United Healthcare Community Plan

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

In This Issue

Take Note

Quarterly CPT® and HCPCS Code Updates

- Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes (for Indiana Only) – Effective Jul. 1, 2022 3
- Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation (for Indiana Only) – Effective Jul. 1, 2022 3
- Enjaymo™ (Sutimlimab-Jome) (for Indiana Only) – Effective Jul. 1, 2022 3
- Immune Globulin (IVIG and SCIG) (for Indiana Only) – Effective Jul. 1, 2022 3
- Leqvio® (Inclisiran) (for Indiana Only) – Effective Jul. 1, 2022 3
- Long-Acting Injectable Antiretroviral Agents for HIV (for Indiana Only) – Effective Jul. 1, 2022 3
- Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions (for Indiana Only) – Effective Jul. 1, 2022 3
- Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors (for Indiana Only) – Effective Jul. 1, 2022 3
- Ryplazim® (Plasminogen, Human-Tvmh) (for Indiana Only) – Effective Jul. 1, 2022 3
- Surgical Treatment for Spine Pain (for Indiana Only) – Effective Jul. 1, 2022 3
- Tezspire™ (Tezepelumab) (for Indiana Only) – Effective Jul. 1, 2022 3
- Vyvgart™ (Efgartigimod Alfa-Fcab) (for Indiana Only) – Effective Jul. 1, 2022 3

Medical Policy Updates

Revised

- Drug Testing (for Indiana Only) – Effective Aug. 1, 2022 4
- Surgical Treatment for Spine Pain (for Indiana Only) – Effective Jul. 1, 2022 4

Medical Benefit Drug Policy Updates

New

- Korsuva™ (Difelikefalin) (for Indiana Only) – Effective Aug. 1, 2022 11

Updated

- Medical Therapies for Enzyme Deficiencies (for Indiana Only) – Effective Jul. 1, 2022 11

In This Issue

Revised

- Gonadotropin Releasing Hormone Analogs (for Indiana Only) – Effective Aug. 1, 2022 12
- Long-Acting Injectable Antiretroviral Agents for HIV (for Indiana Only) – Effective Aug. 1, 2022 12
- Off-Label/Unproven Specialty Drug Treatment (for Indiana Only) – Effective Aug. 1, 2022 14
- Oncology Medication Clinical Coverage (for Indiana Only) – Effective Aug. 1, 2022 16
- Tezspire™ (Tezepelumab-Ekko) (for Indiana Only) – Effective Aug. 1, 2022 19
- White Blood Cell Colony Stimulating Factors (for Indiana Only) – Effective Jul. 1, 2022 21

Quarterly CPT® and HCPCS Code Updates

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

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

Policy Title	Policy Type	Summary of Changes
Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes (for Indiana Only)	Medical Policy	• Added HCPCS codes G0308 and G0309
Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation (for Indiana Only)	Medical Policy	• Added CPT code 0720T
Enjaymo™ (Sutimlimab-Jome) (for Indiana Only)	Medical Benefit Drug Policy	• Replaced HCPCS code C9399 with C9094
Immune Globulin (IVIG and SCIG) (for Indiana Only)	Medical Benefit Drug Policy	• Added HCPCS code J1551
Leqvio® (Inclisiran) (for Indiana Only)	Medical Benefit Drug Policy	• Replaced HCPCS codes J3490, and J3590 with J1306
Long-Acting Injectable Antiretroviral Agents for HIV (for Indiana Only)	Medical Benefit Drug Policy	• Replaced HCPCS codes C9399 and J3490 with J0739
Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions (for Indiana Only)	Medical Policy	• Added CPT codes 0326U, 0329U, and 0331U • Revised description for CPT code 0016M
Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors (for Indiana Only)	Medical Benefit Drug Policy	• Replaced HCPCS code C9399 with C9097
Ryplazim® (Plasminogen, Human-Tvmh) (for Indiana Only)	Medical Benefit Drug Policy	• Replaced J3490 and J3590 with J2998 • Removed C9090
Surgical Treatment for Spine Pain (for Indiana Only)	Medical Policy	• Added CPT code 0719T
Tezspire™ (Tezepelumab) (for Indiana Only)	Medical Benefit Drug Policy	• Replaced HCPCS codes J3490, and J3590 with J2356
Vyvgart™ (Efgartigimod Alfa-Fcab) (for Indiana Only)	Medical Benefit Drug Policy	• Replaced HCPCS codes J3490, and J3590 with J9332

Medical Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Drug Testing (for Indiana Only)	Aug. 1, 2022	Template Update • Changed policy type classification from "Utilization Review Guideline" to "Medical Policy" Coverage Rationale • Removed coverage statements and service applicability language; refer to the *Indiana Health Coverage Programs, Bulletin BT202183, September 14, 2021,* for medical necessity clinical coverage criteria Supporting Information • Updated *FDA* and *References* sections to reflect the most current information	For medical necessity clinical coverage criteria, refer to the Indiana Health Coverage Programs, Bulletin BT202183, September 14, 2021.
Surgical Treatment for Spine Pain (for Indiana Only)	Jul. 1, 2022	Notice of Revision: The following summary of changes has been modified and the effective date has been changed to Jul. 1, 2022; amended updates to be applied are noted in red below. Related Policies • Added reference link to the Medical Policy titled: ○ *Discogenic Pain Treatment (for Indiana Only)* ○ *Vertebral Body Tethering for Scoliosis (for Indiana Only)* Coverage Rationale • Replaced language indicating "a surgical spine procedure that is	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 InterQual® 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 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

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Surgical Treatment for Spine Pain (for Indiana Only) (continued)	Jul. 1, 2022	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]" • Revised medical necessity clinical coverage criteria for spinal stabilization procedures for the treatment of spinal stenosis (CPT codes 22867, 22868, 22869, and 22870); ~~added~~ replaced instruction to refer to "the Indiana Health Coverage Program Bulletin, BT2020111, October 6, 2020" with "the *Indiana Health Coverage Programs Provider Reference Module: Surgical Services*" • Removed language indicating the following techniques for lumbar interbody fusion (LIF) are proven and medically necessary: ○ Anterior LIF (ALIF) including lateral approaches, e.g.,	• Laminectomy procedure to provide surgical exposure to treat lesions within the spinal canal For medical necessity clinical coverage criteria for spinal stabilization procedures for the treatment of spinal stenosis (CPT Codes 22867, 22868, 22869 and 22870), refer to the Indiana Health Coverage Programs Provider Reference Module: Surgical Services. 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) • 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 • Stand-alone facet fusion without an accompanying decompressive procedure ○ 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 Indiana Only). **Documentation Requirements** Medical notes documenting the following, when applicable: • Condition requiring procedure • History and co-morbid medical condition(s) ○ Smoking history/ status, including date of last smoking cessation

Medical Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Surgical Treatment for Spine Pain (for Indiana Only) (continued)	Jul. 1, 2022	extreme lateral interbody fusion (XLIF®), Direct lateral interbody fusion (DLIF) ○ Posterior LIF (PLIF), including transforaminal lumbar interbody fusion (TLIF) ● Revised list of unproven and not medically necessary spinal procedures: ○ Added "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" ○ Removed: ▪ Transforaminal lumbar interbody fusion (TLIF) which utilizes only endoscopy visualization (such as a percutaneous incision with video visualization) ▪ Interlaminar lumbar instrumented fusion (ILIF) utilizing an interspinous process fusion device ▪ Spinal stabilization systems: – Stabilization systems for the treatment of degenerative	● 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 (refer to the 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) ○ Quantification of relevant muscle strength

Medical Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Surgical Treatment for Spine Pain (for Indiana Only) (continued)	Jul. 1, 2022	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 *Documentation Requirements* • Added language to indicate medical notes documenting the following are required, when applicable: ○ Condition requiring procedure ○ History and co-morbid medical condition(s) ▪ 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	• 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.]

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Surgical Treatment for Spine Pain (for Indiana Only) (continued)	Jul. 1, 2022	clinically significant improvement between at least two measurements, on a validated pain or function scale or quantifiable symptoms despite concurrent Conservative Therapies (Refer to the 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	

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Surgical Treatment for Spine Pain (for Indiana Only) (continued)	Jul. 1, 2022	and ID number on the image(s) ▪ Upon request, diagnostic imaging must be submitted via the external portal at 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) ▪ Quantification of relevant muscle strength ○ Whether the surgery will be performed with direct	

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Surgical Treatment for Spine Pain (for Indiana Only) (continued)	Jul. 1, 2022	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.] **Definitions** • Added definition of "Staged Multi-Session" **Applicable Codes** • Added CPT code 0719T *(quarterly edit)* • Removed CPT code 20939; refer to the Medical Policy titled *Spinal Fusion Enhancement Products (for Indiana Only)* **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	

Medical Benefit Drug Policy Updates

New

Policy Title	Effective Date	Coverage Rationale
Korsuva™ (Difelikefalin) (for Indiana Only)	Aug. 1, 2022	**Initial Therapy** Korsuva (difelikefalin) is proven and medically necessary for the treatment of moderate-to-severe pruritus associated with chronic kidney disease in adults undergoing hemodialysis when the following criteria are met: • Diagnosis of moderate-to-severe pruritus associated with chronic kidney disease; and • Patient is on hemodialysis; and • Pruritus is not attributed to a cause other than end stage renal disease or its complications (e.g., pruritic dermatological disease, cholestatic liver disease); and • Pruritus is not limited to occurring only during the dialysis session; and • Pruritis is not localized to just the palms of the hands, and • History of failure, contraindication, or intolerance to other pruritis treatments (e.g., antihistamines, corticosteroids, gabapentin, pregabalin, capsaicin); and • Prescribed by or in consultation with a nephrologist; and • Dosing is in accordance with the United States Food and Drug Administration approved labeling; and • Initial authorization will be for no longer than 3 months. **Continuation Therapy** Korsuva (difelikefalin) will be reauthorized based on all of the following criteria: • Documentation of a positive clinical response (i.e., reduction in itch from baseline); and • Prescribed by or in consultation with a nephrologist; and • Dosing is in accordance with the United States Food and Drug Administration approved labeling; and • Reauthorization will be for no longer than 12 months.

Updated

Policy Title	Effective Date	Summary of Changes
Medical Therapies for Enzyme Deficiencies (for Indiana Only)	Jul. 1, 2022	**Coverage Rationale** • Replaced instruction to "refer to the InterQual® *2021, Apr. 2021 Release,* CP: Specialty Rx Non-Oncology, Agalsidase beta (Fabrazyme)" with "refer to the *current release of the* InterQual® *guideline*, CP: Specialty Rx Non-Oncology, Agalsidase beta (Fabrazyme)" **Supporting Information** • Updated *References* section to reflect the most current information

Medical Benefit Drug Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Gonadotropin Releasing Hormone Analogs (for Indiana Only)	Aug. 1, 2022	**Coverage Rationale** • Revised list of applicable gonadotropin releasing hormone analog (GnRH analog) drug products; added Camcevi™ (leuprolide mesylate) **Applicable Codes** • Added HCPCS code J1952 **Supporting Information** • Updated *Background*, *FDA*, and *References* sections to reflect the most current information	This policy refers to the following gonadotropin releasing hormone analog (GnRH analog) drug products: • Camcevi™ (leuprolide mesylate) • Fensolvi® (leuprolide acetate) • Firmagon® (degarelix) • Lupaneta Pack™ (leuprolide acetate injection & norethindrone acetate tablets) • Lupron Depot® (leuprolide acetate) • Lupron Depot-PED® (leuprolide acetate) • Trelstar® (triptorelin pamoate) • Triptodur® (triptorelin) • Zoladex® (goserelin acetate) Refer to the policy for complete details.

Long-Acting Injectable Antiretroviral Agents for HIV (for Indiana Only)	Aug. 1, 2022	**Coverage Rationale**
		Cabenuva
		• Revised coverage criteria for initial therapy; removed criterion requiring the provider confirms that tolerability will be assessed using a 28-day oral lead-in of Vocabria (cabotegravir) and Edurant® (rilpivirine) tablets prior to the first injection of Cabenuva
		Supporting Information
		• Updated *References* section to reflect the most current information
			This policy refers to the following long-acting injectable antiretroviral products:
			• Apretude (cabotegravir)
			• Cabenuva (cabotegravir/rilpivirine)
			
			Apretude (cabotegravir) is proven to reduce the risk of sexually acquired HIV-1 infection in at-risk adults and adolescents weighing at least 35kg. Apretude is medically necessary when the following additional criteria are met:
			• For initial therapy, all of the following:
			  ○ Used for HIV-1 pre-exposure prophylaxis (PrEP); and
			  ○ Patient has a negative HIV-1 test; and
			  ○ Provider confirms that the patient will be tested for HIV-1 infection with each subsequent injection; and
			  ○ Patient is not an appropriate candidate for oral PrEP (e.g. difficulty with adherence to prior oral PrEP, significant renal disease); and
			  ○ Provider attests that patient demonstrates treatment readiness by both of the following:
			  ▪ Patient understands the risks of missed doses of Apretude
			  ▪ Patient has the ability to adhere to the required every 2 months injection and testing appointments;

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

Medical Benefit Drug Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Long-Acting Injectable Antiretroviral Agents for HIV (for Indiana Only) (continued)	Aug. 1, 2022		and ○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Initial authorization is for no more than 12 months • For continuation therapy, all of the following: ○ Patient has previously received treatment with Cabenuva; and ○ Provider confirms that the patient has achieved and maintained viral suppression (HIV-1 RNA less than 50 copies per mL) while on Cabenuva therapy; and ○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Authorization is for no more than 12 months Cabenuva is unproven and not medically necessary for the treatment of human immunodeficiency virus type-1 (HIV-1) in patients who are not currently virally suppressed (HIV-1 RNA less than 50 copies per mL).
Off-Label/Unproven Specialty Drug Treatment (for Indiana Only)	Aug. 1, 2022	Coverage Rationale • Replaced reference(s) to: ○ "*Injectable* specialty drug" with "specialty drug" ○ "*Injectable* oncology medications" with "oncology medications" • Added language to indicate this policy provides parameters for coverage of off-label and unproven indications of FDA-approved medications covered under the medical benefit for patient self-administered specialty drugs covered under the medical benefit Supporting Information • Updated *References* section to	Description This policy provides parameters for coverage of off-label and unproven indications of FDA-approved medications covered under the medical benefit for one of the following: • Provider administered or supervised specialty drug or patient self-administered specialty drug covered under the medical benefit with a corresponding UnitedHealthcare policy that does not address the requested indication • Provider administered or supervised specialty drug or patient self-administered specialty drug covered under the medical benefit with a corresponding UnitedHealthcare policy that lists the drug as unproven for the requested indication • Provider administered or supervised specialty drug or patient self-administered specialty drug covered under the medical benefit without a UnitedHealthcare drug policy This policy does not address coverage for self-administered medications

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Off-Label/Unproven Specialty Drug Treatment (for Indiana Only) (continued)	Aug. 1, 2022	reflect the most current information	covered under the pharmacy benefit. Please refer to pharmacy benefit coverage. This policy does not address coverage of oncology medications (including, but not limited to octreotide acetate, leuprolide acetate, leucovorin and levoleucovorin), including therapeutic radiopharmaceuticals, covered under the medical benefit based upon the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium® (NCCN Compendium®). Refer to the Medical Benefit Drug Policy titled Oncology Medication Clinical Coverage (for Indiana Only) for more information. This policy does not address coverage of vaccines. **Indications of Coverage** A specialty drug may be determined medically necessary for the requested off-label or unproven indication when all of the criteria are met: • The drug is approved by the U.S. Food and Drug Administration; and • The requested drug is a covered benefit by the member's state Medicaid agency; and • One of the following: ○ The requested drug is considered 'unproven' per UnitedHealthcare drug policy, where applicable ○ The indication for the requested drug is not addressed by a UnitedHealthcare drug policy, where applicable ○ A UnitedHealthcare drug policy does not exist for the requested drug and • The requested drug is intended to treat a chronic and seriously debilitating, or Serious Rare Disease; and • The patient has not failed a previous course or trial of the requested drug; and • The patient is not currently in an eligible clinical trial; and • Documented history of failure, contraindication, or intolerance to standard, conventional therapies to treat or manage the disease or condition, where available; and • Diagnosis is clinically supported as a use by at least one of the following:

Medical Benefit Drug Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Off-Label/Unproven Specialty Drug Treatment (for Indiana Only) (continued)	Aug. 1, 2022		○ One of the following compendia: ▪ The American Hospital Formulary Service Drug Information (AHFS-DI) under the Therapeutic Uses section ▪ The Elsevier Gold Standard's Clinical Pharmacology under the Indications section ▪ DRUGDEX System by Micromedex® has a Strength of Recommendation rating of Class I, Class IIa, or Class IIb under the Therapeutic Uses section or ○ Clinical indications supported by InterQual® Specialty Rx; or ○ Two (2) articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is validated and uncontested contradictory evidence presented in a major peer-reviewed medical journal. (Examples of accepted journals include, but are not limited to, Journal of American Medical Association, New England Journal of Medicine, and Lancet. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. Evidence limited to case studies or case series is not sufficient to meet the standard of this criterion.)
Oncology Medication Clinical Coverage (for Indiana Only)	Aug. 1, 2022	Coverage Rationale • Revised list of UnitedHealthcare non-preferred oncology products; added Alymsys (bevacizumab-maly)	Description This policy provides parameters for coverage of injectable oncology medications (including, but not limited to, octreotide acetate, leuprolide acetate, leucovorin, and levoleucovorin), including therapeutic radiopharmaceuticals, covered under the medical benefit based upon the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium® (NCCN Compendium®). The Compendium lists the appropriate drugs and biologics for specific cancers using U.S. Food and Drug Administration (FDA)-approved disease indications and specific NCCN panel recommendations. Each recommendation is supported by a level of evidence category. Coverage of White Blood Cell Colony Stimulating Factors and Erythropoiesis-Stimulating Agents are addressed in separate policies. This policy does not provide coverage criteria for Chimeric Antigen Receptor (CAR)-T Cell products. Coverage determinations are based on

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Oncology Medication Clinical Coverage (for Indiana Only) (continued)	Aug. 1, 2022		the member's benefits and the OptumHealth Transplant Solutions criteria for covered transplants in the Clinical Guideline titled Chimeric Antigen Receptor T-cell Therapy. **Coverage Rationale** The Oncology Products table below lists the UnitedHealthcare preferred oncology products and respective non-preferred products. Coverage will be provided for the UnitedHealthcare preferred oncology product contingent on the coverage criteria in the Diagnosis-Specific Criteria section. Coverage for any respective non-preferred oncology product will be provided contingent on the criteria in the Preferred Product Criteria and the Diagnosis-Specific Criteria sections. ***Preferred Product Criteria*** Treatment with the respective non-preferred product specified in the Oncology Products table below is medically necessary for oncology indications when both of the following are met: • History of intolerance or contraindication to one of UnitedHealthcare's preferred oncology products; and • Physician attests that, in their clinical opinion, the same intolerance, contraindication, or adverse event would not be expected to occur with the respective non-preferred product **Oncology Products** Below are UnitedHealthcare preferred oncology products with therapeutically equivalent and/or biosimilar* non-preferred products as determined by the UnitedHealthcare Pharmacy & Therapeutic Committee:

Preferred Oncology Product	Non-Preferred Oncology Product
Mvasi® (bevacizumab-awwb)	Avastin® (bevacizumab) Zirabev® (bevacizumab-bvzr) Alymsys (bevacizumab-maly)

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Oncology Medication Clinical Coverage (for Indiana Only) (continued)	Aug. 1, 2022		

Kanjinti® (trastuzumab-anns)	Herceptin® (trastuzumab) Herceptin Hylecta™ (trastuzumab and hyaluronidase-oysk) Herzuma® (trastuzumab-pkrb) Ogivri® (trastuzumab-dkst) Ontruzant® (trastuzumab-dttb) Trazimera™ (trastuzumab-qyyp)
Gemcitabine	Infugem™ (gemcitabine in sodium chloride injection)
Leucovorin	Levoleucovorin

*Biosimilar means that the biological product is FDA-approved based on data demonstrating that it is highly similar to an already FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product.

Diagnosis-Specific Criteria

Injectable Oncology Medications

UnitedHealthcare recognizes indications and uses of injectable oncology medications, including therapeutic radiopharmaceuticals, in the NCCN Drugs and Biologics Compendium with Categories of Evidence and Consensus of 1, 2A, and 2B as proven and Categories of Evidence and Consensus of 3 as unproven and not medically necessary. (However, refer to the Benefit Considerations Section of the policy.)

UnitedHealthcare will cover all chemotherapy agents for individuals under the age of 19 years for oncology indications. The majority of pediatric patients receive treatments on national pediatric protocols that are quite similar in concept to the NCCN patient care guidelines.

Medical Benefit Drug Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Oncology Medication Clinical Coverage (for Indiana Only) (continued)	Aug. 1, 2022		Refer to Preferred Product Criteria for the UnitedHealthcare preferred oncology products that have therapeutically equivalent and/or biosimilar products available.
Tezspire™ (Tezepelumab-Ekko) (for Indiana Only)	Aug. 1, 2022	**Title Change** • Previously titled *Tezspire™ (Tezepelumab) (for Indiana Only)* **Coverage Rationale** • Revised coverage criteria; added criterion requiring one of the following: ○ History of failure, contraindication, or intolerance to a 4-month trial of an anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Fasenra (benralizumab)] ○ Patient's asthma is not of the eosinophilic phenotype ○ Patient is currently on Tezspire	Tezspire is proven and medically necessary when all of the following criteria is met: • For initial therapy, all of the following: ○ Diagnosis of severe asthma; and ○ Classification of asthma as uncontrolled or inadequately controlled as defined by at least one of the following: ▪ Poor symptom control (e.g., ACQ score consistently greater than 1.5 or ACT score consistently less than 20); or ▪ Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months; or ▪ Asthma-related emergency treatment (e.g., emergency room visit, hospital admission, or unscheduled physician's office visit for nebulizer or other urgent treatment); or ▪ Airflow limitation [e.g., after appropriate bronchodilator withhold FEV1 less than 80% predicted (in the face of reduced FEV1/FVC defined as less than the lower limit of normal)]; or ▪ Patient is currently dependent on maintenance therapy with oral corticosteroids for the treatment of asthma and ○ Used in combination with one of the following: ▪ One maximally-dosed (appropriately adjusted for age) combination inhaled corticosteroid (ICS)/long-acting beta$_2$ agonist (LABA) product [e.g., Advair/AirDuo Respiclick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol)]; or ▪ Combination therapy including both of the following: – One high-dose (appropriately adjusted for age) ICS product [e.g., ciclesonide (Alvesco®), mometasone furoate (Asmanex®), beclomethasone dipropionate (QVAR®)]; and

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Tezspire™ (Tezepelumab-Ekko) (for Indiana Only) (continued)	Aug. 1, 2022		– One additional asthma controller medication [e.g., LABA - olodaterol (Striverdi®) or indacaterol (Arcapta®), leukotriene receptor antagonist – montelukast (Singulair®), theophylline] and ○ One of the following: ○ History of failure, contraindication, or intolerance to a 4 month trial of an anti-interleukin 5 therapy [e.g., Nucala (mepolizumab), Fasenra (benralizumab)]; or ○ Patient's asthma is not of the eosinophilic phenotype; or ○ Patient is currently on Tezspire and ○ Patient is not receiving Tezspire in combination with any of the following: ▪ Anti-interleukin 5 therapy [e.g., Cinqair (reslizumab), Fasenra (benralizumab), Nucala (mepolizumab)] ▪ Anti-IgE therapy [e.g., Xolair (omalizumab)] ▪ Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)] ○ Tezspire dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Tezspire is prescribed by a pulmonologist or allergist/immunologist; and ○ Initial authorization will be for no more than 6 months. • For continuation of therapy, all of the following: ○ Documentation of a positive clinical response as demonstrated by at least one of the following: ▪ Reduction in the frequency of exacerbations ▪ Decreased utilization of rescue medications ▪ Increase in percent predicted FEV1 from pretreatment baseline ▪ Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.) and ○ Used in combination with an ICS-containing controller medication; and

Medical Benefit Drug Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Tezspire™ (Tezepelumab-Ekko) (for Indiana Only) (continued)	Aug. 1, 2022		○ Patient is not receiving Tezspire in combination with any of the following: ▪ Anti-interleukin 5 therapy [e.g., Cinqair (reslizumab), Fasenra (benralizumab), Nucala (mepolizumab)] ▪ Anti-IgE therapy [e.g., Xolair (omalizumab)] ▪ Anti-interleukin 4 therapy [e.g., Dupixent (dupilumab)] and ○ Tezspire dosing is in accordance with the United States Food and Drug Administration approved labeling; and ○ Reauthorization will be for no more than 12 months.
White Blood Cell Colony Stimulating Factors (for Indiana Only)	Jul. 1, 2022	Notice of Revision: The following summary of changes has been modified. Revisions to the previous policy update announcement are outlined in red below. Please take note of the amended updates to be applied on 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~~	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)

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
White Blood Cell Colony Stimulating Factors (for Indiana Only) (continued)	Jul. 1, 2022	• 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 neutropenia (FN) ○ Secondary prophylaxis of febrile neutropenia (FN) ○ Treatment of febrile neutropenia ○ Severe chronic neutropenia (SCN) ○ Hematopoietic syndrome of acute radiation syndrome **Definitions** • Added definition of: ○ Adverse Event ○ Febrile Neutropenia ○ Neutropenia ○ Severe Neutropenia **Applicable Codes** • Added HCPCS codes C9096, J3490, and J3590 **Supporting Information** • Added *Background*, *Clinical Evidence*, *FDA*, and *References* sections	○ Neulasta® (pegfilgrastim): CP: Specialty Rx Oncology, Pegfilgrastim (Neulasta) ○ Nyvepria™ (pegfilgrastim-apgf): CP: Specialty Rx Oncology, Nyvepria (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

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		bone marrow transplant (BMT); or ▪ Used for mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis; or ▪ 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;

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
White Blood Cell Colony Stimulating Factors (for Indiana Only) (continued)	Jul. 1, 2022		or ○ 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)[16] – 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 therapy (bridge to stem cell transplant, organ transplant, definitive surgery for oligometastatic disease);

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
White Blood Cell Colony Stimulating Factors (for Indiana Only) (continued)	Jul. 1, 2022		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 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

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		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

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 Guidelineupdates. 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.