United Healthcare Community Plan

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Medical Policy Update Bulletin: May 2022

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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	Medical Policy
Abnormal Uterine Bleeding and Uterine Fibroids (for Nebraska Only)	Medical Policy
Abnormal Uterine Bleeding and Uterine Fibroids (for New Jersey Only)	Medical Policy
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Airway Clearance Devices (for Nebraska Only)	Medical Policy
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Articular Cartilage Defect Repairs	Medical Policy
Articular Cartilage Defect Repairs (for Nebraska Only)	Medical Policy
Attended Polysomnography for Evaluation of Sleep Disorders	Medical Policy
Attended Polysomnography for Evaluation of Sleep Disorders (for New Jersey Only)	Medical Policy
Beds and Mattresses	Coverage Determination Guideline
Beds and Mattresses (for Nebraska Only)	Coverage Determination Guideline
Catheter Ablation for Atrial Fibrillation	Medical Policy
Catheter Ablation for Atrial Fibrillation (for Nebraska Only)	Medical Policy
Catheter Ablation for Atrial Fibrillation (for New Jersey Only)	Medical Policy
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Chemotherapy Observation or Inpatient Hospitalization (for Nebraska Only)	Utilization Review Guideline
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Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes	Medical Policy
Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes (for Nebraska Only)	Medical Policy
Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes (for New Jersey Only)	Medical Policy
Cosmetic and Reconstructive Procedures	Coverage Determination Guideline
Deep Brain and Cortical Stimulation	Medical Policy
Deep Brain and Cortical Stimulation (for Nebraska Only)	Medical Policy

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Policy Title	Policy Type
Electrical and Ultrasound Bone Growth Stimulators (for New Jersey Only)	Medical Policy
Electroencephalographic (EEG) Monitoring and Video Recording (for Nebraska Only)	Medical Policy
Electroencephalographic (EEG) Monitoring and Video Recording (for New Jersey Only)	Medical Policy
Hip Resurfacing and Replacement Surgery (Arthroplasty) (for New Jersey Only)	Medical Policy
Hysterectomy	Medical Policy
Hysterectomy (for Nebraska Only)	Medical Policy
Hysterectomy (for New Jersey Only)	Medical Policy
Implanted Electrical Stimulator for Spinal Cord	Medical Policy
Implanted Electrical Stimulator for Spinal Cord (for Nebraska Only)	Medical Policy
Implanted Electrical Stimulator for Spinal Cord (for New Jersey Only)	Medical Policy
Knee Replacement Surgery (Arthroplasty), Total and Partial (for New Jersey Only)	Medical Policy
Lower Extremity Invasive Diagnostic and Endovascular Procedures	Medical Policy
Lower Extremity Invasive Diagnostic and Endovascular Procedures (for Nebraska Only)	Medical Policy
Lower Extremity Invasive Diagnostic and Endovascular Procedures (for New Jersey Only)	Medical Policy
Manual Wheelchairs	Coverage Determination Guideline
Manual Wheelchairs (for Nebraska Only)	Coverage Determination Guideline
Minimally Invasive Procedures for Gastroesophageal Reflux Disease (GERD) and Achalasia	Medical Policy
Minimally Invasive Procedures for Gastroesophageal Reflux Disease (GERD) and Achalasia (for Nebraska Only)	Medical Policy
Obstructive and Central Sleep Apnea Treatment	Medical Policy
Obstructive Sleep Apnea Treatment (for Nebraska Only)	Medical Policy
Obstructive Sleep Apnea Treatment (for New Jersey Only)	Medical Policy
Orthognathic (Jaw) Surgery	Coverage Determination Guideline
Orthognathic (Jaw) Surgery (for Nebraska Only)	Coverage Determination Guideline
Orthognathic (Jaw) Surgery (for New Jersey Only)	Coverage Determination Guideline
Patient Lifts	Coverage Determination Guideline
Patient Lifts (for Nebraska Only)	Coverage Determination Guideline
Pediatric Gait Trainers, Standing Systems, and Walkers	Coverage Determination Guideline

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Policy Title	Policy Type
Pediatric Gait Trainers, Standing Systems, and Walkers (for New Jersey Only)	Coverage Determination Guideline
Plagiocephaly and Craniosynostosis Treatment	Medical Policy
Plagiocephaly and Craniosynostosis Treatment (for Nebraska Only)	Medical Policy
Pneumatic Compression Devices	Medical Policy
Pneumatic Compression Devices (for Nebraska Only)	Medical Policy
Pneumatic Compression Devices (for New Jersey Only)	Medical Policy
Power Mobility Devices	Coverage Determination Guideline
Power Mobility Devices (for Nebraska Only)	Coverage Determination Guideline
Rhinoplasty and Other Nasal Surgeries	Coverage Determination Guideline
Rhinoplasty and Other Nasal Surgeries (for Nebraska Only)	Coverage Determination Guideline
Speech Generating Devices	Coverage Determination Guideline
Surgery of the Elbow	Medical Policy
Surgery of the Elbow (for Nebraska Only)	Medical Policy
Surgery of the Foot	Medical Policy
Surgery of the Hand or Wrist	Medical Policy
Surgery of the Hip	Medical Policy
Surgery of the Hip (for Nebraska Only)	Medical Policy
Surgery of the Knee	Medical Policy
Surgery of the Knee (for Nebraska Only)	Medical Policy
Surgery of the Shoulder	Medical Policy
Surgery of the Shoulder (for Nebraska Only)	Medical Policy
Surgery of the Shoulder (for New Jersey Only)	Medical Policy
Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins	Medical Policy
Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins (for Nebraska Only)	Medical Policy
Surgical Treatment for Spine Pain	Medical Policy
Surgical Treatment for Spine Pain (for Nebraska Only)	Medical Policy
Surgical Treatment for Spine Pain (for New Jersey Only)	Medical Policy

Take Note

Policy Title	Policy Type
Temporomandibular Joint Disorders	Medical Policy
Temporomandibular Joint Disorders (for Nebraska Only)	Medical Policy
Temporomandibular Joint Disorders (for New Jersey Only)	Medical Policy
Total Artificial Disc Replacement for the Spine	Medical Policy
Total Artificial Disc Replacement for the Spine (for Nebraska Only)	Medical Policy
Video Electroencephalographic (vEEG) Monitoring and Recording	Medical Policy
Wheelchair Options and Accessories	Coverage Determination Guideline
Wheelchair Options and Accessories (for Nebraska Only)	Coverage Determination Guideline
Wheelchair Seating	Coverage Determination Guideline
Wheelchair Seating (for Nebraska Only)	Coverage Determination Guideline

Medical Policy Updates

New		
Policy Title	**Effective Date**	**Coverage Rationale**
Percutaneous Patent Foramen Ovale (PFO) Closure (for New Jersey Only)	Aug. 1, 2022	Note: This policy does not apply to individuals < 18 years of age. Percutaneous patent foramen ovale closure for the prevention of recurrent ischemic stroke is proven and medically necessary when used according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings, and precautions and all of the following criteria are met: • History of cryptogenic stroke confirmed by imaging; and • A cardiologist and a neurologist agree that the stroke is likely embolic in nature; and • Other causes of ischemic stroke have been ruled out including, but not limited to, carotid disease, hypercoagulable states or atrial fibrillation; and • Individual is 18–60 years of age Due to insufficient evidence of efficacy, percutaneous patent foramen ovale closure is unproven and not medically necessary for all other stroke or related neurological indications including, but not limited to, primary prevention of stroke, transient ischemic attacks, and migraine prevention.
Percutaneous Vertebroplasty and Kyphoplasty (for New Jersey Only)	Aug. 1, 2022	Percutaneous vertebroplasty and kyphoplasty are proven and medically necessary for treating pain causing Functional or Physical Impairment in cervical, thoracic or lumbar vertebral bodies within 4 months of pain onset that has failed to respond to optimal medical therapy for the following indications: • Osteoporotic vertebral compression fracture (VCF) • Steroid-induced vertebral fracture • Osteolytic metastatic disease involving a vertebral body • Multiple myeloma involving a vertebral body • Vertebral hemangioma with aggressive features • Unstable fractures due to osteonecrosis (e.g., Kummel disease) and Computed tomography (CT) or magnetic resonance imaging (MRI) has ruled out other causes of spinal pain, including but not limited to: • Foraminal stenosis • Facet arthropathy • Herniated intervertebral disk • Other spinal degenerative disease • Other significant coexistent spinal or bony pain generators and The following are not present:

New		
Policy Title	**Effective Date**	**Coverage Rationale**
Percutaneous Vertebroplasty and Kyphoplasty (for New Jersey Only) (continued)	Aug. 1, 2022	• Clinical evidence of spinal cord compression as confirmed by CT or MRI; or • Significant vertebral collapse or destruction (e.g., vertebra reduced to less than one-third of its original height) as confirmed by CT or MRI; or • Healed VCF as confirmed by CT or MRI; or • Lesions of the sacrum or coccyx (refer to the Medical Policy titled Surgical Treatment for Spine Pain (for New Jersey Only) for additional information on percutaneous sacral augmentation); or • Asymptomatic vertebral compression fractures (VCFs); or • VCFs responding appropriately to conservative therapy Percutaneous vertebroplasty and kyphoplasty are unproven and not medically necessary for treating indications other than those listed above due to insufficient evidence of efficacy.

Radiation Therapy: Fractionation, Image-Guidance, and Special Services (for New Jersey Only)	Jun. 1, 2022	**Radiation Therapy Fractionation**
		Bone Metastases
		When providing external beam radiation therapy for the treatment of a bone metastasis the following are medically necessary:
		• Single fraction of radiation therapy
		• Delivery of up to 10 fractions when any of the following criteria are met:
		  ○ Treatment of a weight bearing bone such as femur; or
		  ○ Treating a bone that has previously undergone surgical stabilization; or
		  ○ Treatment of spinal cord compression
		• Delivery of greater than 10 fractions is medically necessary for the following:
		  ○ Treatment of a site that has previously received radiation therapy
		
		Breast Adenocarcinoma
		When providing external beam radiation therapy for breast adenocarcinoma the following are medically necessary:
		• Delivery of up to 21 fractions (inclusive of a boost to the tumor bed)
		• Delivery of up to 33 fractions (inclusive of a boost to the tumor bed) is medically necessary when any of the following criteria are met:
		  ○ Treatment of supraclavicular and/or internal mammary lymph nodes; or
		  ○ Post-mastectomy radiation therapy; or
		  ○ Individual has received previous thoracic radiation therapy

New		
Policy Title	**Effective Date**	**Coverage Rationale**
Radiation Therapy: Fractionation, Image-Guidance, and Special Services (for New Jersey Only) (continued)	Jun. 1, 2022	○ Individual has a connective tissue disorder such as lupus or scleroderma When providing external beam radiation therapy for breast cancer, delivery of greater than 33 fractions (inclusive of a boost to the tumor bed) is not medically necessary. ***Locally Advanced Non-Small Cell Lung Cancer*** When providing external beam radiation therapy, with or without chemotherapy, for locally advanced non-small cell lung cancer, the following is medical necessary: ● Delivery of up to 30 fractions When providing external beam radiation therapy, with or without chemotherapy, for locally advanced non-small cell lung cancer, delivery of greater than 30 fractions is not medically necessary. ***Prostate Adenocarcinoma*** When providing external beam radiation therapy for prostate adenocarcinoma the following are medically necessary: ● Delivery of up to 20 fractions for definitive treatment in an individual with limited metastatic disease ● Delivery of up to 28 fractions for localized prostate cancer ● Delivery of up to 45 fractions for localized prostate cancer when any of the following criteria are met: ○ Individual with high-risk prostate cancer is undergoing radiation treatment to pelvic lymph nodes; or ○ Radiation therapy is delivered post-prostatectomy; or ○ External beam radiation therapy is being delivered in combination with brachytherapy; or ○ Individual has a history of inflammatory bowel disease such as ulcerative colitis or Crohn's disease; or ○ Individual has received previous pelvic radiation therapy When providing external beam radiation therapy for localized prostate cancer, delivery greater than 45 fractions is not medically necessary. **Image-Guided Radiation Therapy (IGRT)** Image guidance for radiation therapy is medically necessary under any of the following circumstances: ● When used with intensity modulated radiation therapy (IMRT); or ● When used with proton beam radiation therapy (PBRT); or ● For left sided breast cancer with the use of

New

Policy Title	Effective Date	Coverage Rationale
Radiation Therapy: Fractionation, Image-Guidance, and Special Services (for New Jersey Only) (continued)	Jun. 1, 2022	○ Deep inspiration breath hold (DIBH) technique; or ○ Prone technique ● When the target has received prior radiation therapy or abuts previously irradiated area; or ● When implanted fiducial markers are being used for target localization; or ● During definitive treatment with radiation therapy using 3D-CRT for the following: ○ Central nervous system tumors ○ Primary head and neck cancer ○ Esophageal cancer ○ Mediastinal tumors ○ Prostate cancer ● Individuals who are severely obese (BMI ≥ 35) and are being treated for abdominal and pelvic tumors ● Tumors with significant respiratory motion and motion assessment and management techniques are being utilized (e.g., 4D CT scan) When the above criteria are not met, IGRT is not medically necessary including but not limited to any of the following circumstances: ● Brachytherapy ● Stereotactic body radiation therapy (SBRT)* ● Stereotactic radiosurgery (SRS)* ● Superficial treatment of skin cancer including superficial radiation therapy or electronic brachytherapy ● To align bony landmarks without implanted fiducials **Special Services** Special services include the need for special dosimetry, special medical physics consultation, and special treatment procedure. Refer to the *Coding Clarification* section of the policy.

Updated

Policy Title	Effective Date	Summary of Changes
Fecal Calprotectin Testing (for New Jersey Only)	Jun. 1, 2022	Applicable Codes ● Added ICD-10 diagnosis codes K51.913 and R19.5

Medical Policy Updates

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

Gastrointestinal Pathogen Nucleic Acid Detection Panel Testing for Infectious Diarrhea (for New Jersey Only)	Jun. 1, 2022	Coverage Rationale
		• Revised coverage criteria; replaced criteria requiring:
		  ○ "Diarrhea for more than 7 days with fever *and suspected bacteremia*" with "diarrhea for more than 7 days with fever, *bloody or mucoid stools, severe abdominal cramping or tenderness, or signs of sepsis*"
		  ○ "On immunosuppressive medications following an organ transplant" with "on immunosuppressive medications *either* following an organ transplant *or when used for treatment of an auto-immune disease*"
		Supporting Information
		• Updated *Clinical Evidence* and *References* sections to reflect the most current information

Hysterectomy (for New Jersey Only)	Jun. 1, 2022	Applicable Codes • Removed CPT code 58285
Meniscus Implant and Allograft (for New Jersey Only)	Jun. 1, 2022	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
Proton Beam Radiation Therapy	Jul. 1, 2022	Applicable Codes • Added ICD-10 diagnosis codes C69.0, C69.00, C69.01, C69.02, C69.1, C69.10, C69.11, C69.12, C69.20, C69.21, C69.22, C69.50, C69.51, C69.52, C69.6, C69.60, C69.61, C69.62, C69.8, C69.80, C69.81, C69.82, C69.9, C69.90, C69.91, and C69.92 • Replaced ICD-10 diagnosis code C61.0 with C61 Supporting Information • Updated *Clinical Evidence* and *References* sections to reflect the most current information
Surgical Treatment for Spine Pain	Jul. 1, 2022	Applicable Codes • Removed CPT code 20939; refer to the Clinical Policy titled *Spinal Fusion Enhancement Products*

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Diagnostic Spinal Ultrasonography (for New Jersey Only)	Jun. 1, 2022	**Title Change** • Previously titled *Spinal Ultrasonography (for New Jersey Only)* **Coverage Rationale** • Replaced language indicating: ○ "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	Spinal and paraspinal ultrasonography are proven and medically necessary only in newborns and infants 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 • 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 in 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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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Diagnostic Spinal Ultrasonography (for New Jersey Only) (continued)	Jun. 1, 2022	policy as proven and medically necessary] due to insufficient evidence of efficacy" • Updated list of proven and medically necessary indications; replaced: ○ "Caudal regression syndrome, including sacral agenesis, anal atresia, or stenosis" with "*evaluation of* caudal regression syndrome, including sacral agenesis, anal atresia, or stenosis" ○ "Evaluation of suspected defects such as cord tethering, diastematomyelia, hydromyelia, or syringomyelia" with "evaluation of suspected *spinal cord* defects such as cord tethering, diastematomyelia, hydromyelia, or syringomyelia" ○ "Post-operative assessment for cord retethering" with "post-operative assessment for *spinal* cord retethering" Supporting Information • Updated *Clinical Evidence* and *References* sections to reflect the most current information	
Epidural Steroid Injections for Spinal Pain (for New Jersey Only)	Jun. 1, 2022	Template Update • Reorganized and renamed policy previously titled *Epidural Steroid and Facet Injections for Spinal Pain*	The following are proven and medically necessary: • Epidural Steroid Injections (ESI) for treating radicular pain caused by spinal stenosis, disc herniation, degenerative changes in the vertebrae or for the short-term management of spine pain when the following criteria are met:

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Epidural Steroid Injections for Spinal Pain (for New Jersey Only) (continued)	Jun. 1, 2022	*(for New Jersey Only)* • Removed content pertaining to facet joint injections; refer to the Medical Policy titled *Facet Joint Injections for Spinal Pain* for applicable coverage guidelines **Coverage Rationale** ***Epidural Steroid Injection Limitations*** • Replaced language indicating: ○ "A maximum of three (3) ESI sessions (per region regardless of level, location, or side) [are allowed] in a *calendar* year when criteria (indications for coverage) are met for each injection" with "a maximum of three (3) ESI sessions (per region, regardless of level, location, or side) [are allowed] in a year when criteria (indications for coverage) are met for each injection" ○ "A *calendar* year is defined as the 12-month period *from January 1st to December 31st*" with "a year is defined as the 12-month period *starting from the date of service of the first approved injection*" **Applicable Codes** • Added ICD-10 diagnosis codes	○ The pain is associated with symptoms of nerve root irritation and/or spine pain due to disc extrusions and/or contained herniations; and ○ The pain is unresponsive to Conservative Treatment, including but not limited to pharmacotherapy, exercise or physical therapy The following are unproven and not medically necessary due to insufficient evidence of efficacy: • The use of ultrasound guidance for ESIs • ESI for all other indications of the spine not included above **Epidural Steroid Injection Limitations** • A maximum of three (3) ESI sessions (per region, regardless of level, location, or side) in a year when criteria (indications for coverage) are met for each injection • A session is defined as one date of service in which ESI(s) is performed • A region is defined by either the region of the cervical or thoracic spine or the region of the lumbar or sacral spine • A year is defined as the 12-month period starting from the date of service of the first approved injection

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Epidural Steroid Injections for Spinal Pain (for New Jersey Only) (continued)	Jun. 1, 2022	G54.2, G54.3, M47.21, M47.22, M47.23, M47.24, M47.25, M50.10, M50.11, M50.121, M50.122, M50.123, M50.13, M54.11, M54.12, M54.13, and M54.18 • Removed ICD-10 diagnosis codes E08.41, E09.41, E10.41, E11.41, E13.41, G54.1, G57.00, G57.01, G57.02, G57.03, G57.70, G57.71, G57.72, G57.73, G57.80, G57.81, G57.82, G57.83, G57.90, G57.91, G57.92, G57.93, G58.8, G58.9, G59, G90.50, G90.521, G90.522, G90.523, G90.529, G90.59, M43.00, M43.01, M43.02, M43.03, M43.04, M43.05, M43.06, M43.07, M43.08, M43.09, M43.10, M43.11, M43.12, M43.13, M43.14, M43.15, M43.16, M43.17, M43.18, M43.19, M43.27, M43.28, M47.16, M47.816, M47.817, M47.818, M47.896, M47.897, M47.898, M48.00, M48.061, M48.07, M48.08, M51.06, M51.26, M51.27, M51.34, M51.35, M51.36, M51.37, M51.46, M51.47, M51.9, M53.2X7, M53.2X8, M53.3, M53.86, M53.87, M53.88, M99.23, M99.24, M99.25, M99.26, M99.27, M99.28, M99.29, M99.33, M99.34, M99.35, M99.36, M99.37, M99.38, M99.39, M99.43, M99.44, M99.45, M99.46, M99.47, M99.48, M99.49, M99.53, M99.54, M99.55, M99.56,	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Epidural Steroid Injections for Spinal Pain (for New Jersey Only) (continued)	Jun. 1, 2022	M99.57, M99.58, M99.59, M99.63, M99.64, M99.65, M99.66, M99.67, M99.68, M99.69, M99.73, M99.74, M99.75, M99.76, M99.77, M99.78, M99.79, S32.000A, S32.001A, S32.002A, S32.008A, S32.009A, S32.010A, S32.011A, S32.012A, S32.018A, S32.019A, S32.020A, S32.021A, S32.022A, S32.028A, S32.029A, S32.030A, S32.031A, S32.032A, S32.038A, S32.039A, S32.040A, S32.041A, S32.042A, S32.048A, S32.049A, S32.050A, S32.051A, S32.052A, S32.058A, S32.059A, S34.4XXA, S74.00XA, S74.01XA, and S74.02XA	
Facet Joint Injections for Spinal Pain (for New Jersey Only)	Jun. 1, 2022	Template Update • Reorganized and renamed policy previously titled *Epidural Steroid and Facet Injections for Spinal Pain (for New Jersey Only)* • Removed content pertaining to epidural steroid injections; refer to the Medical Policy titled *Epidural Steroid Injections for Spinal Pain (for New Jersey Only)* for applicable coverage guidelines Coverage Rationale *Proven and Medically Necessary* • Revised coverage criteria for initial diagnostic Facet Joint Injection/Medial Branch Block; replaced criterion requiring "*the*	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

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Facet Joint Injections for Spinal Pain (for New Jersey Only) (continued)	Jun. 1, 2022	*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)" *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	○ 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 demonstrable improvement in the physical functions previously limited by the facetogenic pain; and ○ A radiofrequency joint denervation/ablation procedure is being considered 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

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Facet Joint Injections for Spinal Pain (for New Jersey Only) (continued)	Jun. 1, 2022	G89.18, G89.28, G97.82, M51.14, M51.15, M51.16, and M51.17 **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	
Functional Endoscopic Sinus Surgery (FESS) (for New Jersey Only)	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*" ***Documentation Requirements (new to policy)*** • Added language to indicate medical notes documenting the following are required, when 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	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: ○ 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 had the disease and the extent of disease including the percent of opacification or the use of a scale such as the Modified Lund-Mackay Scoring System; and ▪ CT findings include one or more of the following: – Bony remodeling – Bony thickening – Opacified sinus – Ostial obstruction (outflow tract obstruction) and mucosal thickening ○ Sino nasal symptoms such as pain, pressure, or drainage are present on the same side as CT scan findings of rhinosinusitis

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Functional Endoscopic Sinus Surgery (FESS) (for New Jersey Only) (continued)	Jun. 1, 2022	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: CT images are required and must be labeled with the: • Date taken • Applicable case number obtained at time of notification, or the member's name and ID number on the images • Whether the imaging was taken pre-or post-medical therapy – CT images can be submitted via the external portal at uhcprovider.com/paan; faxes will not be accepted	• 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 – 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) ○ Sino nasal 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, when 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

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Functional Endoscopic Sinus Surgery (FESS) (for New Jersey Only) (continued)	Jun. 1, 2022	▪ CT scan report quantifying the severity of Chronic Rhinosinusitis using the Modified Lund-Mackay Scoring System (for each side for which treatment is being requested) ○ 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: CT images are required and must be labeled with the: • Date taken • Applicable case number obtained at time of notification, or the member's name and ID number on the images	▪ 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 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 • 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 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

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Functional Endoscopic Sinus Surgery (FESS) (for New Jersey Only) (continued)	Jun. 1, 2022	• Whether the images were taken pre- or post-medical therapy – CT images can be submitted via the external portal at uhcprovider.com/paan; faxes will not be accepted ▪ CT scan report quantifying the severity of Acute Rhinosinusitis using the Modified Lund-Mackay Scoring System (for each side for which treatment is being requested) **Definitions** • Added definition of "Modified Lund-Mackay Scoring System" **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, and *References* sections to reflect the most current information	
Genitourinary Pathogen Nucleic Acid Detection Panel Testing	Jul. 1, 2022	**Related Policies** *Indiana* • Removed reference link to the Medical Policy titled *Genitourinary Pathogen Nucleic Acid Detection Panel Testing (for Indiana Only)* (retired) **Coverage Rationale**	The following are proven and medically necessary to evaluate symptomatic individuals for vaginitis: • Direct and amplified DNA probe testing for Trichomoniasis vaginalis • Direct probe testing for Candida sp. Due to insufficient evidence of efficacy, the following are unproven and not medically necessary: • Amplified DNA probe testing for vulvovaginitis due to Candida sp.

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Genitourinary Pathogen Nucleic Acid Detection Panel Testing (continued)	Jul. 1, 2022	• Added language to indicate screening of asymptomatic individuals for vaginitis is unproven and not medically necessary • Replaced language indicating "[the listed indications are] proven and medically necessary to evaluate symptomatic *women* for Vaginitis" with "[the listed indications are] proven and medically necessary to evaluate symptomatic *individuals* for Vaginitis" **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	• Direct and amplified DNA probe testing for bacterial vaginosis (i.e., Gardnerella vaginalis) • Multiplex polymerase chain reaction (PCR) panel testing of genitourinary pathogens, including but not limited to pathogens commonly associated with vaginitis • Screening of asymptomatic individuals for vaginitis Note: This policy does not apply to tests for gonorrhea and chlamydia.
Implanted Electrical Stimulator for Spinal Cord	Jul. 1, 2022	**Coverage Rationale** • Replaced language indicating: ○ "Implanted electrical spinal cord stimulators, *including high-frequency spinal cord stimulators and burst spinal cord stimulators*, are proven and medically necessary for treating the [listed] indications" with "implanted electrical spinal cord stimulators are proven and medically necessary for treating the [listed] indications *in certain circumstances when performed according to U.S. Food and Drug Administration (FDA) labeled indications,*	Implanted electrical spinal cord stimulators, are proven and medically necessary for treating the following indications in certain circumstances, when performed according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings and precautions: • Complex regional pain syndrome (CRPS) • Painful lower limb diabetic neuropathy • Failed back surgery syndrome Implanted electrical spinal cord stimulators are unproven and not medically necessary for treating refractory angina pectoris due to insufficient evidence of efficacy. Dorsal root ganglion (DRG) stimulation is proven and medically necessary for treating refractory complex regional pain syndrome (CRPS I, CPRS II) in certain circumstances when performed according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings and precautions.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Implanted Electrical Stimulator for Spinal Cord (continued)	Jul. 1, 2022	*contraindications, warnings and precautions*" ○ "Implanted electrical spinal cord stimulators are unproven and not medically necessary for treating refractory angina pectoris" with "implanted electrical spinal cord stimulators are unproven and not medically necessary for treating refractory angina pectoris *due to insufficient evidence of efficacy*" ○ "Dorsal root ganglion (DRG) stimulation is proven and medically necessary for treating refractory complex regional pain syndrome (CRPS I, CPRS II) when *used* according to U.S. Food and Drug Administration (FDA) *guidelines*" with "dorsal root ganglion (DRG) stimulation is proven and medically necessary for treating refractory complex regional pain syndrome (CRPS I, CPRS II) *in certain circumstances* when *performed* according to U.S. Food and Drug Administration (FDA) *labeled indications, contraindications, warnings and precautions*" • Revised list of indications for which	Dorsal root ganglion (DRG) stimulation is unproven and not medically necessary for treating all other indications due to insufficient evidence of efficacy. For medical necessity clinical coverage criteria, refer to the InterQual® 2022, Apr. 2022 Release, CP: Procedures, Spinal Cord Stimulator (SCS) Insertion. Click here to view the InterQual® criteria. Note: Coverage of a replacement battery/generator for a previously implanted electrical stimulator is appropriate when the individual's existing battery/generator is malfunctioning, cannot be repaired, and is no longer under warranty.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Implanted Electrical Stimulator for Spinal Cord (continued)	Jul. 1, 2022	implanted electrical spinal cord stimulators are proven and medically necessary; replaced "diabetic neuropathy" with "*painful lower limb* diabetic neuropathy" Supporting Information • Updated *Clinical Evidence* and *References* sections to reflect the most current information	

Intraoperative Hyperthermic Intraperitoneal Chemotherapy (HIPEC) (for New Jersey Only)	Jun. 1, 2022	Coverage Rationale
		• Removed language indicating intraoperative hyperthermic intraperitoneal chemotherapy (HIPEC), when performed in conjunction with Cytoreductive Surgery (CRS), is proven and medically necessary for treating peritoneal Carcinomatosis resulting from small bowel cancer, provided there are no extra-abdominal metastases
		Supporting Information
		• Updated *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information
			Note: This Medical Policy does not apply to normothermic (no hyperthermia is used) postoperative Intraperitoneal chemotherapy, delivered via an indwelling port or catheter, used to treat ovarian cancer.
			
			When performed in conjunction with Cytoreductive Surgery (CRS), intraoperative hyperthermic intraperitoneal chemotherapy (HIPEC) is proven and medically necessary for treating the following conditions:
			• Ovarian cancer following neoadjuvant chemotherapy
			• Peritoneal mesothelioma
			• Pseudomyxoma Peritonei (PMP) resulting from a mucus-producing tumor
			• Peritoneal Carcinomatosis resulting from the following cancers, provided there are no extra-abdominal metastases:
			  ○ Adenocarcinoma of the appendix or goblet cell carcinoma
			  ○ Colon
			  ○ Rectum
			
			Due to insufficient evidence of efficacy, intraoperative HIPEC is unproven and not medically necessary for all other indications including, but not limited to, peritoneal Carcinomatosis resulting from the following cancers:
			• Gastric
			• Ovarian, except as noted above

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Manipulation Under Anesthesia	Jul. 1, 2022	**Application** *Indiana* • Removed reference link to the Medical Policy titled *Manipulation Under Anesthesia (for Indiana Only)* (retired) **Coverage Rationale** • Replaced language indicating "manipulation under anesthesia (MUA) is proven and medically necessary for shoulder joint for adhesive capsulitis (frozen shoulder)" with "MUA is proven and medically necessary for shoulder joint for adhesive capsulitis (frozen shoulder) *when certain criteria are met*" • Added instruction to refer to the InterQual® 2022, Apr. 2022 Release, CP: Procedures, Manipulation Under Anesthesia, Shoulder for medical necessity clinical coverage criteria • Removed language indicating MUA is unproven and not medically necessary for any shoulder condition other than adhesive capsulitis (frozen shoulder) **Applicable Codes** • Removed pelvis ICD-10 diagnosis codes M99.14, S32.10XA, S32.111A, S32.112A, S32.119A, S32.121A, S32.122A, S32.129A,	Manipulation under anesthesia (MUA) is proven and medically necessary for: • Knee joint for arthrofibrosis following total knee arthroplasty, knee surgery, or fracture • Shoulder joint for adhesive capsulitis (frozen shoulder) when certain criteria are met. For medical necessity clinical coverage criteria, refer to the InterQual® 2022, Apr. 2022 Release, CP: Manipulation Under Anesthesia, Shoulder. Click here to view the InterQual® criteria. MUA is unproven and not medically necessary for all other conditions (whether for single or serial manipulations) including but not limited to the following, due to insufficient evidence of efficacy: • Ankle • Finger • Hip joint or adhesive capsulitis of the hip • Knee joint - any condition other than for arthrofibrosis following total knee arthroplasty, knee surgery, or fracture • Pelvis • Spine • Temporomandibular joint (TMJ) • Toe • Wrist This policy does not apply to the following: • Manipulation of the finger on the day following the injection of collagenase clostridium histolyticum (Xiaflex®) to treat Dupuytren's contracture • Closed reduction of a fracture or joint dislocation unless specified • Elbow joint for arthrofibrosis following elbow surgery or fracture

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Manipulation Under Anesthesia (continued)	Jul. 1, 2022	S32.131A, S32.132A, S32.139A, S32.14XA, S32.15XA, S32.16XA, S32.17XA, S32.19XA, S32.2XXA, S32.301A, S32.302A, S32.309A, S32.311A, S32.312A, S32.313A, S32.391A, S32.392A, S32.399A, S32.401A, S32.402A, S32.409A, S32.411A, S32.412A, S32.413A, S32.421A, S32.422A, S32.423A, S32.431A, S32.432A, S32.433A, S32.441A, S32.442A, S32.443A, S32.451A, S32.452A, S32.453A, S32.461A, S32.462A, S32.463A, S32.471A, S32.472A, S32.473A, S32.481A, S32.482A, S32.483A, S32.491A, S32.492A, S32.499A, S32.501A, S32.502A, S32.509A, S32.511A, S32.512A, S32.519A, S32.591A, S32.592A, S32.599A, S32.601A, S32.602A, S32.609A, S32.611A, S32.612A, S32.613A, S32.614A, S32.615A, S32.616A, S32.691A, S32.692A, S32.699A, S32.810A, S32.811A, S32.82XA, S32.89XA, S32.9XXA, and S33.2XXA Supporting Information • Updated *Clinical Evidence* and *References* sections to reflect the most current information	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Nerve Graft to Restore Erectile Function During Radical Prostatectomy (for New Jersey Only)	Jun. 1, 2022	Coverage Rationale • Replaced language indicating "sural or *other* nerve grafts to restore erectile function during radical prostatectomy are unproven and not medically necessary" with "*autologous (e.g.*, sural*) or allogenic* nerve grafts to restore erectile function during *or after* radical prostatectomy are unproven and not medically necessary" Supporting Information • Updated *Clinical Evidence* and *References* sections to reflect the most current information	Autologous (e.g., sural) or allogenic nerve grafts to restore erectile function during or after radical prostatectomy are unproven and not medically necessary due to insufficient evidence of efficacy.
Neurophysiologic Testing and Monitoring (for New Jersey Only)	Jun. 1, 2022	Coverage Rationale • Revised list of known or suspected disorders for which nerve conduction studies with or without late responses (e.g., F-wave and H-reflex tests) and neuromuscular junction testing when performed in conjunction with needle electromyography-are proven and medically necessary: ○ Added: ▪ Peripheral neuropathy/polyneuropathy (e.g., inherited, metabolic, traumatic, entrapment syndromes) ▪ Treatment guidance (e.g., muscle localization for	**Nerve Conduction Studies** The following are proven and medically necessary: • Nerve conduction studies with or without late responses (e.g., F-wave and H-reflex tests) and neuromuscular junction testing when performed in conjunction with needle electromyography for any of the following known or suspected disorders: ○ Peripheral neuropathy/polyneuropathy (e.g., inherited, metabolic, traumatic, entrapment syndromes) ○ Plexopathy ○ Neuromuscular junction disorders (e.g., myasthenia gravis) ○ Myopathy ○ Motor neuron disease ○ Radiculopathy (cervical, thoracic, or lumbosacral) ○ Treatment guidance (e.g., muscle localization for botulinum toxin injections when required to identify affected muscles warranting injection) • Nerve conduction studies with or without late responses (e.g., F-wave and H-reflex tests) when performed without needle electromyography for

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Neurophysiologic Testing and Monitoring (for New Jersey Only) (continued)	Jun. 1, 2022	botulinum toxin injections, when required to identify affected muscles warranting injection) ○ Removed: ▪ Peripheral nerve entrapment syndromes ▪ Generalized neuropathies ▪ Hereditary, metabolic, or degenerative polyneuropathy ▪ Spine disorder with nerve root impingement symptoms ▪ Guidance for botulinum toxin injection for spasmodic dysphonia or segmental dystonia when it is difficult to isolate affected muscles ▪ Traumatic nerve lesions ○ Replaced: ▪ "Plexopathy *(acquired disorder in tissue along nerves that causes motor and sensory dysfunction)*" with "plexopathy" ▪ "Neuromuscular junction disorders" with "neuromuscular junction disorders *(e.g., myasthenia gravis)*"	individuals who have any of the above known or suspected disorders with any of the following clinical indications: ○ Individuals treated with anticoagulants; or ○ Individuals with lymphedema; or ○ Individuals being evaluated for carpal tunnel syndrome The following are unproven and not medically necessary due to insufficient evidence of efficacy: ● Nerve conduction studies for all conditions other than those listed above as proven ● Non-invasive automatic, portable, or automated point of care nerve conduction monitoring systems (e.g., the NC-stat® System, the Brevio® NCS-Monitor, and the Advance™ System) that test only distal motor latencies and conduction velocities for the purpose of electrodiagnostic testing **Other Neurophysiological Testing** The following are unproven and not medically necessary due to insufficient evidence of efficacy: ● Surface electromyography (SEMG) ● SEMG based seizure monitoring systems ● Macro-electromyography (macro-EMG) testing ● Physiologic recording of movement disorder symptoms, including bradykinesia, dyskinesia, and tremor using wearable devices with accelerometers or gyroscopes ● Quantitative sensory testing, including monofilament testing, pressure-specified sensory testing, computer assisted sensory examinations, and current perception threshold (CPT) testing ● Visual evoked potential testing for diagnosing and evaluating glaucoma This policy does not address intraoperative neurophysiologic testing.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Neurophysiologic Testing and Monitoring (for New Jersey Only) (continued)	Jun. 1, 2022	▪ "Myopath*ies*" with "myopath*y*" ▪ "Cervical, thoracic, *and/or* lumbosacral radiculopathy" with "radiculopathy (cervical, thoracic, *or* lumbosacral)" **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	
Neuropsychological Testing Under the Medical Benefit (for New Jersey Only)	Jun. 1, 2022	**Coverage Rationale** • Replaced language indicating "neuropsychological testing is proven and medically necessary for evaluating individuals with the [listed] conditions when the result of testing will *influence clinical decision making*" 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*" • Revised list of conditions for which neuropsychological testing is proven and medically necessary: ○ Added "neurotoxin exposure in an individual with history of radiation therapy or chemotherapy"	Neuropsychological testing is proven and medically necessary for evaluating individuals with the following conditions when the results of testing will be used to support a diagnosis, prognosis, or treatment plan: • Attention-deficit/hyperactivity disorder (ADHD) when all of the following are present: ○ Specific neurocognitive behavioral deficits related to ADHD need to be evaluated; and ○ Testing has been recommended by a physician and is related or secondary to a known or suspected organic-medical condition resulting from brain injury or disease process (e.g., concussion, intractable seizure disorder, cancer treatment effects, genetic disorders, inborn errors of metabolism) *The scope of these criteria is applicable only to neuropsychological testing that is covered by the medical benefit. These criteria do not apply to evaluate or determine educational interventions.* • Confirmed space-occupying brain lesion including but not limited to the following: ○ Brain abscess ○ Brain tumors ○ Arteriovenous malformations within the brain • Demyelinating disorders including multiple sclerosis • Intellectual disability or intellectual developmental disorder when all of the

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Neuropsychological Testing Under the Medical Benefit (for New Jersey Only) (continued)	Jun. 1, 2022	○ 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)*, 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" ▪ "Individuals being considered for epilepsy surgery" with "the individual is being considered *for a medical or surgical procedure that*	following are present: ○ The intellectual disability or intellectual developmental disorders associated with a known or suspected medical cause (e.g., Traumatic Brain Injury, in utero toxin exposure, early seizure disorder, sickle cell disease, genetic disorders); and ○ The intellectual disability or intellectual developmental disorder meets all of the following criteria (DSM-5): ▪ Deficits in intellectual function, such as reasoning, problem solving, planning, abstract thinking, judgment, academic learning, and learning from experience, confirmed by both clinical assessment and individualized, standardized intelligence testing ▪ Deficits in adaptive functioning that result in failure to meet developmental and sociocultural standards for personal independence and social responsibility. Without ongoing support, the adaptive deficits limit functioning in one or more activities of daily life, such as communication, social participation, and independent living across multiple environments, such as home, school, work and community; and ▪ Onset of intellectual and adaptive deficits during the developmental period *The scope of these criteria is applicable only to neuropsychological testing that is covered by the medical benefit. These criteria do not apply to evaluate or determine educational interventions*. ● Encephalopathy including acquired immunodeficiency syndrome (AIDS) encephalopathy, human immunodeficiency virus (HIV) encephalopathy, hepatic encephalopathy, Lyme disease encephalopathy including neuroborreliosis, Wernicke's encephalopathy and systemic lupus erythematosus (SLE) encephalopathy ● Neurocognitive Disorders including Mild Cognitive Impairment(MCI), 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 following cognitive

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Neuropsychological Testing Under the Medical Benefit (for New Jersey Only) (continued)	Jun. 1, 2022	*may affect brain function (e.g.,* epilepsy surgery, *resection of brain tumors or arteriovenous malformations, deep brain stimulation, stem cell or organ transplants)*" • Revised list of unproven and not medically necessary services: ○ Added: ▪ Neuropsychological testing that is comprised exclusively of self-administered or self-scored inventories, or as screening tests of cognitive function or neurological disease whether paper-and-pencil or computerized (e.g., AIMS, Folstein Mini-Mental Status Examination) ▪ Neuropsychological testing that is used as a routine screening tool ▪ Neuropsychological testing that is administered for educational or vocational purposes that do not alter or direct medical or health management ▪ Repeat neuropsychological testing that is not required for medical decision-	domains (DSM-5): ○ Complex attention ○ Executive function ○ Learning and memory ○ Language ○ Perceptual-motor ○ Social cognition • Neurotoxin exposure with at least one of the following: ○ Demonstrated serum levels of neurotoxins ○ Individual with one or more of the following: ▪ Documented prenatal alcohol, drug, or toxin exposure ▪ History of radiation therapy or chemotherapy • Seizure disorder including individuals with epilepsy • Stroke • Traumatic Brain Injury (TBI) • The individual is being considered for a medical or surgical procedure that may affect brain function (e.g., epilepsy surgery, resection of brain tumors or arteriovenous malformations, deep brain stimulation, stem cell or organ transplants) The following are unproven and not medically necessary due to insufficient evidence of efficacy: • Baseline neuropsychological testing in asymptomatic individuals at risk for sport-related concussions • Computerized cognitive testing such as to Cognivue®, Mindstreams® Cognitive Health Assessment, and BrainCare™ and Qb Test • Computerized neuropsychological testing when used as a stand-alone test for evaluating concussions • Neuropsychological testing for the following diagnoses alone without other proven conditions as noted above: ○ Headaches including migraine headache ○ History of myocardial infarction ○ Intermittent explosive disorder

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Neuropsychological Testing Under the Medical Benefit (for New Jersey Only) (continued)	Jun. 1, 2022	making ▪ The individual is neurologically, cognitively, or psychologically unable to participate in a meaningful way in the neuropsychological testing process ▪ The individual has been diagnosed previously with brain dysfunction, such as Alzheimer's disease, and there is no expectation that neuropsychological testing would impact the individual's medical, functional, or behavioral management ○ Replaced: ▪ "Baseline neuropsychological testing in asymptomatic individuals at risk for sport-related concussions *or brain injuries*" with "baseline neuropsychological testing in asymptomatic individuals at risk for sport-related concussions" ▪ "Computerized cognitive testing *including but not limited to* Cognivue®, Mindstreams® Cognitive	• Neuropsychological testing that is comprised exclusively of self-administered or self-scored inventories, or as screening tests of cognitive function or neurological disease whether paper-and-pencil or computerized (e.g., AIMS, Folstein Mini-Mental Status Examination) • Neuropsychological testing that is used as a routine screening tool • Neuropsychological testing that is administered for educational or vocational purposes that do not alter or direct medical or health management • Repeat neuropsychological testing that is not required for medical decision-making • The individual is neurologically, cognitively, or psychologically unable to participate in a meaningful way in the neuropsychological testing process • The individual has been diagnosed previously with brain dysfunction, such as Alzheimer's disease, and there is no expectation that neuropsychological testing would impact the individual's medical, functional, or behavioral management

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Neuropsychological Testing Under the Medical Benefit (for New Jersey Only) (continued)	Jun. 1, 2022	Health Assessment, and BrainCare™ *for diagnosing dementia or cognitive impairment*" with "computerized cognitive testing *such as* to Cognivue®, Mindstreams® Cognitive Health Assessment, BrainCare™, *and Qb Test*" ▪ "Computerized neuropsychological testing for evaluating concussions *or brain injuries*" with "computerized neuropsychological testing *when used as a stand-alone test* for evaluating concussions" **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	
Spinal Fusion Enhancement Products	Jul. 1, 2022	**Coverage Rationale** • Revised list of products that are proven and medically necessary for the enhancement of spinal fusion; replaced "autografts" with "autografts *(including bone marrow aspirate used for bone grafting)*" **Applicable Codes** • Added CPT code 20939	The following are proven and medically necessary for the enhancement of spinal fusion: • Autografts (including bone marrow aspirate used for bone grafting) • Demineralized bone matrix (DBM) without added products listed below as unproven and not medically necessary • Allograft-based products not listed below as unproven and not medically necessary • Infuse® Bone Graft [recombinant human bone morphogenetic protein-2 (rhBMP-2)] of the lumbar spine when the following criteria are met:

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Spinal Fusion Enhancement Products (continued)	Jul. 1, 2022	**Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, and *References* section to reflect the most current information	○ The approach is anterior or oblique and used in conjunction with an FDA-approved interbody fusion device ○ Skeletally mature individual (18 years of age or older or radiographic evidence of epiphyseal closure) with degenerative disc disease (DDD) ○ The fusion involves vertebral bodies L2-S1, without or with spondylolisthesis of no more than grade 1 (25% displacement) at the involved level ○ The fusion is single-level • The InFUSE/MASTERGRAFT™ Posterolateral Revision Device System (or InFUSE BMP used with MASTERGRAFT) when used according to U.S. Food and Drug Administration (FDA) indications in individuals who meet all the following criteria: ○ Implanted via a posterolateral approach ○ Presence of symptomatic posterolateral lumbar spine pseudoarthrosis ○ Skeletally mature patient (older than 21 years of age or radiographic evidence of epiphyseal closure) ○ Autologous bone and/or bone marrow harvest is not feasible or is not expected to promote fusion. The following are unproven and not medically necessary for the enhancement of spinal fusion due to insufficient evidence of efficacy: • Allograft based products ○ Cell-based [e.g., mesenchymal stem cells (MSC)] ○ Ceramic-based products [e.g., beta tricalcium phosphate (b-TCP), calcium phosphate, calcium sulfate and bioactive glass] used alone or in combination with other grafts including bone marrow aspirate ○ Human amniotic tissue materials, including amniotic fluid stem cell substitutes for the treatment of spine disease or in spine surgery • Recombinant human bone morphogenetic protein-2 (e.g., rhBMP-2, InFUSE) and the InFUSE/MASTERGRAFT™ (or InFUSE BMP used with Mastergraft or Mastergraft alone) Posterolateral Revision Device for all other indications not included above • The OptiMesh® Expandable Interbody Fusion System

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Spinal Fusion Enhancement Products (for New Jersey Only)	Jun. 1, 2022	**Title Change** • Previously titled *Bone or Soft Tissue Healing and Fusion Enhancement Products (for New Jersey Only)* **Related Policies** • Added reference link to the Medical Policy titled *Skin and Soft Tissue Substitutes (for New Jersey Only)* • Removed reference link to the Medical Policy titled *Ablative Treatment for Spinal Pain (for New Jersey Only)* **Coverage Rationale** *Proven and Medically Necessary* • Replaced language indicating "the [listed products] are proven and medically necessary for the enhancement of fusion *and/or bone healing*" with "the [listed products] are proven and medically necessary for the enhancement of *spinal* fusion" • Revised list of proven and medically necessary products; replaced: ○ "Allograft-based products" with "Allograft-based products *not listed [in the policy] as unproven and not medically necessary*" ○ "Demineralized Bone Matrix (DBM)" with "Demineralized Bone Matrix (DBM) *without added products listed [in the*	The following are proven and medically necessary for the enhancement of spinal fusion: • Autografts • Demineralized bone matrix (DBM) without added products listed below as unproven and not medically necessary • Allograft-based products not listed below as unproven and not medically necessary • Infuse® Bone Graft (Recombinant human bone morphogenetic protein-2 [rhBMP-2]) of the lumbar spine when the following criteria are met: ○ The approach is anterior or oblique and used in conjunction with an FDA-approved interbody fusion device ○ Skeletally mature individual (18 years of age or older or radiographic evidence of epiphyseal closure) with degenerative disc disease (DDD) ○ The fusion involves vertebral bodies L2-S1, without or with spondylolisthesis of no more than grade 1 (25% displacement) at the involved level ○ The fusion is single-level • The InFUSE/MASTERGRAFT™ Posterolateral Revision Device System (or InFUSE BMP used with MASTERGRAFT) when used according to U.S. Food and Drug Administration (FDA) indications in individuals who meet all the following criteria: ○ Implanted via a posterolateral approach ○ Presence of symptomatic posterolateral lumbar spine pseudoarthrosis ○ Skeletally mature patient (older than 21 years of age or radiographic evidence of epiphyseal closure) ○ Autologous bone and/or bone marrow harvest is not feasible or is not expected to promote fusion. The following are unproven and not medically necessary for the enhancement of spinal fusion due to insufficient evidence of efficacy: • Allograft based products ○ Cell-based [e.g., mesenchymal stem cells [MSC]) ○ Ceramic-based products (e.g., beta tricalcium phosphate [b-TCP],

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Spinal Fusion Enhancement Products (for New Jersey Only) (continued)	Jun. 1, 2022	*policy] as unproven and not medically necessary*" ○ "Recombinant human bone morphogenetic protein-2 (*e.g.,* rhBMP-2, Infuse® Bone Graft) of the lumbar spine" with "Infuse® Bone Graft [recombinant human bone morphogenetic protein-2 (rhBMP-2)] of the lumbar spine" ○ "The InFUSE/ MASTERGRAFT™ Posterolateral Revision Device system" with "the InFUSE/ MASTERGRAFT™ Posterolateral Revision Device System *(or InFUSE BMP used with MASTERGRAFT)*" • Revised coverage criteria for: Infuse® Bone Graft ○ Replaced criterion requiring "the fusion involves vertebral bodies *L4*-S1, with or without spondylolisthesis of no more than grade 1 (25% displacement) at the involved level" with "the fusion involves vertebral bodies *L2*-S1, without or with spondylolisthesis of no more than grade 1 (25% displacement) at the involved level" ○ Removed criterion requiring	calcium phosphate, calcium sulfate and bioactive glass) used alone or in combination with other grafts including bone marrow aspirate ○ Human amniotic tissue materials, including amniotic fluid stem cell substitutes for the treatment of spine disease or in spine surgery • Recombinant human bone morphogenetic protein-2 (e.g., rhBMP-2, InFUSE) and the InFUSE/MASTERGRAFT™ (or InFUSE BMP used with Mastergraft or Mastergraft alone) Posterolateral Revision Device for all other indications not included above • The OptiMesh® Expandable Interbody Fusion System

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Spinal Fusion Enhancement Products (for New Jersey Only) (continued)	Jun. 1, 2022	failure of at least 6 months of non-operative medical treatment InFUSE/MASTERGRAFT™ Posterolateral Revision Device System ○ Removed criterion requiring treatment of 2 or more levels of the lumbar spine *Unproven and Not Medically Necessary* ● Replaced language indicating "the [listed products] are unproven and not medically necessary for the enhancement of fusion *and/or bone healing*" with "the [listed products] are unproven and not medically necessary for the enhancement of *spinal* fusion" ● Revised list of unproven and not medically necessary products: ○ Added language to indicate the following are Allograft based products: ▪ Cell-based products ▪ Ceramic-based products ▪ Human amniotic *tissue* materials ○ Removed recombinant human bone morphogenetic protein-7 (rhBMP-7) including but not limited to, Osteogenic Protein-1 (OP-1® Implant & Putty) with or	

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Spinal Fusion Enhancement Products (for New Jersey Only) (continued)	Jun. 1, 2022	without use of other devices ○ Replaced: ▪ "Recombinant human bone morphogenetic protein-2 (e.g., rhBMP-2, InFUSE) and InFUSE/ MASTERGRAFT™ Posterolateral Revision Device for all other indications not included [in the policy as proven and medically necessary]" with "recombinant human bone morphogenetic protein-2 (e.g., rhBMP-2, InFUSE) and InFUSE/ MASTERGRAFT™ *(or InFUSE BMP used with MASTERGRAFT or MASTERGRAFT alone)* Posterolateral Revision Device for all other indications not [listed in the policy as proven and medically necessary]" ▪ "The OptiMesh® *deployable grafting system*" with "the OptiMesh® *Expandable Interbody Fusion System*" **Definitions** ● Removed definition of "RhBMP–7/Osteogenic Protein-1 (OP–1® Implant & Putty)"	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Spinal Fusion Enhancement Products (for New Jersey Only) (continued)	Jun. 1, 2022	**Applicable Codes** • Removed CPT codes 20932, 20933, 20934, 22558, and 22585 **Supporting Information** • Updated *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	
Surgery of the Hip (for New Jersey Only)	Jun. 1, 2022	**Title Change** • Previously titled *Hip Resurfacing and Replacement Surgery (Arthroplasty) (for New Jersey Only)* **Coverage Rationale** • Revised language to indicate: ○ Surgery of the hip and surgical treatment for femoroacetabular impingement (FAI) syndrome is proven and medically necessary in certain circumstances; for medical necessity clinical coverage criteria, refer to the InterQual® 2022, Apr. 2022 Release, CP: Procedures: ▪ Arthroscopy, Diagnostic, +/- Synovial Biopsy, Hip ▪ Arthroscopy, Surgical, Hip ▪ Arthroscopy, Surgical, Hip (Pediatric) ▪ Arthrotomy, Hip ▪ Hemiarthroplasty, Hip ▪ Removal and Replacement, Total Joint Replacement (TJR), Hip	Surgery of the hip and surgical treatment for femoroacetabular impingement (FAI) syndrome is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® 2022, Apr. 2022 Release, CP: Procedures: • Arthroscopy, Diagnostic, +/- Synovial Biopsy, Hip • Arthroscopy, Surgical, Hip • Arthroscopy, Surgical, Hip (Pediatric) • Arthrotomy, Hip • Hemiarthroplasty, Hip • Removal and Replacement, Total Joint Replacement (TJR), Hip • Total Joint Replacement (TJR), Hip Click here to view the InterQual® criteria. Surgical treatment for femoroacetabular impingement (FAI) syndrome is unproven and not medically necessary in the presence of advanced osteoarthritis (i.e., Tönnis Grade 2 or 3) and/or severe cartilage damage (i.e., Outerbridge Grade III or IV). **Documentation Requirements** Provide medical notes documenting the following, when applicable: • Upon request, we may require the specific diagnostic image(s) that shows the abnormality for which surgery is being requested, which may include MRI, CT scan, X-ray, and/or bone scan; consultation with requesting surgeon may be of benefit to select the optimal image(s) ○ Note: When requested, diagnostic images must be labeled with the:

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Surgery of the Hip (for New Jersey Only) (continued)	Jun. 1, 2022	▪ Total Joint Replacement (TJR), Hip ○ Surgical treatment for femoroacetabular impingement (FAI) syndrome is unproven and not medically necessary in the presence of advanced osteoarthritis (i.e., Tönnis Grade 2 or 3) and/or severe cartilage damage (i.e., Outerbridge Grade III or IV) *Documentation Requirements* ● Added language to indicate specific diagnostic images may be required when requested ● Revised list of clinical information to be documented in the medical notes, when applicable; added: ○ Date of previous hip fracture fixation, if applicable ○ Prior therapies/treatments tried, failed, or contraindicated; include the dates and reason for discontinuation ○ For femoroacetabular impingement (FAI) syndrome (CPT codes 29914, 29915, and 29916), include radiographic reports of presence and severity of cartilage damage using Tönnis or Outerbridge grading ● Removed list of examples of	▪ Date taken ▪ Applicable case number obtained at time of notification, or the member's name and ID number on the image(s) ○ Upon request, diagnostic imaging must be submitted via the external portal at www.uhcprovider.com/paan; faxes will not be accepted ● Diagnostic imaging report(s) ● Condition requiring procedure ● Severity of pain and details of functional disability(ies) interfering with activities of daily living (preparing meals, dressing, driving, walking) using a standard scale; such as the: ○ Western Ontario and McMaster Universities Arthritis Index (WOMAC) or ○ Hip Dysfunction and Osteoarthritis Outcome Score (HOOS) ● Physician's treatment plan, including pre-op discussion ● Pertinent physical examination of the relevant joint ● Co-morbid medical conditions (cardiovascular diseases, hypertension, diabetes, cancer, pulmonary diseases, neurodegenerative diseases) ● Prior therapies/treatments tried, failed, or contraindicated; include the dates and reason for discontinuation ● Date of previous hip fracture fixation, if applicable ● If the location is being requested as an inpatient stay, provide medical notes to support at least one of the following: ○ Surgery is bilateral ○ Member has significant co-morbidities; include the list of comorbidities and current treatment ▪ Member does not have appropriate resources to support post-operative care after an outpatient procedure; include the barriers to care as an outpatient In addition to the above, for Femoroacetabular Impingement (FAI) Syndrome (29914 29915 29916), also include radiographic reports of presence and severity of cartilage damage using Tönnis or Outerbridge grading.

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Surgery of the Hip (for New Jersey Only) (continued)	Jun. 1, 2022	therapies tried and failed • Added list of examples of co-morbid medical conditions: cardiovascular diseases, hypertension, diabetes, cancer, pulmonary diseases, neurodegenerative diseases **Definitions** • Added definition of: ○ Disabling Pain ○ Outerbridge Grades ○ Significant Radiographic Findings ○ Tönnis Classification of Osteoarthritis by Radiographic Changes **Applicable Codes** • Added CPT codes 27299, 29860, 29861, 29862, 29863, 29914, 29915, 29916, and 29999 • Removed CPT code 27122 **Supporting Information** • Added *Clinical Evidence* section • Updated *FDA* and *References* sections to reflect the most current information	
Surgery of the Knee (for New Jersey Only)	Jun. 1, 2022	**Title Change** • Previously titled *Knee Replacement Surgery (Arthroplasty), Total and Partial (for New Jersey Only)* **Coverage Rationale** • Replaced language indicating "knee *replacement surgery (arthroplasty)*	Surgery of the knee is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® 2022, Apr. 2022 Release, CP: Procedures: • Arthroscopy, Diagnostic, +/- Synovial Biopsy, Knee • Arthroscopy or Arthroscopically Assisted Surgery, Knee • Arthrotomy, Knee • Removal and Replacement, Total Joint Replacement (TJR), Knee • Total Joint Replacement (TJR), Knee

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Surgery of the Knee (for New Jersey Only) (continued)	Jun. 1, 2022	is proven and medically necessary in certain circumstances" with "*surgery of the* knee is proven and medically necessary in certain circumstances" • Revised language pertaining to medical necessity clinical coverage criteria; added InterQual® 2022, Apr. 2022 Release, CP: Procedures: ○ Arthroscopy, Diagnostic, +/- Synovial Biopsy, Knee ○ Arthroscopy or Arthroscopically Assisted Surgery, Knee ○ Arthrotomy, Knee *Documentation Requirements* • Added language to indicate specific diagnostic images may be required when requested • Revised list of clinical information to be documented in the medical notes, when applicable: ○ Added: ▪ Reports of all recent imaging studies and applicable diagnostic tests, including when applicable: – Microbiological findings – Synovial fluid cytology – Erythrocyte sedimentation rate (ESR) – C-reactive protein	• Unicondylar or Patellofemoral Knee Replacement Click here to view the InterQual® criteria. **Documentation Requirements** Medical notes documenting the following, as applicable: • Upon request, we may require the specific diagnostic image(s) that show the abnormality for which surgery is being requested, which may include MRI, CT scan, X-ray, and/or bone scan; consultation with requesting surgeon may be of benefit to select the optimal images ○ Note: When requested, diagnostic images must be labeled with: ▪ The date taken ▪ Applicable case number obtained at time of notification, or the member's name and ID number on the image(s) ○ Upon request, diagnostic imaging must be submitted via the external portal at www.uhcprovider.com/paan; faxes will not be accepted • Reports of all recent imaging studies and applicable diagnostic tests, including: ○ Microbiological findings ○ Synovial exam ○ Erythrocyte sedimentation rate (ESR) ○ C-reactive protein (CRP) • Condition requiring procedure • Severity of pain and details of functional disability(ies) interfering with activities of daily living (preparing meals, dressing, driving, walking) using a standard scale, such as the *Western Ontario and McMaster Universities Arthritis Index (WOMAC) or the Knee injury and Osteoarthritis Outcome Score (KOOS)* • Pertinent physical examination of the relevant joint • Consideration of arthroscopic approach • Co-morbid medical condition(s) • Prior therapies/treatments tried, failed, or contraindicated; include the dates and reason for discontinuation

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Surgery of the Knee (for New Jersey Only) (continued)	Jun. 1, 2022	(CRP) ▪ Consideration of arthroscopic approach ▪ Prior therapies/treatments tried, failed, or contraindicated; include the dates and reason for discontinuation ○ Removed list of examples of therapies tried and failed **Definitions** • Added definition of: ○ Knee Injury and Osteoarthritis Outcome Score (KOOS) ○ Western Ontario and McMaster Universities Arthritis Index (WOMAC) **Applicable Codes** • Added CPT codes 27437, 27438, 27440, 27441, 27442, 27443, 29850, 29851, 29855, 29856, 29870, 29871, 29873, 29874, 29875, 29876, 29877, 29880, 29881, 29882, 29883, 29884, 29885, 29886, 29887, 29888, and 29889 **Supporting Information** • Updated *FDA* and *References* sections to reflect the most current information	• Date of failed previous surgery to the same joint (proximal tibial or distal femoral osteotomy, if applicable) • Physician's treatment plan including pre-op discussion • For revision surgery, also include: ○ Details of complication ○ Complete (staged) surgical plan • If the location is being requested as an inpatient stay, provide medical notes to support the following, when applicable: ○ Surgery is bilateral ○ Member has significant co-morbidities; include the list of comorbidities and current treatment ○ Member does not have appropriate resources to support post-operative care after an outpatient procedure; include the barriers to care as an outpatient

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Surgery of the Shoulder (for New Jersey Only)	Jun. 1, 2022	**Coverage Rationale** • Revised language pertaining to medical necessity clinical coverage criteria; added reference to the InterQual® 2022, Apr. 2022 Release, CP: Procedures, Removal and Replacement, Total Joint Replacement (TJR), Shoulder ***Documentation Requirements*** • Added language to indicate specific diagnostic images may be required when requested • Revised list of clinical information to be documented in the medical notes, when applicable: ○ Added: ▪ Reports of all recent imaging studies and applicable diagnostic tests, including when applicable: – Microbiological findings – Synovial fluid cytology – Erythrocyte sedimentation rate (ESR) – C-reactive protein (CRP) ▪ Feasibility of arthroscopic approach ▪ Member has the ability to participate in post-surgical rehabilitation	Surgery of the shoulder is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the: • InterQual® 2022, Apr. 2022 Release, CP: Procedures: ○ Arthroscopy or Arthroscopically Assisted Surgery, Shoulder ○ Arthroscopy or Arthroscopically Assisted Surgery, Shoulder (Adolescent) ○ Arthrotomy, Shoulder ○ Diagnostic, +/- Synovial Biopsy, Shoulder ○ Joint Replacement, Shoulder • InterQual® Client Defined 2022, CP: Procedures, Removal and Replacement, Total Joint Replacement (TJR), Shoulder (Custom) - UHG Click here to view the InterQual® criteria. **Documentation Requirements** Medical notes documenting the following, when applicable: • Pertinent physical examination of the relevant joint • Severity of pain as documented on a validated pain scale • Functional disability(ies) as documented on a validated functional disability scale or described as interfering with activities of daily living (preparing meals, dressing, driving, walking) • Upon request, we may require the specific diagnostic image(s) that documents the severity of joint disease using a validated scale (e.g., Walch classification of primary glenohumeral osteoarthritis) and shows the abnormality for which surgery is being requested, which may include MRI, CT scan, X-ray, and/or bone scan; consultation with requesting surgeon may be of benefit to select the optimal image(s) ○ Note: When requested, diagnostic images must be labeled with the: ▪ Date taken ▪ Applicable case number obtained at time of notification, or the member's name and ID number on the image(s) ○ Upon request, diagnostic imaging must be submitted via the external portal at www.uhcprovider.com/paan; faxes will not be accepted

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Surgery of the Shoulder (for New Jersey Only) (continued)	Jun. 1, 2022	▪ For revision surgery, also include: – Details of complication – Complete (staged) surgical plan ▪ If the location is being requested as an inpatient stay, provide medical notes to support at least one of the following: – Surgery is bilateral – Member has significant co-morbidities; include the list of comorbidities and current treatment – Member does not have appropriate resources to support post-operative care after an outpatient procedure; include the barriers to care as an outpatient ○ Removed "diagnostic image(s) report(s)" ○ Replaced "condition requiring procedure" with "condition requiring procedure, *including relevant past history with dates*" **Applicable Codes** ● Removed CPT code 23412	● Advanced joint disease using a validated scale (e.g., Walch classification of primary glenohumeral osteoarthritis) ● Reports of all recent imaging studies and applicable diagnostic tests, including when applicable: ○ Microbiological findings ○ Synovial fluid cytology ○ Erythrocyte sedimentation rate (ESR) ○ C-reactive protein (CRP) ● Condition requiring procedure, including relevant past history with dates ● Physician's treatment plan including pre-op discussion ● Feasibility of arthroscopic approach ● Co-morbid medical condition(s) ● Therapies tried (including dates) and failed as documented by a lack of clinically significant improvement between at least two measurements concurrent to the therapy, on validated pain or functional disability scale(s) or quantifiable symptoms; these therapies could include: ○ Nonoperative Therapy (i.e., orthotics, medications/injections, physical therapy, other pain management procedures, etc.) ○ Surgery ● Member has the ability to participate in post-surgical rehabilitation ● For revision surgery, also include: ○ Details of complication ○ Complete (staged) surgical plan ● If the location is being requested as an inpatient stay, provide medical notes to support at least one of the following: ○ Surgery is bilateral ○ Member has significant co-morbidities; include the list of comorbidities and current treatment ○ Member does not have appropriate resources to support post-operative care after an outpatient procedure; include the barriers to care as an outpatient

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Surgical Treatment for Spine Pain (for New Jersey Only)	Jun. 1, 2022	Coverage Rationale • Replaced language indicating "a surgical spine procedure that is performed to alleviate symptoms or prevent clinical deterioration of a congenital or idiopathic deformity or bone disease is proven and medically necessary if not addressed in the [InterQual® criteria listed in the policy]" with "a surgical spine procedure that is performed to alleviate symptoms or prevent clinical deterioration of a congenital or idiopathic deformity or bone disease *other than scoliosis* is proven and medically necessary if not addressed in the [InterQual® criteria listed in the policy]" • Added language to indicate: ○ Interspinous process fusion devices are proven and medically necessary when used in conjunction with any of the following procedures: ▪ Open laminar and/or facet decortication and fusion ▪ Autograft inter-and extra-spinous process decortication and fusion ▪ Interbody fusion of the same motion segment ○ Dividing treatment of symptomatic, multi-site spinal	Spinal procedures for the treatment of spine pain are proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the following InterQual® 2022, Apr. 2022 Release, CP: Procedures: • Decompression +/- Fusion, Cervical • Decompression +/- Fusion, Lumbar • Decompression +/- Fusion, Thoracic • Fusion, Cervical Spine • Fusion, Lumbar Spine • Fusion, Thoracic Spine Click here to view the InterQual® criteria. The following techniques for lumbar interbody fusion (LIF) are proven and medically necessary: • Anterior LIF(ALIF) including lateral approaches, e.g., extreme lateral interbody fusion (XLIF®), Direct lateral interbody fusion (DLIF) • Posterior LIF (PLIF), including transforaminal lumbar interbody fusion (TLIF) The following indications for a surgical spine procedure that is performed to alleviate symptoms or prevent clinical deterioration are considered proven and medically necessary if not addressed in the above criteria: • Congenital or idiopathic deformity or bone disease other than scoliosis • Muscular dystrophy • Laminectomy procedure to provide surgical exposure to treat lesions within the spinal canal Interspinous process fusion devices is proven and medically necessary when used in conjunction with any of the following procedures: • Open laminar and/or facet decortication and fusion • Autograft inter-and extra-spinous process decortication and fusion • Interbody fusion of the same motion segment

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Surgical Treatment for Spine Pain (for New Jersey Only) (continued)	Jun. 1, 2022	pathology via anterior or posterior approach into serial, multiple, or staged sessions when one session can address all sites is unproven and not medically necessary • Removed language indicating interlaminar lumbar instrumented fusion (ILIF) utilizing an interspinous process fusion device is unproven and not medically necessary *Documentation Requirements* • Revised list of clinical information to be documented in the medical notes, when applicable: ○ Added: ▪ Smoking history/status, including date of last smoking cessation ▪ Degree and progression of curvature (for scoliosis) ▪ Quantification of relevant muscle strength ▪ Results of biopsy(ies) ▪ Results of bone aspirate ▪ List of conditions included in diagnostic image reports (when applicable): – Disc herniation – Discitis – Epidural abscess – Nerve root compression	The following spinal procedures are unproven and not medically necessary due to insufficient evidence of efficacy (this includes procedures that utilize interbody cages, screws, and pedicle screw fixation devices): • Laparoscopic anterior lumbar interbody fusion (LALIF) • Transforaminal lumbar interbody fusion (TLIF) which utilizes only endoscopy visualization (such as a percutaneous incision with video visualization) • Axial lumbar interbody fusion (AxiaLIF®) • Spinal decompression and interspinous process decompression systems for the treatment of lumbar spinal stenosis (e.g., Interspinous process decompression (IPD), Minimally invasive lumbar decompression (mild®) • Dividing treatment of symptomatic, multi-site spinal pathology via anterior or posterior approach into serial, multiple, or staged sessions when one session can address all sites • Spinal stabilization systems ○ Stabilization systems for the treatment of degenerative spondylolisthesis ○ Total facet joint arthroplasty, including facetectomy, laminectomy, foraminotomy, vertebral column fixation ○ Percutaneous sacral augmentation (sacroplasty) with or without a balloon or bone cement for the treatment of back pain • Stand-alone facet fusion without an accompanying decompressive procedures; this includes procedures performed with or without bone grafting and/or the use of posterior intrafacet implants such as fixation systems, facet screw systems or anti-migration dowels For information on vertebral body tethering, refer to the Medical policy titled Vertebral Body Tethering for Scoliosis (for New Jersey Only). **Documentation Requirements** Medical notes documenting the following, when applicable: • Condition requiring procedure • History and co-morbid medical condition(s)

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Surgical Treatment for Spine Pain (for New Jersey Only) (continued)	Jun. 1, 2022	– Quantification of subluxation, translation by flexion, angulation when appropriate – Segment (s) instability – Spinal cord compression ○ Replaced language indicating "diagnostic image(s) *are* required" with "diagnostic image(s) *may be* required *upon request*" **Definitions** ● Added definition of "Staged Multi-Session" **Applicable Codes** ● Added CPT codes 20930, 20931, and 20939 **Supporting Information** ● Updated *Clinical Evidence* and *References* sections to reflect the most current information	○ Smoking history/ status, including date of last smoking cessation ● Member's symptoms, pain, location, and severity including functional impairment that is interfering with activities of daily living (meals, walking, getting dressed, driving) ● Failure of Conservative Therapy through lack of clinically significant improvement between at least two measurements, on a validated pain or function scale or quantifiable symptoms despite concurrent Conservative Therapies (see definition), if applicable ● Progressive deficits with clinically significant worsening based on at least two measurements over time, if applicable ● Disabling Symptoms, if applicable ● Upon request, we may request the specific diagnostic image(s) that shows the abnormality for which surgery is being requested which may include MRI, CT scan, X-ray, and/or bone scan; consultation with requesting surgeon may be needed to select the optimal image(s) ○ Note: When requested, diagnostic images must be labeled with the: ▪ Date taken ▪ Applicable case number obtained at time of notification, or the member's name and ID number on the image(s) ○ Upon request, diagnostic imaging must be submitted via the external portal at www.uhcprovider.com/paan; faxes will not be accepted ● Diagnostic image(s) report(s), including presence or absence of: ○ Segment (s) instability ○ Spinal cord compression ○ Disc herniation ○ Nerve root compression ○ Quantification of subluxation, translation by flexion, angulation when appropriate ○ Discitis ○ Epidural abscess ● Physical exam, including neurologic exam, including degree and progression of curvature (for scoliosis), if applicable ○ Degree and progression of curvature (for scoliosis)

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Surgical Treatment for Spine Pain (for New Jersey Only) (continued)	Jun. 1, 2022		○ Quantification of relevant muscle strength • Whether the surgery will be performed with direct visualization or only with endoscopic visualization • Complete report(s) of diagnostic tests ○ Results of biopsy(ies) ○ Results of bone aspirate • Describe the surgical technique(s) planned [e.g., AxiaLIF®, XLIF, ILIF, OLIF, LALIF, image-guided minimally invasive lumbar decompression (mild®), percutaneous endoscopic discectomy with or without laser, etc.]
Total Artificial Disc Replacement for the Spine (for New Jersey Only)	Jun. 1, 2022	Coverage Rationale • Revised language pertaining to medical necessity clinical coverage criteria for: ○ Cervical artificial total disc replacement with an FDA-approved prosthetic intervertebral disc: Added reference to the InterQual® 2022, Apr. 2022 Release, CP: Procedures, Artificial Disc Replacement, Cervical ○ Lumbar artificial total disc replacement with an FDA-approved prosthetic intervertebral disc: Replaced coverage criteria with reference to the InterQual® Client Defined 2022, CP: Procedures, Artificial Disc Replacement, Lumbar (Custom) - UHG • Added language to clarify cervical artificial disc replacement at one level combined with cervical spinal	Cervical artificial total disc replacement with an FDA-approved prosthetic intervertebral disc is proven and medically necessary for treating one-level or two contiguous levels of cervical Degenerative Disc Disease (C3 to C7), in a Skeletally Mature individual with symptomatic radiculopathy and/or myelopathy. For medical necessity clinical coverage criteria, refer to the InterQual® 2022, Apr. 2022 Release, CP: Procedures, Artificial Disc Replacement, Cervical. Click here to view the InterQual® criteria. Cervical artificial disc replacement at one level combined with cervical spinal fusion surgery at another level (adjacent or non-adjacent), as part of the same surgical plan, is unproven and not medically necessary due to insufficient evidence of efficacy. Lumbar artificial total disc replacement with an FDA-approved prosthetic intervertebral disc is proven and medically necessary for treating single level lumbar Degenerative Disc Disease with symptomatic intractable discogenic low back pain in a Skeletally Mature individual when there are no contraindications. Contraindications to lumbar artificial total disc replacement include but are not limited to the following: • Moderate or severe facet arthropathy or pars defect at the operative level on a preoperative MRI scan, CT scan or plain radiograph

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Total Artificial Disc Replacement for the Spine (for New Jersey Only) (continued)	Jun. 1, 2022	fusion surgery at another level (adjacent or non-adjacent), *as part of the same surgical plan*, is unproven and not medically necessary due to insufficient evidence of efficacy **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	• Lumbosacral spinal fracture • Scoliosis of the lumbosacral spine • Active systemic infection or infection localized to the site of implantation • Tumor in the peritoneum, retroperitoneum or site of implantation • Osteoporosis or osteopenia as defined by recent (within one year) DEXA scan • Isolated radicular compression syndromes especially due to disc herniation • Spinal stenosis or radiculopathy • Previous lumbar spine surgery where the previous surgery destabilized the spine or where the spine at the level of the previous surgery is an alternate source of pain • Vascular, urological, or other peritoneal or retroperitoneal pathology that may preclude safe and adequate anterior spine exposure as required for the surgery For medical necessity clinical coverage criteria, refer to the InterQual® Client Defined 2022, CP: Procedures, Artificial Disc Replacement, Lumbar (Custom) - UHG. Click here to view the InterQual® criteria. Lumbar artificial total disc replacement is unproven and not medically necessary in the following situations due to insufficient evidence of efficacy: • More than one spinal level • Prior history of lumbar fusion or when combined with a lumbar fusion at any level • Treating any other indications not listed above
Whole Exome and Whole Genome Sequencing (for New Jersey Only)	Jun. 1, 2022	**Coverage Rationale** • Added language to indicate this policy applies to genetic testing in an outpatient setting or upon discharge from an inpatient setting • Revised coverage criteria for Whole	**Whole Exome Sequencing (WES)** Whole Exome Sequencing (WES) is proven and medically necessary for the following: • Diagnosing or evaluating a genetic disorder when the results are expected to directly influence medical management and clinical outcomes and all of the following criteria are met:

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Whole Exome and Whole Genome Sequencing (for New Jersey Only) (continued)	Jun. 1, 2022	Exome Sequencing (WES): ○ Replaced criterion requiring: ▪ "WES is ordered by a board-certified medical geneticist, neonatologist, neurologist, or developmental *and behavioral* pediatrician" with "WES is ordered by a board-certified medical geneticist, neonatologist, neurologist, or developmental pediatrician" ▪ "*There is a clinical diagnosis of a genetic condition that can be caused by multiple genes and* WES is a more practical approach to identifying the underlying genetic cause than are individual tests of multiple genes" with "WES is a more practical approach to identifying the underlying genetic cause than are individual tests of multiple genes" ○ Removed criterion requiring "there is likely a genetic disorder and multiple targeted gene tests have failed to identify	○ Clinical presentation is nonspecific and does not fit a well-defined syndrome for which a specific or targeted gene test is available. If a specific genetic syndrome is suspected, a single gene or targeted gene panel should be performed prior to determining if WES is necessary; and ○ WES is ordered by a board-certified medical geneticist, neonatologist, neurologist, or developmental pediatrician; and ○ One of the following: ▪ Clinical and/or family history strongly suggest a genetic cause for which a specific clinical diagnosis cannot be made with any clinically available targeted genetic tests; or ▪ WES is a more practical approach to identifying the underlying genetic cause than are individual tests of multiple genes • Comparator (e.g., parents or siblings) WES for evaluating a genetic disorder when the above criteria have been met and WES is performed concurrently or has been previously performed on the individual Due to insufficient evidence of efficacy, WES is unproven and not medically necessary for all other indications, including but not limited to the following: • Evaluation of fetal demise • Molecular profiling of tumors for the diagnosis, prognosis or management of cancer • Preimplantation Genetic Testing (PGT) in embryos • Prenatal genetic diagnosis or screening • Screening and evaluating disorders in individuals when the above criteria are not met **Whole Genome Sequencing (WGS)** Whole Genome Sequencing (WGS) is not medically necessary for evaluating any genetic disorder due to the availability of clinically equivalent diagnostic tests. *This policy applies to genetic testing in an outpatient setting or upon

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Whole Exome and Whole Genome Sequencing (for New Jersey Only) (continued)	Jun. 1, 2022	the underlying cause" Supporting Information • Updated *Description of Services*, *Clinical Evidence* and *References* sections to reflect the most current information	discharge from an inpatient setting.

Replaced		
Policy Title	**Effective Date**	**Summary of Changes**
Femoroacetabular Impingement Syndrome (for New Jersey Only)	Jun. 1, 2022	• Policy replaced; refer to the Medical Policy titled Surgery of the Hip (for New Jersey Only)

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. Requests outside of this criteria will be reviewed for medical necessity on a case-by-case basis.

Medical Benefit Drug Policy Updates

Updated		
Policy Title	**Effective Date**	**Summary of Changes**
Alpha1-Proteinase Inhibitors	May 1, 2022	Application • Removed language indicating this Medical Benefit Drug Policy does not apply to the state of Pennsylvania
Benlysta® (Belimumab)	May 1, 2022	Application *Texas* • Added language to indicate this Medical Benefit Drug Policy does not apply to the state of Texas; refer to the state's Medicaid clinical policy
Gamifant® (Emapalumab-Lzsg)	May 1, 2022	Application *Texas* • Added language to indicate this Medical Benefit Drug Policy does not apply to the state of Texas; refer to the state's Medicaid clinical policy
Givlaari® (Givosiran)	May 1, 2022	Application *Texas* • Added language to indicate this Medical Benefit Drug Policy does not apply to the state of Texas; refer to the state's Medicaid clinical policy
Intravenous Enzyme Replacement Therapy (ERT) for Gaucher Disease	May 1, 2022	Application *Florida* • Revised language to indicate this Medical Benefit Drug Policy only applies to the state of Florida for Elelyso® (taliglucerase) (HCPCS code J3060); for all other products, refer to the state's Medicaid clinical policy *Texas* • Added language to indicate this Medical Benefit Drug Policy does not apply to the state of Texas; refer to the state's Medicaid clinical policy
Luxturna® (Voretigene Neparvovec-Rzyl)	May 1, 2022	Application *Texas* • Added language to indicate this Medical Benefit Drug Policy does not apply to the state of Texas; refer to the state's Medicaid clinical policy
Medical Therapies for Enzyme Deficiencies	May 1, 2022	Application *Florida* • Revised language to indicate this Medical Benefit Drug Policy only applies to the state of Florida for Fabrazyme® (agalsidase beta) (HCPCS code J0180), Naglazyme® (galsulfase) (HCPCS code J1458), and Nulibry™ (fosdenopterin) (HCPCS codes C9399, J3490, and J3590); for all other products, refer to the state's Medicaid clinical policy

Medical Benefit Drug Policy Updates

Updated

Policy Title	Effective Date	Summary of Changes
Medical Therapies for Enzyme Deficiencies (continued)	May 1, 2022	*Texas* • Added instruction to refer to the state's Medicaid clinical policy and use drug specific criteria found within the *Texas Medicaid Provider Procedures Manual* if available for the specific product; otherwise this Medical Benefit Drug Policy applies
Oncology Medication Clinical Coverage	May 1, 2022	Application *Kentucky* • Updated language to indicate this Medical Benefit Drug Policy applies to the state of Kentucky
Oxlumo™ (Lumasiran)	May 1, 2022	Application *Texas* • Added language to indicate this Medical Benefit Drug Policy does not apply to the state of Texas; refer to the state's Medicaid clinical policy
Saphnelo™ (Anifrolumab-Fnia)	May 1, 2022	Application *Texas* • Added language to indicate this Medical Benefit Drug Policy does not apply to the state of Texas; refer to the state's Medicaid clinical policy
Viltepso® (Viltolarsen)	May 1, 2022	Application *Texas* • Added language to indicate this Medical Benefit Drug Policy does not apply to the state of Texas; refer to the state's Medicaid clinical policy Supporting Information • Updated *Clinical Evidence* and *References* sections to reflect the most current information
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

Revised

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	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.

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Actemra® (Tocilizumab) Injection for Intravenous Infusion (continued)	Jun. 1, 2022	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)] – 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	This policy refers only to Actemra (tocilizumab) injection for intravenous infusion. Actemra (tocilizumab) for self-administered subcutaneous injection is obtained under the pharmacy benefit. Refer to the policy for complete details.

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Actemra® (Tocilizumab) Injection for Intravenous Infusion (continued)	Jun. 1, 2022	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 (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	

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
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: – 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	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 – 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

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Denosumab (Prolia® & Xgeva®) (continued)	Jun. 1, 2022	• 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	○ 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 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

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Denosumab (Prolia® & Xgeva®) (continued)	Jun. 1, 2022	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 U.S. Food and Drug	○ 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 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

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Denosumab (Prolia® & Xgeva®) (continued)	Jun. 1, 2022	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: – 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-	○ 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. • 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

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Denosumab (Prolia® & Xgeva®) (continued)	Jun. 1, 2022	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 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	○ 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 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

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Denosumab (Prolia® & Xgeva®) (continued)	Jun. 1, 2022	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 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	○ 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: ▪ 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

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Denosumab (Prolia® & Xgeva®) (continued)	Jun. 1, 2022	○ 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 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	○ 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: ▪ 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 ○ Diagnosis of localized or metastatic giant cell tumor of the bone; and ○ Disease is one of the following: ▪ Unresectable ▪ Surgical resection is likely to result in severe morbidity 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

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Denosumab (Prolia® & Xgeva®) (continued)	Jun. 1, 2022	– 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 treat patients at high risk for fracture receiving adjuvant aromatase 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	○ Authorization is for no more than 12 months • Reauthorization/Continuation of Care Criteria For patients currently on Xgeva for the treatment of giant cell tumor of the bone, 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 hypercalcemia of malignancy when all of the following criteria are met: • Initial Therapy ○ Patient is one of the following: ▪ 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 ○ 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

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Denosumab (Prolia® & Xgeva®) (continued)	Jun. 1, 2022	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	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 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

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Denosumab (Prolia® & Xgeva®) (continued)	Jun. 1, 2022	• 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 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.,	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 ○ 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 for no more than 12 months • Reauthorization/Continuation of Care Criteria For patients currently on Xgeva for the treatment of osteopenia/osteoporosis in patients with systemic mastocytosis with bone pain not responding to bisphosphonates, 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

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
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 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 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	**Unproven and Not Medically Necessary** Denosumab is unproven and not medically necessary for the following indications: • Combination therapy of denosumab and intravenous bisphosphonates • Bone loss associated with hormone-ablation therapy (other than aromatase inhibitors) in breast cancer • Cancer pain • Central giant cell granuloma • Hyper-parathyroidism • Immobilization hypercalcemia • Osteogenesis imperfecta • Osteopenia

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Denosumab (Prolia® & Xgeva®) (continued)	Jun. 1, 2022	– 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 units (1 mg per unit); 1 vial/ 1 ml **Supporting Information** • Updated *Clinical Evidence* and *FDA* sections to reflect the most current information	
Rituximab (Riabni™, Rituxan®, Ruxience®, & Truxima®)	Jun. 1, 2022	**Coverage Rationale** • Added language to indicate the preferred product criteria in [the policy] apply to the state of Minnesota	This policy refers only to the following drug products, rituximab injections for intravenous infusion for non-oncology conditions: • Riabni™ (rituximab-arrx) • Rituxan®(rituximab) • Rituxan Hycela®(rituximab and hyaluronidase human)* • Ruxience®(rituximab-pvvr)

Medical Benefit Drug Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Rituximab (Riabni™, Rituxan®, Ruxience®, & Truxima®) (continued)	Jun. 1, 2022	**Applicable Codes** • Revised description for HCPCS code Q5115	• Truxima®(rituximab-abbs) • Any FDA-approved rituximab biosimilar product not listed here "Rituximab" will be used to refer to all rituximab products without hyaluronidase. *Rituxan Hycela is unproven and not medically necessary for the treatment of non-oncology indications. For oncology indications and for Rituxan Hycela (rituximab/hyaluronidase human), 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®). Refer to the policy for complete details.

Vyvgart™ (Efgartigimod Alfa-Fcab)	Jun. 1, 2022	**Application**
		Florida
		• Added language to indicate this Medical Benefit Drug Policy does not apply to the state of Florida; refer to the state's Medicaid clinical policy
		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
			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

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Vyvgart™ (Efgartigimod Alfa-Fcab) (continued)	Jun. 1, 2022	score from pre-treatment baseline"	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 ▪ 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

Medical Benefit Drug Policy Updates

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Vyvgart™ (Efgartigimod Alfa-Fcab) (continued)	Jun. 1, 2022		▪ 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.
White Blood Cell Colony Stimulating Factors	Jun. 1, 2022	Application *Washington* • Added language to indicate this Medical Benefit Drug Policy does not apply to the state of Washington; refer to the state's Medicaid clinical policy Coverage Rationale • Added language to indicate the preferred product criteria in [the policy] apply to the states of Kentucky and Minnesota	This policy refers to the following white blood cell colony stimulating factors (CSFs): • Long-acting pegfilgrastim agents: ○ Fulphila® (pegfilgrastim-jmdb) ○ Neulasta® (pegfilgrastim) ○ Nyvepria™ (pegfilgrastim-apgf) ○ Udenyca® (pegfilgrastim-cbqv) ○ Ziextenzo® (pegfilgrastim-bmez) • Short-acting filgrastim agents: ○ Granix® (tbo-filgrastim) ○ Neupogen® (filgrastim) ○ Nivestym® (filgrastim-aafi) ○ Zarxio® (filgrastim-sndz) • Leukine® (sargramostim) (see Diagnosis-Specific Criteria) • Any FDA-approved white blood cell colony stimulating factor product not listed here* *Any U.S. Food and Drug Administration (FDA) approved white blood cell colony stimulating factor product not listed by name in this policy will be considered non-preferred until reviewed by UnitedHealthcare. Refer to the policy for complete details.

Coverage Determination Guideline Updates

Updated		
Policy Title	**Effective Date**	**Coverage Rationale**
Breast Reconstruction Post Mastectomy and Poland Syndrome (for Nebraska Only)	Jul. 1, 2022	Applicable Codes • Added CPT codes 15771 and 15772
Panniculectomy and Body Contouring Procedures (for New Jersey Only)	Jun. 1, 2022	Coverage Rationale • Removed notation indicating documentation may be requested as part of the review, including but not limited to photographs and physician office notes (refer to the *Documentation Requirements* section of the policy) • Updated documentation requirements; replaced criterion requiring: ○ "High quality color photographs of a full frontal view of the hanging pannus, a full-frontal view of pannus elevated that allows any skin damage can be evaluated, and a full-lateral view of the hanging pannus" with "high quality color photographs; *for Panniculectomy, photographs* of a full frontal view of the hanging pannus, a full-frontal view of pannus elevated that allows any skin damage can be evaluated, and a full-lateral view of the hanging pannus" ○ "*Submission of* diagnostic photographs *is required* via the external portal" with "diagnostic photographs *can be submitted* via the external portal" Supporting Information • Updated *References* section to reflect the most current information
Private Duty Nursing (PDN) Services	May 1, 2022	Additional State Considerations *California, Kansas, Maryland, Ohio, Rhode Island, and Wisconsin* • Replaced reference to "MCG™ Care Guidelines, [*25th* edition, *2021*], Private Duty Nursing" with "MCG™ Care Guidelines, [*26th* edition, *2022*], Private Duty Nursing"
Private Duty Nursing (PDN) Services (for Florida Only)	May 1, 2022	Coverage Rationale • Replaced references to "MCG™ Care Guidelines, [*25th* edition, *2021*], Private Duty Nursing" with "MCG™ Care Guidelines, [*26th* edition, *2022*], Private Duty Nursing"
Private Duty Nursing (PDN) Services (for Nebraska Only)	May 1, 2022	Coverage Rationale • Replaced reference to "MCG™ Care Guidelines, [*25th* edition, *2021*], Private Duty Nursing" with "MCG™ Care Guidelines, [*26th* edition, *2022*], Private Duty Nursing"
Private Duty Nursing (PDN) Services (for New Jersey Only)	May 1, 2022	Coverage Rationale • Replaced references to "MCG™ Care Guidelines, [*25th* edition, *2021*], Private Duty Nursing" with "MCG™ Care Guidelines, [*26th* edition, *2022*], Private Duty Nursing"

Coverage Determination Guideline Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Rhinoplasty and Other Nasal Surgeries (for New Jersey Only)	Jun. 1, 2022	Coverage Rationale *Documentation Requirements* • Revised list of clinical information to be documented in the medical notes, when applicable, to reflect/include: ○ Diagnosis ○ Detailed history of nasal symptoms including evaluation and management notes for the date of service and the note for the day the decision to perform surgery was made ○ Evidence of chronic sinusitis with treatment, response, and duration ○ History of treatments tried, failed, or contraindicated ○ Specific diagnostic image(s) that shows the abnormality for which surgery is being requested; consultation with requesting surgeon may be of benefit to select the optimal image(s) ▪ Note: Diagnostic images 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	**Indications for Coverage** Some states require coverage for services that UnitedHealthcare considers Cosmetic Procedures, such as repair of external Congenital Anomalies in the absence of a Functional Impairment. Please check the federal, state or contractual requirements for benefit coverage. Lysis intranasal Synechia (CPT code 30560) is considered reconstructive when: • There is a documented Functional Impairment (e.g., obstruction, pain or bleeding) due to intranasal Synechia (adhesions/scar bands); and • The Functional Impairment will be eliminated by lysis of the Synechia Repair of nasal vestibular stenosis or alar collapse (CPT code 30465and 30468) is considered reconstructive and medically necessary when all of the following criteria are present: • Prolonged, persistent obstructed nasal breathing due to internal and/or External Nasal Valve compromise (refer to the *Definitions* section of the policy); and • Internal valve compromise due to collapse of the upper lateral cartilage and/or External Nasal Valve compromise due to collapse of the alar (lower lateral) cartilage resulting in an anatomic Mechanical Nasal Airway Obstruction that is a primary contributing factor for obstructed nasal breathing; and • Photos clearly document internal and/or external valve collapse as the primary cause of an anatomic Mechanical Nasal Airway Obstruction and are consistent with the clinical exam; and • Other causes have been ruled out as the primary cause of nasal obstruction (e.g., sinusitis, allergic rhinitis, vasomotor rhinitis, nasal polyposis, adenoid hypertrophy, nasopharyngeal masses, nasal septal deviation, turbinate hypertrophy and choanal atresia) Note: For placement of absorbable nasal implants (e.g., Latera), refer to the Medical Policy titled Omnibus Codes (for New Jersey Only).

Coverage Determination Guideline Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Rhinoplasty and Other Nasal Surgeries (for New Jersey Only) (continued)	Jun. 1, 2022	image(s) ▪ Submission of diagnostic image(s) is required via the external portal at uhcprovider.com/paan; faxes will not be accepted ○ Diagnostic image(s) report(s) ○ Details of functional impairment, if applicable ○ Physician's plan of care ○ High-quality color image(s) (full face photos in cases of post-traumatic nasal deformity) ▪ Note: All images must be labeled with the: – Date taken – Applicable case number obtained at time of notification, and the member's name and ID number on the image(s) ▪ Submission of color image(s) is required via the external portal at uhcprovider.com/paan; faxes will not be accepted ○ In addition to the above, additional documentation requirements may apply for CPT code 30560; refer to the Coverage Determination Guideline titled *Cosmetic and*	Rhinophyma (CPT code 30120) is considered reconstructive and medically necessary when all of the following criteria are present: ● One of the following: ○ Prolonged, persistent obstructed nasal breathing due to rhinophyma; or ○ Chronic infection or bleeding unresponsive to medical management due to rhinophyma; and ● Photos clearly document rhinophyma as the primary cause of an anatomic Mechanical Nasal Airway Obstruction or chronic infection and are consistent with the clinical exam; and ● The proposed procedure is designed to correct the anatomic Mechanical Nasal Airway Obstruction and relieve the nasal airway obstruction by correcting the deformity or the proposed procedure is designed to address the chronic infection Rhinoplasty for Congenital Anomalies (CPT codes 30460 and 30462) is considered reconstructive and medically necessary when the following are present: ● Rhinoplasty is considered reconstructive when performed for a nasal deformity associated with congenital craniofacial anomalies including, but not limited to Pierre Robin, Apert Syndrome, Fraser Syndrome, Binder Syndrome, Goldenhar Syndrome, Nasal dermoids, Tessier Nasal Cleft (most commonly #1) or associated with a cleft lip or cleft palate Rhinoplasty-primary (CPT codes 30410 and 30420) is considered reconstructive and medically necessary when all of the following criteria are present: ● Prolonged, persistent obstructed nasal breathing due to nasal bone and septal deviation that are the primary causes of an anatomic Mechanical Nasal Airway Obstruction; and ● The nasal airway obstruction cannot be corrected by septoplasty alone as documented in the medical record; and ● Photos clearly document the nasal bone/septal deviation as the primary cause of an anatomic Mechanical Nasal Airway Obstruction and are

Coverage Determination Guideline Updates

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale

Rhinoplasty and Other Nasal Surgeries (for New Jersey Only) (continued)	Jun. 1, 2022	*Reconstructive Procedures (for New Jersey Only)*
		Supporting Information
		• Updated *References* section to reflect the most current information
			consistent with the clinical exam; and
			• The proposed procedure is designed to correct the anatomic Mechanical Nasal Airway Obstruction and relieve the nasal airway obstruction by centralizing the nasal bony pyramid (30410) and also straightening the septum (30420); and
			• One of the following is present:
			  ○ Nasal fracture with nasal bone displacement severe enough to cause nasal airway obstruction; or
			  ○ Residual large cutaneous defect following resection of a malignancy or nasal trauma; and
			• Nasal airway obstruction is causing significant symptoms (e.g., chronic rhinosinusitis, difficulty breathing); and
			• Obstructive symptoms persist despite conservative management for 4 weeks or greater, which includes, where appropriate, nasal steroids or immunotherapy
			
			Rhinoplasty-secondary (CPT codes 30430, 30435, and 30450) is primarily cosmetic. However, it is considered reconstructive and medically necessary when all of the following criteria are present:
			• Required as treatment of a complication/residual deformity from primary surgery performed to address a Functional Impairment when a documented Functional Impairment persists due to the complication/deformity (these codes are usually cosmetic); and
			• Photos clearly document the secondary deformity/complication as the primary cause of an anatomic Mechanical Nasal Airway Obstruction and are consistent with the clinical exam; and
			• The proposed procedure is designed to correct the anatomic Mechanical Nasal Airway Obstruction and relieve the nasal airway obstruction by correcting the deformity or treating the complication (these codes are usually cosmetic); and
			• Nasal airway obstruction is causing significant symptoms (e.g., chronic rhinosinusitis, difficulty breathing); and
			• Obstructive symptoms persist despite conservative management for 4

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Rhinoplasty and Other Nasal Surgeries (for New Jersey Only) (continued)	Jun. 1, 2022		weeks or greater, which includes, where appropriate, nasal steroids or immunotherapy Rhinoplasty-tip (CPT code 30400) is primarily cosmetic. However, it is considered reconstructive and medically necessary when all of the following criteria are present: • Prolonged, persistent obstructed nasal breathing due to tip drop that is the primary cause of an anatomic Mechanical Nasal Airway Obstruction (this code is usually cosmetic); and • Photos clearly document tip drop as the primary cause of an anatomic Mechanical Nasal Airway Obstruction and are consistent with the clinical exam (acute columellar-labial angle); and • The proposed procedure is designed to correct the anatomic Mechanical Nasal Airway Obstruction and relieve the nasal airway obstruction by lifting the nasal tip; and • Nasal airway obstruction is causing significant symptoms (e.g., chronic rhinosinusitis, difficulty breathing); and • Obstructive symptoms persist despite conservative management for 4 weeks or greater, which includes, where appropriate, nasal steroids or immunotherapy Septal Dermatoplasty (CPT code 30620) is considered reconstructive when: • There is a documented Functional Impairment (e.g., obstruction, pain or bleeding) due to diseased nasal mucosa; and • The Functional Impairment will be eliminated by a skin graft **Documentation Requirements** Provide medical notes documenting the following: • Diagnosis • Detailed history of nasal symptoms, including evaluation and management notes for the date of service and the note for the day the decision to perform surgery was made • Evidence of chronic sinusitis with treatment, response, and duration

Coverage Determination Guideline Updates

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale

Rhinoplasty and Other Nasal Surgeries (for New Jersey Only) (continued)	Jun. 1, 2022		• History of treatments tried, failed, or contraindicated
			• Specific diagnostic image(s) that show abnormality for which surgery is being requested; consultation with requesting surgeon may be of benefit to select the optimal images
			  ○ Note: Diagnostic images must be labeled with:
			  ▪ The date taken and
			  ▪ Applicable case number obtained at time of notification, or member's name and ID number on the image(s)
			• Submission of diagnostic image(s) is required via the external portal at www.uhcprovider.com/paan; faxes will not be accepted
			• Diagnostic image(s) report(s)
			• Details of functional impairment, if applicable
			• Physician's plan of care
			• High-quality color image(s) (full face photos in cases of post-traumatic the nasal deformity
			  ○ Note: All image(s) must be labeled with the:
			  ▪ Date taken and
			  ▪ Applicable case number obtained at time of notification, and member's name and ID number on the image(s)
			  ○ Submission of color image(s) is required via the external portal at www.uhcprovider.com/paan; faxes will not be accepted
			• In addition to the above, additional documentation requirements may apply for CPT code 30560; refer to the Coverage Determination Guideline titled Cosmetic and Reconstructive Procedures (for New Jersey Only)
			
			Coverage Limitations and Exclusions
			UnitedHealthcare excludes Cosmetic Procedures from coverage including but not limited to the following:
			• Procedures that correct an anatomical Congenital Anomaly without improving or restoring Physiological Function are considered Cosmetic Procedures. The fact that a Covered Person may suffer psychological consequences or socially avoidant behavior as a result of an Injury, Sickness or Congenital Anomaly does not classify surgery (or other procedures done

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Rhinoplasty and Other Nasal Surgeries (for New Jersey Only) (continued)	Jun. 1, 2022		to relieve such consequences or behavior) as a Reconstructive Procedure. • Rhinoplasty, unless rhinoplasty criteria above are met. • Any procedure that does not meet the reconstructive criteria. • Rhinoplasty procedures performed to improve appearance (check member specific benefit plan document).

Utilization Review Guideline Updates

Updated

Policy Title	Effective Date	Summary of Changes
Elective Inpatient Services	Jul. 1, 2022	**Application** • Added language to indicate this Medical Benefit Drug Policy does not apply to the state of New Jersey; refer to the state's Medicaid clinical policy **Coverage Rationale** • Updated list of procedure-related factors that may increase risk of anesthetic complications; removed "class III obesity (body mass index greater than 40) with hemodynamic or respiratory problems" (duplicative of "American Society of Anesthesiologists class III or greater") **Definitions** • Added definition of "Hemodynamic Instability" • Updated definition of "Acute Kidney Injury" **Supporting Information** • Updated *References* section to reflect the most current information
Elective Inpatient Services (for New Jersey Only)	Jun. 1, 2022	**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*"

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Provider Administered Drugs – Site of Care (for New Jersey Only)	Jun. 1, 2022	**Related Policies** • Added reference link to the Medical Benefit Drug Policy titled: ○ *Alpha$_1$-Proteinase Inhibitors* ○ *Amondys 45™ (Casimersen)* ○ *Complement Inhibitors (Soliris® and Ultomiris®)* ○ *Exondys 51® (Eteplirsen)* ○ *Immune Globulin (IVIG and SCIG)* ○ *Medical Therapies for Enzyme Deficiencies* ○ *Vyondys 53™ (Golodirsen)*	This guideline addresses the criteria for consideration of allowing hospital outpatient facility medication infusion services. This includes claim submission for hospital based services with the following CMS/AMA Place of Service codes: • 22 On Campus-Outpatient Hospital; and • 19 Off Campus-Outpatient Hospital Alternative sites of care, such as non-hospital outpatient infusion, physician office, ambulatory infusion or home infusion services are well accepted places of service for medication infusion therapy. If a patient does not meet criteria for outpatient hospital facility infusion, alternative sites of care may be used. Outpatient hospital facility-based intravenous medication infusion is medically necessary for individuals who meet at least one of the following criteria (submission of medical records is required):

Utilization Review Guideline Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Provider Administered Drugs – Site of Care (for New Jersey Only) (continued)	Jun. 1, 2022	**Application and Coverage Rationale** • Revised list of medications that require healthcare provider administration; added: ○ Aldurazyme® (laronidase) ○ Amondys 45™ (casimersen) ○ Aralast NP® (A1-PI) ○ Asceniv™ (IV) ○ Bivigam® (IV) ○ Carimune® NF (IV) ○ Cutaquig® (SC) ○ Cuvitru® (SC) ○ Elaprase® (idursulfase) ○ Exondys 51® (eteplirsen) ○ Fabrazyme® (agalsidase beta) ○ Flebogamma® DIF (IV) ○ Gammagard® Liquid (IV, SC) ○ Gammagard® S/D (IV) ○ Gammaked™ (IV, SC) ○ Gammaplex® (IV) ○ Gamunex®-C (IV, SC) ○ Glassia® (A1-PI) ○ Hizentra® (SC) ○ HyQvia® (SC) ○ Kanuma® (sebelipase alfa) ○ Lumizyme® (alglucosidase alfa) ○ Mepsevii™ (vestronidase alfa-vjbk) ○ Naglazyme® (galsulfase) ○ Octagam® (IV) ○ Panzyga® (IV) ○ Privigen® (IV)	• Documentation that the individual is medically unstable for administration of the prescribed medication at the alternative sites of care as determined by any of the following: ○ The individual's complex medical status or therapy requires enhanced monitoring and potential intervention above and beyond the capabilities of the office or home infusion setting; or ○ The individual's documented history of a significant comorbidity (e.g., cardiopulmonary disorder) or fluid overload status that precludes treatment at an alternative Site of Care; or ○ Outpatient treatment in the home or office setting presents a health risk due to a clinically significant physical or cognitive impairment; or ○ Difficulty establishing and maintaining patent vascular access; or ○ To initiate or re-initiate products for a short duration (e.g., 4 weeks) or • Documentation (e.g., infusion records, medical records) of episodes of severe or potentially life-threatening adverse events (e.g., anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure) that have not been responsive to acetaminophen, steroids, diphenhydramine, fluids, infusion rate reductions, or other pre-medications, thereby increasing risk to the individual when administration is in the home or office setting; or • Initial infusion or re-initiation of therapy after more than 6 months; or • Homecare or infusion provider has deemed that the individual, home caregiver, or home environment is not suitable for home infusion therapy (if the prescriber cannot infuse in the office setting) Ongoing outpatient hospital facility-based infusion duration of therapy will be no more than 6 months to allow for reassessment of the individual's ability to receive therapy at an alternative Site of Care. • Actemra® (tocilizumab) • Aldurazyme® (laronidase) • Amondys 45™ (casimersen) • Aralast NP® (A1-PI) • Asceniv™ (IV)

Utilization Review Guideline Updates

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Provider Administered Drugs – Site of Care (for New Jersey Only) (continued)	Jun. 1, 2022	○ Prolastin®-C (A1-PI) ○ Revcovi® (elapegademase-lvlr) ○ Soliris® (eculizumab) ○ Ultomiris® (ravulizumab-cwvz) ○ Vimizim® (elosulfase alfa) ○ Viltepso™ (viltolarsen) ○ Vyondys 53™ (golodirsen) ○ Xembify® (SC) ○ Zemaira® (A1-PI) **Applicable Codes** ● Added CPT codes 90283 and 90284 ● Added HCPCS codes J0180, J0221, J0256, J0257, J1300, J1303, J1322, J1426, J1427, J1428, J1429, J1458, J1459, J1554, J1555, J1556, J1557, J1558, J1559, J1561, J1566, J1568, J1569, J1572, J1575, J1599, J1743, J1931, J2840, J3397, and J3590	● Avsola™ (infliximab-axxq) ● Bivigam® (IV) ● Carimune® NF (IV) ● Cutaquig® (SC) ● Cuvitru® (SC) ● Elaprase® (idursulfase) ● Entyvio® (vedolizumab) ● Exondys 51® (eteplirsen) ● Fabrazyme® (agalsidase beta) ● Flebogamma® DIF (IV) ● Gammagard® Liquid (IV, SC) ● Gammagard® S/D (IV) ● Gammaked™ (IV, SC) ● Gammaplex® (IV) ● Gamunex®-C (IV, SC) ● Glassia® (A1-PI) ● Hizentra® (SC) ● HyQvia® (SC) ● Ilumya™ (tildrakizumab-asmn) ● Inflectra® (infliximab-dyyb) ● Kanuma® (sebelipase alfa) ● Lumizyme® (alglucosidase alfa) ● Mepsevii™ (vestronidase alfa-vjbk) ● Naglazyme® (galsulfase) ● Octagam® (IV) ● Orencia® (abatacept) ● Panzyga® (IV) ● Privigen® (IV) ● Prolastin®-C (A1-PI) ● Remicade® (infliximab) ● Renflexis® (infliximab-abda) ● Revcovi® (elapegademase-lvlr) ● Simponi Aria® (golimumab)

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Provider Administered Drugs – Site of Care (for New Jersey Only) (continued)	Jun. 1, 2022		• Soliris® (eculizumab) • Ultomiris® (ravulizumab-cwvz) • Vimizim® (elosulfase alfa) • Viltepso™ (viltolarsen) • Vyondys 53™ (golodirsen) • Xembify® (SC) • Zemaira® (A1-PI)

General Information

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

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

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

Policy Update Classifications

New

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

Updated

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

Revised

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

Replaced

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

Retired

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

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