United Healthcare Community Plan

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

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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	Effective Date	Summary of Changes
Autologous Cellular Therapy (for Kentucky Only)	Medical Policy	• Added CPT codes 0717T and 0718T
Cell-Free Fetal DNA Testing (for Kentucky Only)	Medical Policy	• Added CPT code 0327U
Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes (for Kentucky Only)	Medical Policy	• Added HCPCS codes G0308 and G0309
Electrical Stimulation for the Treatment of Pain and Muscle Rehabilitation (for Kentucky Only)	Medical Policy	• Added CPT code 0720T
Enjaymo™ (Sutimlimab-Jome)	Medical Benefit Drug Policy	• Replaced HCPCS code C9399 with C9094
Genitourinary Pathogen Nucleic Acid Detection Panel Testing (for Kentucky Only)	Medical Policy	• Added CPT code 0330U
Immune Globulin (IVIG and SCIG)	Medical Benefit Drug Policy	• Added HCPCS code J1551
Leqvio® (Inclisiran)	Medical Benefit Drug Policy	• Replaced HCPCS codes C9399, J3490, and J3590 with J1306
Long-Acting Injectable Antiretroviral Agents for HIV	Medical Benefit Drug Policy	• Replaced HCPCS codes C9399 and J3490 with J0739
Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions (for Kentucky Only)	Medical Policy	• Added CPT codes 0326U, 0329U, and 0331U • Revised description for CPT code 0016M
Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors	Medical Benefit Drug Policy	• Replaced HCPCS code C9399 with C9097
Ryplazim® (Plasminogen, Human-Tvmh)	Medical Benefit Drug Policy	• Replaced J3490 and J3590 with J2998 • Removed C9090
Skin and Soft Tissue Substitutes (for Kentucky Only)	Medical Policy	• Revised description for HCPCS code A2004
Surgical Treatment for Spine Pain (for Kentucky Only)	Medical Policy	• Added CPT code 0719T

Take Note

Policy Title	Effective Date	Summary of Changes
Tezspire™ (Tezepelumab)	Medical Benefit Drug Policy	• Replaced HCPCS codes C9399, J3490, and J3590 with J2356
Vyvgart™ (Efgartigimod Alfa-Fcab)	Medical Benefit Drug Policy	• Replaced HCPCS codes C9399, J3490, and J3590 with J9332

Medical Policy Updates

New

Policy Title	Effective Date	Coverage Rationale

Preimplantation Genetic Testing (for Kentucky Only)	Aug. 1, 2022	Preimplantation Genetic Testing (PGT) for monogenic/single gene defects (PGT-M) or inherited structural chromosome rearrangements (PGT-SR) is proven and medically necessary using polymerase chain reaction (PCR), next generation sequencing (e.g., Chromosomal Rearrangements), or chromosomal microarray for the following:
		• The embryo is at increased risk of a recognized inherited disorder with both of the following:
		  ○ The increased risk of a recognized inherited disorder is due to one of the following:
		  ▪ The parents are carriers of an autosomal recessive disease
		  ▪ At least one parent is a carrier of an autosomal dominant, sex-linked, or mitochondrial condition
		  ▪ At least one parent is a carrier of a balanced structural chromosome rearrangement
		  ○ The medical condition being prevented must result in Significant Health Problems or Severe Disability and be caused by a single gene (PGT-M) or structural changes of a parents' chromosome (PGT-SR)
		• Human leukocyte antigen (HLA) typing on an embryo in order for the future child to provide bone marrow or blood to treat an affected sibling
		
		PGT is unproven and not medically necessary for all other populations and conditions due to insufficient evidence of efficacy.
		This includes but is not limited to PGT using chromosome microarray, PCR, or next generation sequencing for the following:
		• Aneuploidy screening (PGT-A)
		• Determining gender when the embryo is not at risk for a sex-inked disorder

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale

Liposuction for Lipedema (for Kentucky Only)	Aug. 1, 2022	Coverage Rationale
		• Revised coverage criteria for the diagnosis of lipedema; replaced criterion requiring "disproportionate adipocyte hypertrophy of the *lower extremities in relationship to the trunk*" with "disproportionate adipocyte hypertrophy of the *affected extremity*"
			Lipedema
			Liposuction for Lipedema is considered reconstructive and medically necessary to treat Functional Impairment when all of the following criteria are met:
			• A diagnosis of Lipedema that meets the following criteria:
			  ○ Absence of pitting edema from Lipedema; and
			  ○ Bilateral and symmetrical manifestation with minimal involvement of the feet; and
			  ○ Disproportionate adipocyte hypertrophy of the affected extremity; and
			  ○ Photographs of the area to be treated that document disproportional fat distribution consistent with diagnosis; and

Medical Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Liposuction for Lipedema (for Kentucky Only) (continued)	Aug. 1, 2022	Supporting Information • Updated *Clinical Evidence* and *References* sections to reflect the most current information	○ Failure of the limb adipose hypertrophy to respond to recommended bariatric surgery or other medically supervised weight loss modalities, if Class II or III Obesity; and ○ Negative Stemmer Sign; and ○ Pressure induced pain and tenderness on palpation • Failure to respond to 6 or more months of Conservative Treatment (compression or manual therapy); and • Treatment plan includes all of the following: ○ Assessment by the referring primary care provider or a specialist in vascular conditions (different from the treating surgeon) confirms that Lipedema is an independent cause of the Functional Impairment (interference with activities of daily living), and the surgery is expected to restore or improve the Functional Impairment; and ○ Treatment for each body area (e.g., extremity) will take place within a 12-month period following the initial surgical treatment of that body area, unless it is medically contraindicated to proceed with complete surgical intervention during the allotted time; and ○ Documentation that the request is not a re-treatment of a previously treated area; and ○ The postoperative plan of care is to continue to wear compression garments as instructed and continue Conservative Treatment Liposuction for Lipedema is not medically necessary when performed for cosmetic purposes (i.e., procedures or services that change or improve appearance without significantly improving Functional Impairment).

Retired

Policy Title	Effective Date	Summary of Changes
Corneal Collagen Crosslinking (for Kentucky Only)	Jul. 1, 2022	• Policy retired; corneal collagen crosslinking no longer requires clinical review
Lung Volume Reduction Surgery (for Kentucky Only)	Jul. 1, 2022	• Policy retired; lung volume reduction surgery no longer requires clinical review

Medical Benefit Drug Policy Updates

New

Policy Title	Effective Date	Coverage Rationale
Korsuva™ (Difelikefalin)	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.

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Gonadotropin Releasing Hormone Analogs	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	Refer to the policy for complete details.

Medical Benefit Drug Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Gonadotropin Releasing Hormone Analogs (continued)	Aug. 1, 2022	Supporting Information • Updated *Background*, *FDA*, and *References* sections to reflect the most current information	
Intravenous Iron Replacement Therapy (Feraheme®, Injectafer®, & Monoferric®) (for Kentucky Only)	Aug. 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 Aug. 1, 2022. Title Change • Previously titled *Intravenous Iron Replacement Therapy (for Kentucky Only)* Coverage Rationale • Removed instruction to refer to the current release of the [listed] InterQual® guideline for medical necessity clinical coverage criteria • Added language to indicate: ○ Feraheme® (ferumoxytol), Injectafer® (ferric carboxymaltose), Monoferric® (ferric derisomaltose), Infed® (iron dextran), and Venofer® (iron sucrose) proven ~~and medically necessary~~ for the treatment of the following indications ~~when the criteria listed in the policy are met~~: ▪ Iron Deficiency Anemia	Refer to the policy for complete details.

Medical Benefit Drug Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Intravenous Iron Replacement Therapy (Feraheme®, Injectafer®, & Monoferric®) (for Kentucky Only) (continued)	Aug. 1, 2022	(IDA) without chronic kidney disease (CKD) ▪ Iron Deficiency Anemia (IDA) associated with chronic kidney disease (CKD), without end stage renal disease (ESRD) ▪ Iron Deficiency Anemia (IDA) associated with chronic kidney disease (CKD), with end stage renal disease (ESRD) ○ Feraheme and Venofer are medically necessary for the treatment of the following indications when the criteria listed in the policy are met: ▪ Iron Deficiency Anemia (IDA) without chronic kidney disease (CKD) ▪ Iron Deficiency Anemia (IDA) associated with chronic kidney disease (CKD), without end stage renal disease (ESRD) ▪ Iron Deficiency Anemia (IDA) associated with chronic kidney disease (CKD), with end stage renal disease (ESRD) ○ Injectafer, Monoferric, and Infed are medically necessary for the treatment of the	

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Intravenous Iron Replacement Therapy (Feraheme®, Injectafer®, & Monoferric®) (for Kentucky Only) (continued)	Aug. 1, 2022	following indications when the criteria listed in the policy are met: ▪ Iron Deficiency Anemia (IDA) without chronic kidney disease (CKD) ▪ Iron Deficiency Anemia (IDA) associated with chronic kidney disease (CKD), without end stage renal disease (ESRD) Definitions • Updated definition of "Iron Deficiency Anemia (IDA) Without Chronic Kidney Disease (CKD) or Acute or Chronic Inflammatory Conditions" Supporting Information • Updated *Clinical Evidence* and *References* sections to reflect the most current information	
Long-Acting Injectable Antiretroviral Agents for HIV	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	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

Medical Benefit Drug Policy Updates

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Long-Acting Injectable Antiretroviral Agents for HIV (continued)	Aug. 1, 2022	reflect the most current information	○ Patient is not an appropriate candidate for oral PrEP (e.g., difficulty with adherence to prior oral PrEP, significant renal disease); and ○ Provider attests that patient demonstrates treatment readiness by both of the following: ▪ Patient understands the risks of missed doses of Apretude ▪ Patient has the ability to adhere to the required every 2 months injection and testing appointments; and ○ 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)

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Long-Acting Injectable Antiretroviral Agents for HIV (continued)	Aug. 1, 2022		showing viral suppression (HIV-1 RNA less than 50 copies per mL) for at least 6 months prior to initiation of Cabenuva; and ○ Provider attests that patient demonstrates treatment readiness by both of the following: ▪ Patient understands the risks of missed doses of Cabenuva ▪ Patient has the ability to adhere to the required monthly or every 2 months injection appointments and ○ 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	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	**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

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Off-Label/Unproven Specialty Drug Treatment (continued)	Aug. 1, 2022	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 reflect the most current information	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 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 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 (FDA); 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

Medical Benefit Drug Policy Updates

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Off-Label/Unproven Specialty Drug Treatment (continued)	Aug. 1, 2022		• 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: ○ 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.)

Medical Benefit Drug Policy Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Oncology Medication Clinical Coverage Policy	Aug. 1, 2022	**Related Policies** • Added reference link to the Medical Benefit Drug Policy titled *Antiemetics for Oncology* **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 US 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 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

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Oncology Medication Clinical Coverage Policy (continued)	Aug. 1, 2022		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 P&T Committee:

Preferred Oncology Product	Non-Preferred Oncology Product
Mvasi (bevacizumab-awwb)	Avastin (bevacizumab) Zirabev (bevacizumab-bvzr) Alymsys (bevacizumab-maly)
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
Ruxience (rituximab-pvvr) Truxima (rituximab-abbs)	Riabni (rituximab-arrx) Rituxan (rituximab) Rituxan Hycela (rituximab/hyaluronidase human, recombinant)
Eligard, Lupron Depot 7.5mg (J9217)	Lupron Depot 3.75mg (J1950)

Revised			
Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Oncology Medication Clinical Coverage Policy (continued)	Aug. 1, 2022		*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. Refer to Preferred Product Criteria for the UnitedHealthcare preferred oncology products that have therapeutically equivalent and/or biosimilar products available.
Tezspire™ (Tezepelumab-Ekko)	Aug. 1, 2022	**Title Change** • Previously titled *Tezspire™ (Tezepelumab)* **Coverage Rationale** • Revised coverage criteria; added criterion requiring one of the following: ○ History of failure, contraindication, or intolerance	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

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Tezspire™ (Tezepelumab-Ekko) (continued)	Aug. 1, 2022	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	▪ 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 – 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

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Tezspire™ (Tezepelumab-Ekko) (continued)	Aug. 1, 2022		(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 ○ 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	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	This policy refers to the following white blood cell colony stimulating factors (CSFs): ● Long-acting pegfilgrastim agents: ○ Fulphila® (pegfilgrastim-jmdb) ○ Neulasta® (pegfilgrastim)

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
White Blood Cell Colony Stimulating Factors (continued)	Jul. 1, 2022	of the additional updates to be applied on Jul. 1, 2022. Coverage Rationale • Revised list of applicable short-acting filgrastim agents; added Releuko® (filgrastim-ayow) • Added language to indicate: ○ Coverage for Releuko will be provided contingent on the criteria in the *Preferred Product Criteria* section and the coverage criteria in the *Diagnosis-Specific Criteria* section [of the policy] ○ Treatment with Releuko is medically necessary for the indications specified in the policy when one of the following is met: ▪ Both of the following: – History of a trial of adequate dose and duration of Zarxio, resulting in minimal clinical response; and – Physician attests that, in their clinical opinion, the clinical response would be expected to be superior with Releuko than experienced with	○ 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) (refer to the 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. **Long-Acting Pegfilgrastim Agents (Fulphila®, Neulasta®, Nyvepria™, Udenyca®, Ziextenzo®): Preferred Product** The long-acting preferred product criteria in this section applies to the following states: CA, HI, KY, MD, MI, MN, NE, NJ, NY, OH, RI, TN, VA. For all other states, coverage will be provided contingent on the coverage criteria in the Diagnosis-Specific Criteria section. Neulasta® and Ziextenzo® are the preferred pegfilgrastim products. Coverage will be provided for Neulasta® and Ziextenzo® contingent on the coverage criteria in the Diagnosis-Specific Criteria section. Coverage for Fulphila®, Nyvepria™, or Udenyca® will be provided contingent on the criteria in this section and the coverage criteria in the Diagnosis-Specific Criteria section.

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White Blood Cell Colony Stimulating Factors (continued)	Jul. 1, 2022	Zarxio ▪ Both of the following: – History of intolerance, contraindication, or adverse event to Zarxio; and – Physician attests that, in their clinical opinion, the same intolerance, contraindication, or adverse event would not be expected to occur with Releuko ○ Releuko is medically necessary for the following indications when the criteria listed in 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	***Preferred Product Criteria*** Treatment with Fulphila®, Nyvepria™, Udenyca®, or other pegfilgrastim biosimilar is medically necessary for the indications specified in the policy when one of the following is met: • Both of the following: ○ History of a trial of adequate dose and duration of Neulasta® or Ziextenzo®, resulting in minimal clinical response; and ○ Physician attests that, in their clinical opinion, the clinical response would be expected to be superior with Fulphila®, Nyvepria™, Udenyca®, or other pegfilgrastim biosimilar product than experienced with Neulasta® or Ziextenzo®; or • Both of the following: ○ History of intolerance, contraindication, or adverse event to Neulasta® or Ziextenzo®; and ○ Physician attests that, in their clinical opinion, the same intolerance, contraindication or adverse event would not be expected to occur with Fulphila, Nyvepria, Udenyca, or other pegfilgrastim biosimilar product **Short-Acting Filgrastim Agents (Granix®, Neupogen®, Nivestym®, Releuko, & Zarxio®): Preferred Product** The short-acting preferred product criteria in this section applies to the following states: CA, HI, KY, MD, MI, MN, NE, NJ, NY, OH, RI, TN, VA. For all other states, coverage will be provided contingent on the coverage criteria in the Diagnosis-Specific Criteria section. Zarxio® is the preferred filgrastim product. Coverage will be provided for Zarxio® contingent on the coverage criteria in the Diagnosis-Specific Criteria section. Coverage for Granix®, Neupogen®, Nivestym®, or Releuko will be provided contingent on the criteria in this section and the coverage criteria in the Diagnosis-Specific Criteria section.

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White Blood Cell Colony Stimulating Factors (continued)	Jul. 1, 2022	of acute radiation syndrome • Revised coverage criteria for: *Bone Marrow/Stem Cell Transplant* ○ Removed criterion requiring medication is: ▪ Dosed in accordance with the U.S. Food and Drug Administration (FDA) approved labeling ▪ Prescribed by or in consultation with a hematologist or oncologist *Primary Prophylaxis of Chemotherapy-Induced Febrile Neutropenia* ○ Added criterion to allow coverage for the applicable products when the patient is receiving myelosuppressive anticancer drugs given with a curative intent (curative chemotherapy, chemotherapy in curative adjuvant/neoadjuvant setting) or the patient is receiving myelosuppressive anticancer drugs for definitive therapy (bridge to stem cell transplant, organ transplant, definitive surgery for oligometastatic disease)	*Preferred Product Criteria* Treatment with Granix, Neupogen, Nivestym, Releuko, or other filgrastim biosimilar is medically necessary for the indications specified in the policy when one of the following is met: • Both of the following: ○ History of a trial of adequate dose and duration of Zarxio, resulting in minimal clinical response; and ○ Physician attests that, in their clinical opinion, the clinical response would be expected to be superior with Granix, Neupogen, Nivestym, Releuko or other filgrastim biosimilar product, than experienced with Zarxio; or • Both of the following: ○ History of intolerance, contraindication, or adverse event to Zarxio; and ○ Physician attests that, in their clinical opinion, the same intolerance, contraindication, or adverse event would not be expected to occur with Granix, Neupogen, Nivestym, Releuko or other filgrastim biosimilar product **Diagnosis-Specific Criteria** For the coverage criteria below, in absence of specified drug products, the term “colony stimulating factors” or “CSFs” will be used in this policy where the coverage criteria apply to all products listed above. • Bone Marrow/Stem Cell Transplant (Leukine, Neupogen, Nivestym, Releuko, Zarxio) Leukine, Neupogen, Nivestym, Releuko, and Zarxio are proven and medically necessary when all of 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

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White Blood Cell Colony Stimulating Factors (continued)	Jul. 1, 2022	○ Updated list of risk factors for chemotherapy-induced febrile neutropenia; replaced persistent neutropenia due to prior chemotherapy, radiation therapy, or bone marrow involvement by tumor measure of "ANC < 1500 neutrophils/mcL" with "< 500 neutrophils/mcL or < 1,000 neutrophils/mcL and a predicted decline to ≤ 500 neutrophils/mcL over the next 48 hours" ○ Replaced language indicating "chemotherapy regimen associated incidence of febrile neutropenia (FN) will be based on the clinical trial(s) with the highest level of evidence *according to the GRADE criteria*" with "chemotherapy regimen associated incidence of FN will be based on the clinical trial(s) with the highest level of evidence" ○ Added language to indicate: ▪ Chemotherapy regimens and associated incidence of FN based on the clinical trial(s) according to the grade based on Common Terminology Criteria for	▪ 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 (Leukine, Neupogen, Nivestym, Releuko, Zarxio) Leukine, Neupogen, Nivestym, Releuko and Zarxio are 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) (Fulphila, Granix, Leukine, Neulasta, Neupogen, Nivestym, Nyvepria, Releuko, Udenyca, Zarxio, Ziextenzo) White blood cell colony stimulating factors are 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;

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White Blood Cell Colony Stimulating Factors (continued)	Jul. 1, 2022	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* ○ Added criterion to allow coverage for the applicable products: ▪ When the patient is receiving myelosuppressive anticancer drugs given with a curative intent (curative chemotherapy, chemotherapy in curative adjuvant/neoadjuvant setting) or the patient is receiving myelosuppressive	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 such as: – 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) (Fulphila, Granix, Leukine, Neulasta, Neupogen, Nivestym, Nyvepria, Releuko, Udenyca, Zarxio, Ziextenzo) White blood cell colony stimulating factors are 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

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White Blood Cell Colony Stimulating Factors (continued)	Jul. 1, 2022	anticancer drugs for definitive therapy (bridge to stem cell transplant, organ transplant, definitive surgery for oligometastatic disease) ▪ 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 ○ Removed criterion allowing coverage for the applicable products when the patient is receiving myelosuppressive anticancer drugs associated with neutropenia (ANC ≤ 1500 neutrophils/mcL) *Treatment of Febrile Neutropenia* ○ Added criterion requiring the patient has not received long-acting prophylactic pegfilgrastim in the last 14 days ○ Removed criterion requiring the score of < 21 on the	▪ 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 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) (Fulphila, Leukine, Neulasta, Neupogen, Nivestym, Nyvepria, Releuko, Udenyca, Zarxio, Ziextenzo) (Off-Label) Fulphila, Leukine, Neulasta, Neupogen, Nivestym, Nyvepria, Releuko, Udenyca, Zarxio, and Ziextenzo are 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) (Neupogen, Nivestym, Releuko, Zarxio)

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
White Blood Cell Colony Stimulating Factors (continued)	Jul. 1, 2022	*Multinational Association of Supportive Care in Cancer (MASCC)* scoring system in patients with cancer and febrile neutropenia ○ Revised list of examples of risk factors for an infection-associated complication: ▪ Added: – 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 ▪ Removed: – Hypotension – Acute renal failure – Acute respiratory failure – Acute heart failure **Definitions** ● Updated definition of "Febrile	Neupogen®, Nivestym®, Releuko, and Zarxio® are 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[50]); and ▪ Medication is dosed in accordance with the U.S. Food and Drug Administration (FDA) approved labeling; and ▪ Prescribed by or in consultation with a hematologist or oncologist ● Hematopoietic Syndrome of Acute Radiation Syndrome (Fulphila®, Leukine®, Neulasta®, Neupogen®, Nivestym®, Nyvepria™, Udenyca®, Releuko, Zarxio®, Ziextenzo®) Fulphila®, Leukine®, Neulasta®, Neupogen®, Nivestym®, Nyvepria™, Releuko, Udenyca®, Zarxio®, and Ziextenzo® are proven and medically necessary when all of the following criteria are met: ○ All of the following: ▪ Patient has been acutely exposed to myelosuppressive doses of radiation; and ▪ Medication is dosed in accordance with the U.S. Food and Drug Administration (FDA) approved labeling; and ▪ Prescribed by or in consultation with a hematologist or oncologist

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
White Blood Cell Colony Stimulating Factors (continued)	Jul. 1, 2022	Neutropenia" Applicable Codes • Added HCPCS codes C9096, C9399, J3490, and J3590. Supporting Information • Updated *FDA* and *References* sections to reflect the most current information	

Coverage Determination Guideline Updates

Updated		
Policy Title	**Effective Date**	**Summary of Changes**
Ambulance Services (for Kentucky Only)	Aug. 1, 2022	Coverage Rationale *Non-Emergency Ambulance (Ground or Air) Between Facilities* • Added reference link to the *Kentucky Administration Regulations 907 KAR 3:066* *Coverage Limitations and Exclusions* • Replaced reference to the "Kentucky Administration *Rules* 3:066" with "Kentucky Administration *Regulations 907 KAR* 3:066" Applicable Codes • Revised description for modifiers E, I, P, and X

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