2022	(baricitinib)] ▪ Authorization is for no more than 12 months **Applicable Codes** ● Added ICD-10 diagnosis codes M31.5 and M31.6 **Supporting Information** ● Updated *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	(upadacitinib), Xeljanz (tofacitinib)]; or ▪ Patient is currently on Actemra and ○ Actemra is dosed according to FDA labeled dosing for rheumatoid arthritis; and ○ Patient is not receiving Actemra in combination with either of the following: ▪ Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] ▪ Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] and ○ Prescribed by or in consultation with a rheumatologist; and ○ Initial authorization is for no more than 12 months ● For continuation of therapy, all of the following: ○ Patient has previously received Actemra injection for intravenous infusion; and ○ Documentation of positive clinical response; and ○ Actemra is dosed according to FDA labeled dosing for rheumatoid arthritis; and ○ Patient is not receiving Actemra in combination with either of the following: ▪ Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] ▪ Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] and ○ Authorization is for no more than 12 months **Systemic Juvenile Idiopathic Arthritis** Actemra is proven and medically necessary for the treatment of systemic juvenile idiopathic arthritis when all of the following criteria are met: ● For initial therapy, all of the following:

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Actemra® (Tocilizumab) Injection for Intravenous Infusion (continued)	Jun. 1, 2022		(FDA) labeled dosing for giant cell arteritis; and ○ Patient is not receiving Actemra in combination with either of the following: ▪ Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] ▪ Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] and ○ Prescribed by or in consultation with a rheumatologist; and ○ Initial authorization is for no more than 12 months ● For continuation of therapy, all of the following: ○ Patient has previously received Actemra injection for intravenous infusion; and ○ Documentation of positive clinical response to Actemra; and ○ Actemra is dosed according to FDA labeled dosing for giant cell arteritis; and ○ Patient is not receiving Actemra in combination with either of the following: ▪ Biologic disease-modifying antirheumatic drug (DMARD) [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Simponi (golimumab)] ▪ Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Olumiant (baricitinib)] and ○ Authorization is for no more than 12 months **Cytokine Release Syndrome** Actemra is proven and medically necessary for the treatment of cytokine release syndrome when all of the following criteria are met: ● For initial therapy, all of the following: ○ Diagnosis of cytokine release syndrome (CRS); and ○ Patient has received treatment with one of the following:

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Actemra® (Tocilizumab) Injection for Intravenous Infusion (continued)	Jun. 1, 2022		▪ Chimeric antigen receptor (CAR) T cell therapy [e.g., Kymriah (tisagenlecleucel), Yescarta (axicabtagene ciloleucel)] ▪ Blincyto (blinatumomab) and ○ Actemra is dosed according to FDA labeled dosing for CRS; and ○ Initial authorization is for no more than 4 doses ● For continuation of therapy, all of the following: ○ Documentation of positive clinical response; and ○ Patient continues to experience signs and symptoms of CRS; and ○ Actemra is dosed according to FDA labeled dosing for CRS; and ○ Authorization is for no more than 4 doses **Acute Graft-Versus-Host Disease (GVHD)** Actemra is proven and medically necessary for the treatment of acute graft-versus-host disease (GVHD) when all of the following criteria are met: ● For initial therapy, all of the following: ○ Diagnosis of steroid refractory acute GVHD; and ○ One of the following: ▪ Patient is receiving Actemra in combination with systemic corticosteroids ▪ Patient is intolerant to systemic corticosteroid therapy and ○ Initial authorization is for no more than 4 doses ● For continuation of therapy, all of the following: ○ Documentation of positive clinical response; and ○ Patient continues to experience acute GVHD; and ○ One of the following: ▪ Patient is receiving Actemra in combination with systemic corticosteroids ▪ Patient is intolerant to systemic corticosteroid therapy and ○ Authorization is for no more than 4 doses

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Actemra® (Tocilizumab) Injection for Intravenous Infusion (continued)	Jun. 1, 2022		**Immune Checkpoint Inhibitor-Related Toxicities** Actemra is proven and medically necessary for the treatment of immune checkpoint inhibitor-related toxicities when all of the following criteria are met: ● Patient has recently received checkpoint inhibitor therapy [e.g., Keytruda (Pembrolizumab), Opdivo (Nivolumab)]; and ● Diagnosis of severe immunotherapy-related inflammatory arthritis; and ● No symptom improvement after 7 days of starting high-dose corticosteroids; and ● History of failure, contraindication, or intolerance to infliximab (e.g., Inflectra, Remicade); and ● One of the following: ○ Patient is receiving Actemra in combination with systemic corticosteroids ○ Patient is intolerant to systemic corticosteroid therapy; and ○ Authorization is for no more than 4 doses
Denosumab (Prolia® & Xgeva®)	Jun. 1, 2022	Coverage Rationale *Prolia (Denosumab)* ● Revised coverage guidelines; replaced reference to InterQual® criteria with language indicating: ○ Prolia is proven and medically necessary for the treatment of postmenopausal patients with osteoporosis or to increase bone mass in patients with osteoporosis at high risk for fracture, when all of the following criteria are met: Initial Therapy ▪ Diagnosis of osteoporosis; and ▪ One of the following:	This policy refers to the following denosumab products: ● Prolia ● Xgeva **Prolia (Denosumab)** Prolia is proven and medically necessary for the treatment of postmenopausal patients with osteoporosis, or to increase bone mass in patients with osteoporosis at high risk for fracture, who meet all of the following criteria: ● Initial Therapy ○ Diagnosis of osteoporosis; and ○ One of the following: ▪ BMD T-score ≤-2.5 based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site); or ▪ History of one of the following resulting from minimal trauma: – Vertebral compression fracture

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Denosumab (Prolia® & Xgeva®) (continued)	Jun. 1, 2022	– BMD T-score ≤-2.5 based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site); or – History of one of the following resulting from minimal trauma: ● Vertebral compression fracture ● Fracture of the hip ● Fracture of the distal radius ● Fracture of the pelvis ● Fracture of the proximal humerus or – Both of the following: ● BMD T-score between -1 and -2.5 (BMD T-score greater than-2.5 and less than or equal to -1) based on BMD measurements from lumber spine (at least two	– Fracture of the hip – Fracture of the distal radius – Fracture of the pelvis – Fracture of the proximal humerus or ▪ Both of the following: – BMD T-score between -1 and -2.5 (BMD T-score greater than-2.5 and less than or equal to -1) based on BMD measurements from lumber spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site) – One of the following: ● FRAX 10-year fracture probabilities: major osteoporotic fracture at 20% or more ● FRAX 10-year fracture probabilities: hip fracture at 3% or more and ○ One of the following: ▪ Both of the following: – History of intolerance to oral bisphosphonate therapy; and – History of failure, contraindication, or intolerance to intravenous bisphosphonate therapy (e.g., pamidronate, zoledronic acid) or ▪ History of failure or contraindication to oral bisphosphonate therapy; or ▪ History of failure, contraindication, or intolerance to IV bisphosphonate therapy and ○ Prolia dosing is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 60 mg every 6 months; and ○ Authorization is for no more than 12 months. ● Reauthorization/Continuation of Care Criteria

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Denosumab (Prolia® & Xgeva®) (continued)	Jun. 1, 2022	vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site) ● One of the following: ○ FRAX 10-year fracture probabilities: major osteoporotic fracture at 20% or more ○ FRAX 10-year fracture probabilities: hip fracture at 3% or more and ▪ One of the following: – Both of the following: ● History of intolerance to oral bisphosphonate therapy; and ● History of failure, contraindication, or intolerance to intravenous bisphosphonate therapy (e.g.,	For patients currently on Prolia for the treatment of postmenopausal patients with osteoporosis, or to increase bone mass in patients with osteoporosis at high risk for fracture, continued use will be approved based on the following criteria: ○ Provider attests to a positive clinical response; and ○ Prolia dosing is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 60 mg every 6 months; and ○ Authorization is for no more than 12 months. Prolia is proven and medically necessary to increase bone mass in patients at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer in patients who meet all of the following criteria: ● Initial Therapy ○ Diagnosis of non-metastatic prostate cancer; and ○ Patient is receiving androgen deprivation therapy; and ○ One of the following: ▪ Both of the following: – History of intolerance to oral bisphosphonate therapy; and – History of failure, contraindication, or intolerance to intravenous bisphosphonate therapy (e.g., pamidronate, zoledronic acid) or ▪ History of failure or contraindication to oral bisphosphonate therapy; or ▪ History of failure, contraindication, or intolerance to IV bisphosphonate therapy and ○ Prolia dosing is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 60 mg every 6 months; and ○ Authorization is for no more than 12 months. ● Reauthorization/Continuation of Care Criteria

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Denosumab (Prolia® & Xgeva®) (continued)	Jun. 1, 2022	pamidronate, zoledronic acid) or – History of failure or contraindication to oral bisphosphonate therapy; or – History of failure, contraindication, or intolerance to IV bisphosphonate therapy and ▪ Prolia dosing is in accordance with the U.S. Food and Drug Administration (FDA) approved labeling: maximum dosing of 60 mg every 6 months; and ▪ Authorization is for no more than 12 months Reauthorization/Continuation of Care Criteria ▪ Treatment of postmenopausal patients with osteoporosis or to increase bone mass in patients with osteoporosis at high risk for fracture, continued use of Prolia will be approved based on the following criteria:	For patients currently on Prolia to increase bone mass in patients at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer, continued use will be approved based on the following criteria: ○ Patient is receiving androgen deprivation therapy; and ○ Provider attests to a positive clinical response; and ○ Prolia dosing is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 60 mg every 6 months; and ○ Authorization is for no more than 12 months. Prolia is proven and medically necessary to treat patients at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer in patients who meet all of the following criteria: ● Initial Therapy ○ Diagnosis of breast cancer; and ○ Patient is receiving aromatase inhibitor therapy; and ○ One of the following: ▪ Both of the following: – History of intolerance to oral bisphosphonate therapy; and – History of failure, contraindication, or intolerance to intravenous bisphosphonate therapy (e.g., pamidronate, zoledronic acid) or ▪ History of failure or contraindication to oral bisphosphonate therapy; or ▪ History of failure, contraindication, or intolerance to IV bisphosphonate therapy and ○ Prolia dosing is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 60 mg every 6 months; and ○ Authorization is for no more than 12 months.

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Denosumab (Prolia® & Xgeva®) (continued)	Jun. 1, 2022	– Provider attests to a positive clinical response; and – Prolia dosing is in accordance with the FDA approved labeling: maximum dosing of 60 mg every 6 months; and – Authorization is for no more than 12 months ○ Prolia is proven and medically necessary to increase bone mass in patients at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer when all of the following criteria are met: Initial Therapy ▪ Diagnosis of non-metastatic prostate cancer; and ▪ Patient is receiving androgen deprivation therapy; and ▪ One of the following: – Both of the following: ● History of intolerance to oral bisphosphonate therapy; and ● History of failure, contraindication, or	● Reauthorization/Continuation of Care Criteria For patients currently on Prolia to treat patients at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer, continued use will be approved based on the following criteria: ○ Patient is receiving aromatase inhibitor therapy; and ○ Provider attests to a positive clinical response; and ○ Prolia dosing is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 60 mg every 6 months; and ○ Authorization is for no more than 12 months. Prolia is proven and medically necessary to treat glucocorticoid-induced osteoporosis in patients at high risk for fracture when all of the following criteria are met: ● Initial Therapy ○ Diagnosis of glucocorticoid-induced osteoporosis; and ○ History of prednisone or its equivalent at a dose ≥ 5 mg/day for ≥ 3 months; and ○ One of the following: ▪ BMD T-score ≤-2.5 based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site); or ▪ History of one of the following resulting from minimal trauma: – Vertebral compression fracture – Fracture of the hip – Fracture of the distal radius – Fracture of the pelvis – Fracture of the proximal humerus or ▪ One of the following: – FRAX 10-year fracture probabilities: major osteoporotic fracture at 20% or more – FRAX 10-year fracture probabilities: hip fracture at 3% or more

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Denosumab (Prolia® & Xgeva®) (continued)	Jun. 1, 2022	intolerance to intravenous bisphosphonate therapy (e.g., pamidronate, zoledronic acid) or – History of failure or contraindication to oral bisphosphonate therapy; or – History of failure, contraindication, or intolerance to IV bisphosphonate therapy and ▪ Prolia dosing is in accordance with the FDA approved labeling: maximum dosing of 60 mg every 6 months; and ▪ Authorization is for no more than 12 months Reauthorization/Continuation of Care Criteria ▪ To increase bone mass in patients at high risk for fracture receiving androgen deprivation therapy for non-metastatic prostate cancer, continued use of Prolia will	and ○ One of the following: ▪ Both of the following: – History of intolerance to oral bisphosphonate therapy; and – History of failure, contraindication, or intolerance to intravenous bisphosphonate therapy (e.g., pamidronate, zoledronic acid) or ▪ History of failure or contraindication to oral bisphosphonate therapy; or ▪ History of failure, contraindication, or intolerance to IV bisphosphonate therapy and ○ Prolia dosing is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 60 mg every 6 months; and ○ Authorization is for no more than 12 months. ● Reauthorization/Continuation of Care Criteria For patients currently on Prolia to treat glucocorticoid-induced osteoporosis in patients at high risk for fracture, continued use will be approved based on the following criteria: ○ Provider attests to a positive clinical response; and ○ Prolia dosing is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 60 mg every 6 months; and ○ Authorization is for no more than 12 months. **Xgeva (Denosumab)** Xgeva is proven and medically necessary for the prevention of skeletal-related events in patients with multiple myeloma and with bone metastases from solid tumors when all of the following criteria are met: ● Initial Therapy ○ Patient is one of the following:

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Denosumab (Prolia® & Xgeva®) (continued)	Jun. 1, 2022	be approved based on the following criteria: – Patient is receiving androgen deprivation therapy; and – Provider attests to a positive clinical response; and – Prolia dosing is in accordance with the FDA approved labeling: maximum dosing of 60 mg every 6 months; and – Authorization is for no more than 12 months ○ Prolia is proven and medically necessary to treat patients at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer when all of the following criteria are met: Initial Therapy ▪ Diagnosis of breast cancer; and ▪ Patient is receiving aromatase inhibitor therapy; and ▪ One of the following: – Both of the following: ● History of intolerance to oral	▪ Patient is ≥ 18 years of age ▪ Patient is a skeletally mature adolescent as defined by having at least 1 mature long bone (e.g., closed epiphyseal growth plate of the humerus) and ○ One of the following: ▪ Diagnosis of multiple myeloma ▪ Presence of metastatic disease secondary to a solid tumor (e.g., bladder, breast, kidney, lung, ovarian, thyroid, etc.) and ○ Individual has an expected survival of 3 months or greater; and ○ Refractory (within the past 30 days), contraindication (including renal insufficiency), or intolerance to treatment with intravenous bisphosphonate therapy (e.g., pamidronate, zoledronic acid); and ○ Xgeva dosing is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 120 mg every 4 weeks; and ○ Authorization is for no more than 12 months ● Reauthorization/Continuation of Care Criteria For patients currently on Xgeva for the prevention of skeletal-related events in patients with multiple myeloma and with bone metastases from solid tumors, continued use will be approved based on the following criteria: ○ Individual has an expected survival of 3 months or greater; and ○ Provider attests to a positive clinical response; and ○ Xgeva dosing is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 120 mg every 4 weeks; and ○ Authorization is for no more than 12 months Xgeva is proven and medically necessary for the treatment of giant cell tumor of the bone when all of the following criteria are met: ● Initial Therapy ○ Patient is one of the following:

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Denosumab (Prolia® & Xgeva®) (continued)	Jun. 1, 2022	inhibitor therapy for breast cancer, continued use of Prolia will be approved based on the following criteria: – Patient is receiving aromatase inhibitor therapy; and – Provider attests to a positive clinical response; and – Prolia dosing is in accordance with the FDA approved labeling: maximum dosing of 60 mg every 6 months; and – Authorization is for no more than 12 months ○ Prolia is proven and medically necessary to treat glucocorticoid-induced osteoporosis in patients at high risk for fracture when all of the following criteria are met: Initial Therapy ▪ Diagnosis of glucocorticoid-induced osteoporosis; and ▪ History of prednisone or its equivalent at a dose ≥ 5 mg/day for ≥ 3 months; and ▪ One of the following:	○ Diagnosis of hypercalcemia of malignancy as defined as albumin-corrected serum calcium level greater than 12.5 mg/dL (3.1 mmol/L); and ○ No pre-existing hypocalcemia (i.e., serum calcium or corrected calcium within normal limits per laboratory reference); and ○ Refractory (within the past 30 days), contraindication (including renal insufficiency), or intolerance to treatment with intravenous bisphosphonate therapy (e.g., pamidronate, zoledronic acid); and ○ Xgeva dosing is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 120 mg every 4 weeks (additional 120 mg doses allowed on Day 8 and 15 in the first month of therapy); and ○ Authorization is for no more than 12 months ● Reauthorization/Continuation of Care Criteria For patients currently on Xgeva for the treatment of hypercalcemia of malignancy, continued use will be approved based on the following criteria: ○ Provider attests to a positive clinical response; and ○ Xgeva dosing is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 120 mg every 4 weeks; and ○ Authorization is for no more than 12 months Xgeva is proven and medically necessary for the prevention of skeletal-related events in men with castration-resistant prostate cancer who have bone metastases when all of the following criteria are met: ● Initial Therapy ○ Diagnosis of castration-resistant prostate cancer; and ○ Presence of metastatic disease; and ○ Refractory (within the past 30 days), contraindication (including renal insufficiency), or intolerance to treatment with intravenous bisphosphonate therapy (e.g., pamidronate, zoledronic acid); and ○ Xgeva dosing is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 120 mg every 4

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Denosumab (Prolia® & Xgeva®) (continued)	Jun. 1, 2022	– BMD T-score ≤ -2.5 based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site); or – History of one of the following resulting from minimal trauma: ● Vertebral compression fracture ● Fracture of the hip ● Fracture of the distal radius ● Fracture of the pelvis ● Fracture of the proximal humerus or – One of the following: ● FRAX 10-year fracture probabilities: major osteoporotic fracture at 20% or more ● FRAX 10-year fracture probabilities: hip fracture at 3% or more	weeks; and ○ Authorization is for no more than 12 months ● Reauthorization/Continuation of Care Criteria For patients currently on Xgeva for the prevention of skeletal-related events in men with castration-resistant prostate cancer who have bone metastases, continued use will be approved based on the following criteria: ○ Provider attests to a positive clinical response; and ○ Xgeva dosing is in accordance with the United States Food and Drug Administration approved labeling: maximum dosing of 120 mg every 4 weeks; and ○ Authorization is for no more than 12 months Xgeva is proven and medically necessary for the treatment of osteopenia/osteoporosis in patients with systemic mastocytosis with bone pain not responding to bisphosphonates when all of the following criteria are met: ● Initial Therapy ○ Diagnosis of systemic mastocytosis; and ○ Patient has bone pain; and ○ Diagnosis of osteoporosis or osteopenia based on one of the following: ▪ BMD T-score ≤-1 based on BMD measurements from lumbar spine (at least two vertebral bodies), hip (femoral neck, total hip), or radius (one-third radius site); or ▪ History of one of the following resulting from minimal trauma: – Vertebral compression fracture – Fracture of the hip – Fracture of the distal radius – Fracture of the pelvis – Fracture of the proximal humerus; and ○ Refractory (within the past 30 days), contraindication (including renal insufficiency), or intolerance to treatment with intravenous bisphosphonate therapy (e.g., pamidronate, zoledronic acid); and

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Denosumab (Prolia® & Xgeva®) (continued)	Jun. 1, 2022	Reauthorization/Continuation of Care Criteria ▪ To treat glucocorticoid-induced osteoporosis in patients at high risk for fracture, continued use of Prolia will be approved based on the following criteria: – Provider attests to a positive clinical response; and – Prolia dosing is in accordance with the FDA approved labeling: maximum dosing of 60 mg every 6 months; and – Authorization is for no more than 12 months Applicable Codes *Prolia* ● Added list of applicable ICD-10 diagnosis codes ● Added maximum dosage requirements: ○ HCPCS code: J0897 ○ National drug code (NDC): 55513-0710-01 ○ Maximum dosage per administration: 60 mg ○ How supplied: 60 mg/1 ml vial ○ Maximum allowed: 60 HCPCS	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Denosumab (Prolia® & Xgeva®) (continued)	Jun. 1, 2022	units (1 mg per unit); 1 vial/1 ml **Supporting Information** ● Updated *Clinical Evidence* and *FDA* sections to reflect the most current information	
Vyvgart™ (Efgartigimod Alfa-Fcab)	Jun. 1, 2022	**Coverage Rationale** ● Revised coverage criteria for continuation of therapy; replaced criterion requiring "improvement and/or maintenance of at least a *3* point improvement (reduction in score) in the MG-ADL score from pre-treatment baseline" with "improvement and/or maintenance of at least a *2* point improvement (reduction in score) in the MG-ADL score from pre-treatment baseline"	**Myasthenia Gravis** Vyvgart™ is proven and medically necessary when the following criteria are met: ● Initial Therapy: ○ Submission of medical records (e.g., chart notes, laboratory values, etc.) to support the diagnosis of generalized myasthenia gravis (gMG) by a neurologist or in consultation with a neurologist confirming all of the following: ▪ Patient has not failed a previous course of Vyvgart™ therapy; and ▪ Positive serologic test for anti-AChR antibodies; and ▪ One of the following: – History of abnormal neuromuscular transmission test demonstrated by single-fiber electromyography (SFEMG) or repetitive nerve stimulation – History of positive anticholinesterase test, e.g., edrophonium chloride test – Patient has demonstrated improvement in MG signs on oral cholinesterase inhibitors as assessed by the treating neurologist and ▪ Patient has a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of class II, III, or IV at initiation of therapy; and ▪ Patient has a Myasthenia Gravis-specific Activities of Daily Living scale (MG-ADL) total score ≥ 5 at initiation of therapy and ○ Both of the following: ▪ History of failure of at least two immunosuppressive agents over the course of at least 12 months (e.g., azathioprine, methotrexate, cyclosporine, mycophenylate, etc.); and

Medical Benefit Drug Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Vyvgart™ (Efgartigimod Alfa-Fcab) (continued)	Jun. 1, 2022		▪ Patient has required 2 or more courses of plasmapheresis/plasma exchanges and/or intravenous immune globulin for at least 12 months without symptom control and ○ Patient is currently on a stable dose (at least 2 months) of immunosuppressive therapy; and ○ Patient is not receiving Vyvgart™ in combination with Soliris (eculizumab); and ○ Vyvgart™ is initiated and titrated according to the U.S. FDA labeled dosing for gMG, up to a maximum of 1200 mg per dose; and ○ Prescribed by or in consultation with a neurologist; and ○ Initial authorization will be for no more than 6 months. ● Continuation of Therapy: ○ Patient has previously been treated with Vyvgart™; and ○ Submission of medical records (e.g., chart notes, laboratory tests) to demonstrate a positive clinical response from baseline as demonstrated by all of the following: ▪ Improvement and/or maintenance of at least a 2-point improvement (reduction in score) in the MG-ADL score from pre-treatment baseline. ▪ Reduction in signs and symptoms of myasthenia gravis ▪ Maintenance, reduction, or discontinuation of dose(s) of baseline immunosuppressive therapy (IST) prior to starting Vyvgart™. Note: add on, dose escalation of IST, or additional rescue therapy from baseline to treat myasthenia gravis or exacerbation of symptoms while on Vyvgart™ therapy will be considered as treatment failure and ○ Patient is not receiving Vyvgart™ in combination with Soliris (eculizumab); and ○ Vyvgart™ is dosed according to the U.S. FDA labeled dosing for gMG: up to a maximum of 1200 mg per dose; and ○ Prescribed by or in consultation with a neurologist; and ○ Reauthorization will be for no more than 12 months.

Coverage Determination Guideline Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Beds and Mattress (for Tennessee Only)	Jun. 1, 2022	Coverage Rationale • Added language to indicate: ○ Pressure reducing support surfaces (group 2) (HCPCS code E0193) are proven and medically necessary in certain circumstances; for medical necessity clinical coverage criteria, refer to InterQual® 2022, Apr. 2022 Release, Medicare: Durable Medical Equipment, Pressure Reducing Support Surfaces (Group 2) ○ Pressure reducing support surfaces (group 3) (HCPCS code E0194) are proven and medically necessary in certain circumstances; for medical necessity clinical coverage criteria, refer to InterQual® 2022, Apr. 2022 Release, Medicare: Durable Medical Equipment, Pressure Reducing Support Surfaces (Group 3) ○ Pediatric cribs (HCPCS code E0300) are proven and medically necessary in certain circumstances; for medical necessity clinical coverage criteria, refer to InterQual® 2022, Apr. 2022 Release, CP: Durable Medical Equipment, Hospital Beds and Cribs	**Indications for Coverage** Hospital beds and accessories are proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® 2022, Apr. 2022 Release, Medicare: Durable Medical Equipment, Hospital Beds and Accessories. Pressure reducing support surfaces (group 2) (HCPCS code E0193) are proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to InterQual® 2022, Apr. 2022 Release, Medicare: Durable Medical Equipment, Pressure Reducing Support Surfaces (Group 2). Pressure reducing support surfaces (group 3) (HCPCS code E0194) are proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to InterQual® 2022, Apr. 2022 Release, Medicare: Durable Medical Equipment, Pressure Reducing Support Surfaces (Group 3). Pediatric cribs (HCPCS code E0300) are proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to InterQual® 2022, Apr. 2022 Release, CP: Durable Medical Equipment, Hospital Beds and Cribs. Click here to view the InterQual® criteria. ***Safety Enclosure with Beds*** Safety enclosure with beds (e.g., pediatric enclosed bed, adult bed, safety enclosure) are covered as DME for individuals that have a risk for safety in bed when all of the following criteria are met: • Use of equipment is required due to a diagnosis related to cognitive impairment (e.g., traumatic brain injury, cerebral palsy, seizure disorder) or a severe behavioral disorder • There is a safety risk that includes but is not limited to any of the following:

Coverage Determination Guideline Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Beds and Mattress (for Tennessee Only) (continued)	Jun. 1, 2022		○ Claustrophobia ○ High risk of falls due to a clinical conditions ○ Uncontrolled movements ○ Violent or self-destructive behaviors such as uncontrolled head banging • Less restrictive alternatives methods such as the following have been tried and have not been successful or are contraindicated: ○ A mattress on the floor ○ Protective helmet ○ Side rails ○ Weighted blankets The physician documentation must include: • A signed physicians order for the enclosed bed • Behavioral Management Program, if applicable • Evaluation for contraindications to use of the equipment • Member assessment for physical, environmental, and behavioral factors • Name and model of protective or enclosure bed with a valid HCPCS code • Physician directed written monitoring plan • The medical, neurologic, or behavioral diagnosis ***Repair and Replacement*** Refer to the Coverage Determination Guideline titled Durable Medical Equipment, Orthotics, Ostomy Supplies, Medical Supplies and Repairs/Replacements (for Tennessee Only). **Coverage Limitations and Exclusions** The following services are excluded from coverage: • Personal care, comfort, or convenience items • Mattresses • Motorized beds • Retail beds/furniture

Coverage Determination Guideline Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Beds and Mattress (for Tennessee Only) (continued)	Jun. 1, 2022		When more than one piece of DME can meet the member's functional needs, benefits are available only for the item that meets the minimum specifications for member needs. Examples include but are not limited to, standard bed vs semi-electric bed vs fully electric or flotation system. This limitation is intended to exclude coverage for deluxe or additional components of a DME item which are not necessary to meet the member's minimal specifications to treat an Injury or Sickness. Note: Examples of mattresses that are excluded from coverage include but are not limited to retail mattresses such as tempurpedic™ and Posturepedic™.

Utilization Review Guideline Updates

Updated		
Policy Title	**Effective Date**	**Summary of Changes**
Elective Inpatient Services (for Tennessee Only)	May 1, 2022	Application ● Added language to indicate this Utilization Review Guideline applies to CoverKids Coverage Rationale ● Replaced notation indicating "this policy does not apply to obstetric *conditions*" with "this policy does not apply to an obstetric *member during pregnancy, childbirth, or the post-partum period*"

General Information

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

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

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

Policy Update Classifications

New

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

Updated

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

Revised

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

Replaced

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

Retired

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

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