United Healthcare Community Plan

UnitedHealthcare Community Plan of Indiana
Medical Policy Update Bulletin: June 2022

InterQual® Release Dates Removed

Effective Jun. 1, 2022, all references to specific InterQual® release dates will be removed from the Medical Policies, Coverage Determination Guidelines, and Utilization Review Guidelines which contain language pertaining to InterQual® criteria; refer to the most current version of the InterQual® criteria, when applicable.

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Medical Policy Updates

Updated

Policy Title	Effective Date	Summary of Changes
Deep Brain and Cortical Stimulation (for Indiana Only)	Jun. 1, 2022	**Coverage Rationale** • Updated language to clarify responsive cortical stimulation is proven and medically necessary for treating *refractory* partial or focal seizure disorder • Removed reference to specific InterQual® release date; refer to the most current InterQual® criteria **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information
Surgical Treatment for Spine Pain (for Indiana Only)	Jul. 1, 2022	**Applicable Codes** • Removed CPT code 20939; refer to the Medical Policy titled *Spinal Fusion Enhancement Products*

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Obstructive and Central Sleep Apnea Treatment (for Indiana Only)	Jul. 1, 2022	**Coverage Rationale** *Nonsurgical Treatment* • Revised list of services/devices that are unproven and not medically necessary for treating Obstructive Sleep Apnea (OSA); added: ○ Non-surgical electrical muscular training ○ Morning repositioning devices *Surgical Treatment* • Revised coverage criteria for implantable hypoglossal nerve stimulation: ○ Added criterion requiring total AHI < 25% for central + mixed apneas ○ Replaced reference to "polysomnography" with "Polysomnography *(Attended)*"	**Nonsurgical Treatment** Removable Oral Appliances are proven and medically necessary for treating Obstructive Sleep Apnea (OSA) as documented by a sleep study (e.g., polysomnography or Home Sleep Apnea Testing). For many individuals, oral appliance therapy (OAT) may be an effective alternative to failed continuous positive airway pressure (CPAP) therapy. Documentation of the following is required: • A patient presenting with symptoms of OSA be seen in a face-to-face evaluation with a qualified physician (MD or DO) trained in sleep medicine or with an Advanced Practice Provider working under the direct supervision of a sleep medicine physician prior to beginning treatment for OAT (AASM and AADSM, December 2012, AAO-HNS, November 2019) • A treating physician (MD or DO) or an Advanced Practice Provider must diagnose OSA and recommend course of treatment (AAO-HNS, November 2019) • If the patient refuses CPAP therapy, documentation of the refusal from the patient's treating physician (MD or DO) or an Advanced Practice Provider must be supplied

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Obstructive and Central Sleep Apnea Treatment (for Indiana Only) (continued)	Jul. 1, 2022	• Revised list of surgical procedures that are unproven and not medically necessary for treating Obstructive Sleep Apnea (OSA); added "distraction osteogenesis for maxillary expansion (DOME)" **Definitions** • Added definition of "Polysomnogram (Attended)" **Applicable Codes** • Added CPT/HCPCS codes 21142, E1399, K1028, and K1029 • Added notation to indicate: ○ HCPCS code E0486 applies to the custom fabricated oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable and includes fitting and adjustment ○ Dental services (e.g., HCPCS codes D9947, D9948, and D9949) are excluded from coverage under the medical plan; the member specific benefit plan document must be referenced prior to determining any coverage decision **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information	For information on snoring and Oral Appliances, refer to the Coverage Determination Guideline titled Durable Medical Equipment, Orthotics, Medical Supplies and Repairs/Replacements (for Indiana Only). For medical necessity clinical coverage criteria for removable Oral Appliances, refer to the InterQual® CP: Durable Medical Equipment, Noninvasive Airway Assistive Devices. Click here to view the InterQual® criteria. The following are unproven and not medically necessary due to insufficient evidence of efficacy: • Devices for treating Positional OSA • Nasal dilator devices for treating OSA • Removable Oral Appliances for treating Central Sleep Apnea • Prefabricated Oral Appliance/Device • Non-surgical electrical muscular training • Morning repositioning devices **Surgical Treatment** The following surgical procedures are proven and medically necessary for treating OSA as documented by polysomnography. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures: • Uvulopalatopharyngoplasty (UPPP) • Osteotomy, Anterior Segment, Mandible • Maxillomandibular Advancement Click here to view the InterQual® criteria. Implantable hypoglossal nerve stimulation is proven and medically necessary in an adult patient with moderate to severe OSA when all the following criteria are met: • Body Mass Index of (BMI) less than or equal to 32kg/m^2; and

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Obstructive and Central Sleep Apnea Treatment (for Indiana Only)
(continued
	Jul. 1, 2022		• Apnea Hypopnea Index (AHI) of ≥ 20 and ≤ 65 as determined with Polysomnography (Attended); and
			• Total AHI < 25% for central + mixed apneas; and
			• Absence of complete concentric collapse at the soft palate level; and
			• Failure or intolerance of Positive Airway Pressure (PAP) treatments [such as continuous positive airway pressure (CPAP) or bi-level positive airway pressure (BPAP) machines]
			  ○ PAP failure is defined as an inability to eliminate OSA (AHI of greater than 20 despite PAP usage) and PAP intolerance is defined as:
			  ▪ Inability to use PAP (greater than 5 nights per week of usage; usage defined as greater than 4 hours of use per night); or
			  ▪ Unwillingness to use PAP (for example, a patient returns the PAP system after attempting to use it)
			
			Implantable neurostimulation devices for the treatment of Central Sleep Apnea (CSA) are unproven and not medically necessary due to insufficient evidence of safety and/or efficacy.
			
			The following surgical procedures are unproven and not medically necessary for treating OSA due to insufficient evidence of efficacy:
			• Laser-assisted uvulopalatoplasty (LAUP)
			• Lingual suspension – Also referred to as tongue stabilization, tongue stitch or tongue fixation
			• Palatal implants
			• Radiofrequency ablation of the soft palate and/or tongue base
			• Transoral robotic surgery (TORS)
			• Distraction osteogenesis for maxillary expansion (DOME)

Spinal Fusion Enhancement Products (for Indiana Only)	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*	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

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Spinal Fusion Enhancement Products (for Indiana Only) (continued)	Jul. 1, 2022	*marrow aspirate used for bone grafting)*" **Applicable Codes** • Added CPT code 20939 **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, and *References* section to reflect the most current information	• 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 of 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

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Spinal Fusion Enhancement Products (for Indiana Only) (continued)	Jul. 1, 2022		• 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 included above • The OptiMesh® Expandable Interbody Fusion System
Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins (for Indiana Only)	Jul. 1, 2022	Coverage Rationale *Varicose Vein Ablative and Stripping Procedures* • Replaced language indicating "*the initial and subsequent radiofrequency ablation, endovenous laser ablation,* stripping, *ligation and excision of the great saphenous vein (GSV) and small saphenous veins (SSV)* are considered reconstructive, proven, and medically necessary in certain circumstances" with "*Varicose Vein ablative and* stripping *procedures* are considered reconstructive, proven, and medically necessary in certain circumstances" • Revised language pertaining to medical necessity clinical coverage criteria: ○ Added reference to the InterQual® CP: Procedures: ▪ Ablation, Endovenous, Varicose Vein ▪ Ligation/Excision, Varicose Vein, +/- Stripping	**Varicose Vein Ablative and Stripping Procedures** Varicose vein ablative and stripping procedures are considered reconstructive, proven, and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures: • Ablation, Endovenous, Varicose Vein • Ligation/Excision, Varicose Vein, +/- Stripping Click here to view the InterQual® criteria. Refer to the Coding Clarification section. Adherence to American Medical Association (AMA) coding guidance is required when requesting coverage of endovenous ablation procedures. Note that only one primary code may be requested for the initial vein treated, and only one add-on code per extremity may be requested for any subsequent vein(s) treated. Endovenous mechanochemical ablation (MOCA) of Varicose Veins is unproven and not medically necessary due to insufficient evidence of efficacy. **Ligation Procedures** The following procedure is proven and medically necessary: • Ligation at the saphenofemoral junction, as a stand-alone procedure, when used to prevent the propagation of an active clot to the deep venous system in individuals with ascending Superficial Thrombophlebitis who fail or are intolerant of anticoagulation therapy. The following procedure is proven and medically necessary in certain circumstances:

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Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins (for Indiana Only) (continued)	Jul. 1, 2022	○ Removed reference to the InterQual® CP: Procedures, Ligation, Subfascial, Endoscopic, Perforating Vein *Other Procedures* • Added language to indicate Sclerotherapy is proven and medically necessary in certain circumstances; for medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Sclerotherapy, Varicose Vein • Removed language indicating endovenous low-nitrogen foam sclerotherapy of incompetent GSV, lesser saphenous veins, and accessory saphenous veins is unproven and not medically necessary for treating Venous Reflux *Documentation Requirements* • Added language to indicate medical notes documenting the following are required, when applicable: ○ Diagnosis ○ History of the medical condition(s) requiring treatment or surgical intervention ○ Documentation of signs and symptoms; including onset,	• Ligation, subfascial, endoscopic surgery for treatment of perforating veins associated with chronic Venous Insufficiency. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Ligation, Subfascial, Endoscopic, Perforating Vein. Click here to view the InterQual® criteria. The following procedures are unproven and not medically necessary for treating Venous Reflux due to insufficient evidence of efficacy: • Ligation of the GSV at the saphenofemoral junction, as a stand-alone procedure • Ligation of the SSV at the saphenopopliteal junction, as a stand-alone procedure • Ligation at the saphenofemoral junction, as an adjunct to radiofrequency ablation or endovenous laser ablation of the main saphenous veins **Ambulatory Phlebectomy** Ambulatory phlebectomy for treating varicose veins is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Ambulatory Phlebectomy, Varicose Vein for: • Hook Phlebectomy • Microphlebectomy • Mini Phlebectomy • Stab Avulsion • Stab Phlebectomy Click here to view the InterQual® criteria. **Other Procedures** Sclerotherapy is proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Sclerotherapy, Varicose Vein.

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Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins (for Indiana Only) (continued)	Jul. 1, 2022	duration, frequency, and which extremity (right, left, or both) ○ Relevant medical history, including: ▪ DVT (deep vein thrombosis) ▪ Aneurysm ▪ Tortuosity ○ Physical exam, including: ▪ Which extremity (right, left, or both) ▪ Vein(s) that will be treated [e.g., great saphenous vein (GSV) and small saphenous vein (SSV), etc.] ▪ Vein diameter including the specific anatomic location where the measurement was taken (e.g., proximal thigh, proximal calf, etc.) ▪ Duration of reflux including the position of member at the time of measurement and the anatomic location where the measurement was taken [e.g., standing, saphenofemoral junction (SFJ)] ○ Severity of pain or other symptoms that interfere with activities of daily living related	Click here to view the InterQual® criteria. The following procedures are unproven and not medically necessary for treating Venous Reflux due to insufficient evidence of efficacy: • Endovascular embolization of Varicose Veins using cyanoacrylate-based adhesive **Documentation Requirements** Medical notes documenting the following, when applicable: • Diagnosis • History of the medical condition(s) requiring treatment or surgical intervention • Documentation of signs and symptoms; including onset, duration, frequency, and which extremity (right, left, or both) • Relevant medical history, including: ○ DVT (deep vein thrombosis) ○ Aneurysm ○ Tortuosity • Physical exam, including: ○ Which extremity (right, left, or both) ○ Vein(s) that will be treated [e.g., great saphenous vein (GSV) and small saphenous vein (SSV), etc.] ○ Vein diameter including the specific anatomic location where the measurement was taken (e.g., proximal thigh, proximal calf, etc.) ○ Duration of reflux including the position of member at the time of measurement and the anatomic location where the measurement was taken [e.g., standing, saphenofemoral junction (SFJ)] • Severity of pain or other symptoms that interfere with activities of daily living related to vein disease • Functional disability(ies), as documented on a validated functional disability scale, (interfering with the ability to stand or sit for long periods of time, such as, preparing meals, performing work functions, driving, walking, etc.) • Diagnostic study/imaging reports

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Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins (for Indiana Only) (continued)	Jul. 1, 2022	to vein disease ○ Functional disability(ies), as documented on a validated functional disability scale, (interfering with the ability to stand or sit for long periods of time, such as, preparing meals, performing work functions, driving, walking, etc.) ○ Diagnostic study/imaging reports ○ Pulses ○ Prior conservative treatments tried, failed, or contraindicated. Include the dates and reason for discontinuation ○ Proposed treatment plan with procedure code, including specific vein(s) that will be treated (e.g., great saphenous vein (GSV) and small saphenous vein (SSV), etc.), which extremity (left, right, or both) and date of procedure for each vein to be treated Definitions • Added definition of: ○ Accessory/Tributary Vein ○ Congenital Anomaly ○ Cosmetic Procedures ○ Duplex Ultrasonography ○ Endovenous Ablation ○ Functional or Physical	• Pulses • Prior conservative treatments tried, failed, or contraindicated. Include the dates and reason for discontinuation • Proposed treatment plan with procedure code, including specific vein(s) that will be treated [e.g., great saphenous vein (GSV) and small saphenous vein (SSV), etc.], which extremity (left, right, or both) and date of procedure for each vein to be treated

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins (for Indiana Only) (continued)	Jul. 1, 2022	Impairment ○ Great Saphenous Vein (GSV) ○ Junctional Reflux ○ Ligation ○ Moderate to Severe Pain ○ Reconstructive Procedures ○ Reticular Vein ○ Sickness ○ Small Saphenous Vein ○ Spider Vein ○ Stripping ○ Superficial Thrombophlebitis ○ Telangiectasia ○ Varicose Veins ○ Venous Reflux/Insufficiency ○ Venous Stasis Dermatitis **Benefit Considerations** • Removed language indicating procedures that correct an anatomical Congenital Anomaly without improving or restoring physiologic function are considered Cosmetic Procedures and therefore excluded from coverage; 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 to relieve such consequences or behavior) as a reconstructive procedure	

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Surgical and Ablative Procedures for Venous Insufficiency and Varicose Veins (for Indiana Only) (continued)	Jul. 1, 2022	Supporting Information • Added *Description of Services* section • Updated *Clinical Evidence* and *References* sections to reflect the most current information	

Medical Benefit Drug Policy Updates

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Complement Inhibitors (Soliris® & Ultomiris®) (for Indiana Only)	Jul. 1, 2022	Coverage Rationale • Removed language indicating Soliris is proven and medically necessary for initial therapy for treatment of generalized Myasthenia Gravis when the patient is currently on a stable dose (at least two months) of immunosuppressive therapy	This policy refers to the following complement inhibitor drug products: • Soliris® (eculizumab) • Ultomiris® (ravulizumab-cwvz) Refer to the policy for complete details.
Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors (for Indiana Only)	Jul. 1, 2022	Coverage Rationale • Revised list of applicable vascular endothelial growth factor (VEGF) inhibitors and dual VEGF/angiopoietin-2 (Ang-2) inhibitors; added Byooviz™ (ranibizumab-nuna) and Vabysmo™ (faricimab-svoa) • Added language to indicate: ○ Dual VEGF/Ang-2 inhibitor administration is no more than 12 doses per year per eye, regardless of diagnosis ○ Byooviz (ranibizumab-nuna) is proven and medically necessary for the treatment of: ▪ Neovascular age - related macular degeneration (AMD) ▪ Macular Edema Following Retinal Vein Occlusion (RVO) ▪ Myopic Choroidal Neovascularization	This policy provides information about the use of certain specialty pharmacy medications administered by the intravitreal route for ophthalmologic conditions. This policy refers to the following vascular endothelial growth factor (VEGF) inhibitors and dual VEGF/angiopoietin-2 (Ang-2) inhibitors: • Avastin® (bevacizumab) • Beovu® (brolucizumab-dbll) • Byooviz™ (ranibizumab-nuna) • Eylea™ (aflibercept) • Lucentis® (ranibizumab) • Macugen® (pegaptanib) • Vabysmo™ (faricimab-svoa) The following information pertains to medical necessity review: **General Requirements** For initial and continuation of therapy, intravitreal VEGF inhibitor administration is no more than 12 doses per year per eye, regardless of diagnosis. **Diagnosis-Specific Requirements** Lucentis is proven and medically necessary for the treatment of certain conditions outlined within the InterQual® criteria. For medical necessity clinical coverage criteria for Lucentis, refer to the current release of the InterQual®

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Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors (for Indiana Only) (continued)	Jul. 1, 2022	(mCNV) ○ Vabysmo (faricimab-svoa) is proven and medically necessary for the treatment of: ▪ Neovascular age-related macular degeneration (AMD) ▪ Diabetic macular edema (DME) **Applicable Codes** ● Added HCPCS codes C9097, J3490, J3590, and Q5124 ● Added list of applicable diagnosis codes for HCPCS codes C9097, J3490, J3590, and Q5124 ● Added Maximum Allowed Frequencies for: *Byooviz (Ranibizumab-Nuna)* ○ Neovascular age-related macular degeneration: The recommended dose is 0.5 mg (0.05 ML) administered by intravitreal injection once a month (approximately 28 days) ▪ Patients may be treated with 3 monthly doses followed by less frequent dosing ▪ Patients may also be treated with one dose every 3 months after 4 monthly doses	guideline, CP: Specialty Rx Non-Oncology Ranibizumab (Lucentis). Click here to view the InterQual® criteria. Eylea is proven and medically necessary for the treatment of certain conditions outlined within the InterQual® criteria. For medical necessity clinical coverage criteria for Eylea, refer to the current release of the InterQual® guideline, CP: Specialty Rx Non-Oncology Aflibercept (Eylea). Click here to view the InterQual® criteria. Beovu is proven and medically necessary for the treatment of certain conditions outlined within the InterQual® criteria. For medical necessity clinical coverage criteria for Beovu, refer to the current release of the InterQual® guideline, CP: Specialty Rx Non-Oncology Brolucizumab (Beovu). Click here to view the InterQual® criteria. Macugen is proven and medically necessary for the treatment of certain conditions outlined within the InterQual® criteria. For medical necessity clinical coverage criteria for Macugen, refer to the current release of the InterQual® guideline, CP: Specialty Rx Non-Oncology Pegaptanib sodium (Macugen). Click here to view the InterQual® criteria. Avastin (bevacizumab) is proven and medically necessary for the treatment of certain conditions outlined within the InterQual® criteria. For medical necessity clinical coverage criteria for Avastin, refer to the current release of the InterQual® guideline, CP: Specialty Rx Non-Oncology Bevacizumab (Avastin) Intravitreal. Click here to view the InterQual® criteria.

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Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors (for Indiana Only) (continued)	Jul. 1, 2022	▪ Maximum of 12 doses per year per eye ○ Macular edema following retinal vein occlusion (RVO): The recommended dose is 0.5 mg (0.05 ML) administered by intravitreal injection once a month (approximately 28 days); maximum of 12 doses per year per eye ○ Myopic choroidal neovascularization (mCNV): The recommended dose is 0.5 mg (0.05 ML) administered by intravitreal injection once a month (approximately 28 days) for up to 3 months *Vabysmo (Faricimab)* ○ Diabetic macular edema: ▪ The recommended dose is 6 mg by intravitreal injection every 4 weeks for the first 4 doses, followed by one of the following three regimens: – Weeks 28 and 44 – Weeks 24, 36, and 48 – Weeks 20, 28, 36 and 44 ▪ Although most patients require dosing every 8 weeks, some patients may need dosing every 4	Byooviz (ranibizumab-nuna) is proven and medically necessary for the treatment of: • Neovascular age-related macular degeneration (AMD) • Macular Edema Following Retinal Vein Occlusion (RVO) • Myopic Choroidal Neovascularization (mCNV) Vabysmo (faricimab-svoa) is proven and medically necessary for the treatment of: • Neovascular age-related macular degeneration (AMD) • Diabetic macular edema (DME)

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Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors (for Indiana Only) (continued)	Jul. 1, 2022	weeks ▪ Maximum of 12 doses per year per eye ○ Neovascular age-related macular degeneration: ▪ The recommended dose is one of the following regimens: – 6 mg administered by intravitreal injection every 4 weeks for at least 4 doses, followed by extensions of up to 4 week interval increments or reductions of up to 8 week interval increments based on response – 6 mg administered every 4 weeks for the first 6 doses, followed by 6 mg dose via intravitreal injections at intervals of every 8 weeks over the next 28 weeks ▪ Although most patients require dosing every 8 weeks, some patients may need dosing every 4 weeks ▪ Maximum of 12 doses per year per eye	

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Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors (for Indiana Only) (continued)	Jul. 1, 2022	Supporting Information • Added *Background*, *Clinical Evidence*, *FDA*, and *References* sections	
White Blood Cell Colony Stimulating Factors (for Indiana Only)	Jul. 1, 2022	Coverage Rationale • Revised list of applicable short-acting filgrastim agents; added Releuko® (filgrastim-ayow) • Replaced Diagnosis-Specific Criteria with instruction to refer to the current release of the InterQual® guideline for medical necessity clinical coverage criteria for: ○ Fulphila ○ Nivestym ○ Nyvepria ○ Udenyca ○ Ziextenzo • Added language to indicate Releuko is proven and medically necessary for the treatment of the following indications when the criteria listed in the policy are met: ○ Bone marrow/stem cell transplant ○ Acute myeloid leukemia (AML) induction or consolidation therapy ○ Primary prophylaxis of chemotherapy-induced febrile	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) ○ Releuko® (filgrastim-ayow) ○ Zarxio® (filgrastim-sndz) • Leukine® (sargramostim) The following drug products are medically necessary for the treatment of certain conditions outlined within the InterQual® criteria; for medical necessity clinical coverage criteria, refer to the current release of the InterQual® guideline: • Long-acting pegfilgrastim agents: ○ Fulphila® (pegfilgrastim-jmdb): CP: Specialty Rx Oncology, Pegfilgrastim-jmdb (Fulphila) ○ Neulasta® (pegfilgrastim): CP: Specialty Rx Oncology, Pegfilgrastim (Neulasta) ○ Nyvepria™ (pegfilgrastim-apgf): CP: Specialty Rx Oncology, Nyvepria

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
White Blood Cell Colony Stimulating Factors (for Indiana Only) (continued)	Jul. 1, 2022	neutropenia (FN) ○ Secondary prophylaxis of febrile neutropenia (FN) ○ Treatment of febrile neutropenia ○ Severe chronic neutropenia (SCN) ○ Hematopoietic syndrome of acute radiation syndrome **Definitions** • Updated definition of "Febrile Neutropenia" **Supporting Information** • Updated *FDA* and *References* sections to reflect the most current information	(pegfilgrastim-apgf) ○ Udenyca® (pegfilgrastim-cbqv): CP: Specialty Rx Oncology, Pegfilgrastim-cbqv (Udenyca) ○ Ziextenzo® (pegfilgrastim-bmez): CP: Specialty Rx Oncology, Pegfilgrastim-bmez (Ziextenzo). • Short-acting filgrastim agents: ○ Granix® (tbo-filgrastim): CP: Specialty Rx Oncology, Tbo-filgrastim (Granix) ○ Neupogen® (filgrastim): CP: Specialty Rx Oncology, Filgrastim (Neupogen) ○ Nivestym® (filgrastim-aafi): CP: Specialty Rx Oncology, Filgrastim-aafi (Nivestym) ○ Zarxio® (filgrastim-sndz): CP: Specialty Rx Oncology, Filgrastim-sndz (Zarxio) • Leukine® (sargramostim): CP: Specialty Rx Oncology, Sargramostim (Leukine) Click here to view the InterQual® criteria. **Short-Acting Filgrastim Agents (Releuko):** Coverage for Releuko will be provided contingent on the coverage criteria in the Diagnosis-Specific Criteria section. **Diagnosis-Specific Criteria** • Bone Marrow/Stem Cell Transplant (Releuko) Releuko is proven and medically necessary when the following criteria are met: ○ One of the following: ▪ Patient has non-myeloid malignancies and is undergoing myeloablative chemotherapy followed by autologous or allogeneic bone marrow transplant (BMT); or ▪ Used for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis; or

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
White Blood Cell Colony Stimulating Factors (for Indiana Only) (continued)	Jul. 1, 2022		▪ Patient has had a peripheral stem cell transplant (PSCT) and has received myeloablative chemotherapy; • Acute Myeloid Leukemia (AML) Induction or Consolidation Therapy (Releuko) Releuko is proven and medically necessary when the following criteria are met: ○ Both of the following: ▪ Diagnosis of AML; and ▪ Patient has completed either induction or consolidation chemotherapy • Primary Prophylaxis of Chemotherapy-Induced Febrile Neutropenia (FN) (Releuko) Releuko is proven and medically necessary when the following criteria are met: ○ One of the following: ▪ Patient is receiving myelosuppressive anticancer drugs given with a curative intent (curative chemotherapy, chemotherapy in curative adjuvant/neoadjuvant setting); or ▪ Patient is receiving myelosuppressive anticancer drugs for definitive therapy (bridge to stem cell transplant, organ transplant, definitive surgery for oligometastatic disease); and ○ One of the following: ▪ Patient is receiving dose dense MVAC (methotrexate, vinblastine, doxorubicin, cisplatin) for bladder cancer; or ▪ Patient is receiving dose dense AC (doxorubicin, cyclophosphamide) followed by dose-dense paclitaxel for breast cancer; or ▪ Patient is receiving chemotherapy regimen(s) associated with > 20% incidence of FN; or

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
White Blood Cell Colony Stimulating Factors (for Indiana Only) (continued)	Jul. 1, 2022		○ Both of the following: ▪ Patient is receiving chemotherapy regimen(s) associated with 10-20% incidence of FN; and ▪ Patient has one or more risk factors for chemotherapy-induced febrile neutropenia: – Persistent neutropenia due to prior chemotherapy, radiation therapy or bone marrow involvement by tumor (< 500 neutrophils/mcL or < 1,000 neutrophils/mcL and a predicted decline to ≤ 500 neutrophils/mcL over the next 48 hours) – Liver dysfunction (bilirubin > 2.0) – Renal dysfunction (creatinine clearance < 50) – Age > 65 years receiving full chemotherapy dose intensity *Note: Chemotherapy regimen associated incidence of FN will be based on the clinical trial(s) with the highest level of evidence. Chemotherapy regimens and associated incidence of FN based on the clinical trial(s) according to the grade based on Common Terminology Criteria for Adverse Events (CTCAE) by the National Cancer Institute (NCI) criteria are available for reference at uhcprovider.com. The reference document is not a substitute for the experience and judgment of a physician or other health care professional. Any clinician must use independent medical judgment in the context of individual clinical circumstances to determine any patient's care or treatment. • Secondary Prophylaxis of Febrile Neutropenia (FN) (Releuko) Releuko is proven and medically necessary when the following criteria are met: ○ One of the following: ▪ Patient is receiving myelosuppressive anticancer drugs given with a curative intent (curative chemotherapy, chemotherapy in curative adjuvant/neoadjuvant setting); or ▪ Patient is receiving myelosuppressive anticancer drugs for definitive

Medical Benefit Drug Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
White Blood Cell Colony Stimulating Factors (for Indiana Only) (continued)	Jul. 1, 2022		therapy (bridge to stem cell transplant, organ transplant, definitive surgery for oligometastatic disease); and ○ One of the following: ▪ Patient has a documented history of a neutropenic event (febrile neutropenia or low neutrophil count leading to delay of subsequent cycle) during a previous cycle of the same chemotherapy regimen at full dose for which primary prophylaxis was not received; or ▪ Patient has a documented history of neutropenic event from a previous course of chemotherapy. • Treatment of Febrile Neutropenia (FN) (Releuko) (Off-Label) Releuko is proven and medically necessary when the following criteria are met: ○ All of the following: ▪ Diagnosis of febrile neutropenia; and ▪ Patient has not received long-acting prophylactic pegfilgrastim in the last 14 days; and ▪ Patient has one or more risk factors for an infection-associated complication such as: – Sepsis syndrome – Age > 65 years – Absolute Neutrophil Count (ANC) < 100/mcL – Neutropenia expected to be > 10 days in duration – Pneumonia – Clinically documented infections including invasive fungal infection – Hospitalization at the time of fever – Prior episode(s) of FN • Severe Chronic Neutropenia (SCN) (Releuko) Reluko is proven and medically necessary when the following criteria are

Medical Benefit Drug Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
White Blood Cell Colony Stimulating Factors (for Indiana Only) (continued)	Jul. 1, 2022		met: ○ All of the following: ▪ Diagnosis of SCN (i.e., congenital, cyclic, and idiopathic neutropenias with chronic ANC ≤ 500 neutrophils/mcL); and ▪ Medication is dosed in accordance with the U.S. FDA approved labeling; and ▪ Prescribed by or in consultation with a hematologist or oncologist • Hematopoietic Syndrome of Acute Radiation Syndrome (Releuko) Reluko is proven and medically necessary when all of the following criteria are met: ○ Patient has been acutely exposed to myelosuppressive doses of radiation; and ○ Medication is dosed in accordance with the U.S. FDA approved labeling; and ○ Prescribed by or in consultation with a hematologist or oncologist

Coverage Determination Guideline Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Patient Lifts (for Indiana Only)	Jul. 1, 2022	**Related Policies** • Added reference link to the Coverage Determination Guideline titled *Durable Medical Equipment, Orthotics, Ostomy Supplies, Medical Supplies and Repairs/Replacements (for Indiana Only)* **Coverage Rationale** • Revised language pertaining to medical necessity clinical coverage criteria; replaced reference to the "InterQual® *Medicare*: Durable Medical Equipment, Patient *Lifts*" with "InterQual® *CP*: Durable Medical Equipment, Patient *Lift System*" **Applicable Codes** • Removed HCPCS code E0625 • Removed coding clarifications pertaining to HCPCS codes E0625, E0630, E0635, E0636, E0636, E0639, E0640, E1035, and E01036	**Indications for Coverage** Patient Lifts are proven and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Durable Medical Equipment, Patient Lift System. Click here to view the InterQual® criteria. **Coverage Limitations and Exclusions** The following services are excluded from coverage: • Personal care, comfort, or convenience items. • Home modifications such as elevators, handrails and ramps. • Chairs, bath chairs, feeding chairs, toddler chairs, chair lifts and recliners. • Stair lifts and stair glides.

Utilization Review Guideline Updates

Updated		
Policy Title	**Effective Date**	**Summary of Changes**
Elective Inpatient Services (for Indiana Only)	Jul. 1, 2022	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

General Information

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

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

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

Policy Update Classifications

New

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

Updated

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

Revised

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

Replaced

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

Retired

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

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