United Healthcare Community Plan

UnitedHealthcare Community Plan of Pennsylvania
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	Policy Type	Summary of Changes
Autologous Cellular Therapy (for Pennsylvania Only)	Jul. 1, 2022	Medical Policy	• Added CPT codes 0717T and 0718T
Enjaymo™ (Sutimlimab-Jome)	Jul. 1, 2022	Medical Benefit Drug Policy	• Replaced HCPCS code C9399 with C9094
Immune Globulin (IVIG and SCIG) (for Pennsylvania Only)	Jul. 1, 2022	Medical Benefit Drug Policy	• Added HCPCS code J1551
Leqvio® (Inclisiran)	Jul. 1, 2022	Medical Benefit Drug Policy	• Replaced HCPCS codes C9399, J3490, and J3590 with J1306
Ryplazim® (Plasminogen, Human-Tvmh)	Jul. 1, 2022	Medical Benefit Drug Policy	• Replaced J3490 and J3590 with J2998 • Removed C9090
Skin and Soft Tissue Substitutes (for Pennsylvania Only)	Aug. 1, 2022	Medical Policy	• Revised description for HCPCS code A2004
Tezspire™ (Tezepelumab)	Jul. 1, 2022	Medical Benefit Drug Policy	• Replaced HCPCS codes C9399, J3490, and J3590 with J2356
Vyvgart™ (Efgartigimod Alfa-Fcab)	Jul. 1, 2022	Medical Benefit Drug Policy	• Replaced HCPCS codes C9399, J3490, and J3590 with J9332

Medical Policy Updates

Updated

Policy Title	Effective Date	Summary of Changes
Fecal Calprotectin Testing (for Pennsylvania Only)	Jul. 1, 2022	**Application** • Added language to indicate any requests for services that do not meet criteria set in the Prior Authorization Review Panel (PARP) will be evaluated on a case-by-case basis; refer to *Pennsylvania Exceptions, Pennsylvania Code, Title 55, Chapter 1101* **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information
Proton Beam Radiation Therapy (for Pennsylvania Only)	Aug. 1, 2022	**Application** • Added language to indicate any requests for services that do not meet criteria set in the Prior Authorization Review Panel (PARP) will be evaluated on a case-by-case basis; refer to *Pennsylvania Exceptions, Pennsylvania Code, Title 55, Chapter 1101* **Applicable Codes** • Added ICD-10 diagnosis codes C69.0, C69.00, C69.01, C69.02, C69.1, C69.10, C69.11, C69.12, C69.20, C69.21, C69.22, C69.50, C69.51, C69.52, C69.6, C69.60, C69.61, C69.62, C69.8, C69.80, C69.81, C69.82, C69.9, C69.90, C69.91, and C69.92 **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Gender Dysphoria Treatment (for Pennsylvania Only)	Aug. 1, 2022	**Application** • Added language to indicate any requests for services that do not meet criteria set in the Prior Authorization Review Panel (PARP) will be evaluated on a case-by-case basis; refer to *Pennsylvania Exceptions, Pennsylvania Code, Title 55, Chapter 1101* **Coverage Rationale** • Added language to indicate: ○ In determining medical necessity for gender confirmation services, Pennsylvania will utilize the *World Professional Association for*	Note: This Medical Policy does not apply to individuals with ambiguous genitalia or disorders of sexual development. In determining medical necessity for gender confirmation services, Pennsylvania will utilize the World Professional Association for Transgender Health (WPATH) Standard of Care as guidelines and any successor WPATH guidelines to determine whether the services are medically necessary. Current Standard of Care guidelines can be found here: https://www.wpath.org/publications/soc. For additional information, refer to the Managed Care Operations Memorandum Coverage of Services Related to Gender Transition MCOPS Memo # 07/2016-007. Gender Confirmation Surgical treatment for Gender Dysphoria may

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Gender Dysphoria Treatment (for Pennsylvania Only) (continued)	Aug. 1, 2022	*Transgender Health (WPATH) Standard of Care* as guidelines and any successor WPATH guidelines to determine whether the services are medically necessary; current *Standard of Care* guidelines can be found here: https://www.wpath.org/publications/soc ○ For additional information, refer to the *Managed Care Operations Memorandum Coverage of Services Related to Gender Transition MCOPS Memo # 07/2016-007* ○ For individuals 17 and younger, refer to the *Standard of Care* for children and adolescents [*World Professional Association for Transgender Health (WPATH) Guidelines*, version 7, 2012] for applicable documentation criteria ○ Although not an explicit criterion, it is recommended that male-to-female members undergo feminizing hormone therapy (minimum 12 months) prior to breast augmentation surgery; the purpose is to maximize breast growth in order to obtain better surgical (aesthetic) results ○ Chest surgery in female-to-male members could be requested earlier [than 18 years of age], preferably after ample time of living in the desired gender role and after one year of testosterone treatment ▪ The intent of this suggested	be indicated for individuals who provide the following documentation: • For breast surgery, a written psychological assessment from at least one Qualified Behavioral Health Provider experienced in treating Gender Dysphoria* is required. The assessment must document that an individual meets all of the following criteria: ○ Persistent, well-documented Gender Dysphoria ○ Capacity to make a fully informed decision and to consent for treatment ○ Must be at least 18 years of age (age of majority)*. For individuals 17 and younger, refer to the Standard of Care for children and adolescents (World Professional Association for Transgender Health [WPATH] Guidelines, version 7, 2012). ○ Favorable psychosocial-behavioral evaluation to provide screening and identification of risk factors or potential postoperative challenges ○ Although not an explicit criterion, it is recommended that male to female members undergo feminizing hormone therapy (minimum 12 months) prior to breast augmentation surgery. The purpose is to maximize breast growth in order to obtain better surgical (aesthetic) results. * Chest surgery in female to male members could be requested earlier, preferably after ample time of living in the desired gender role and after one year of testosterone treatment. The intent of this suggested sequence is to give adolescents sufficient opportunity to experience and socially adjust in a more masculine gender role, before undergoing irreversible surgery. However, different approaches may be more suitable, depending on an adolescents specific clinical situation and goals for gender identity expression. • For genital surgery, a written psychological assessment from at least two Qualified Behavioral Health Providers experienced in treating Gender Dysphoria*, who have independently assessed the

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Gender Dysphoria Treatment (for Pennsylvania Only) (continued)	Aug. 1, 2022	sequence is to give adolescents sufficient opportunity to experience and socially adjust in a more masculine gender role, before undergoing irreversible surgery; however, different approaches may be more suitable, depending on an adolescent's specific clinical situation and goals for gender identity expression • Replaced language indicating: ○ "Surgical treatment for Gender Dysphoria may be indicated for individuals who provide the [listed] documentation" with "*Gender Confirmation* surgical treatment for Gender Dysphoria may be indicated for individuals who provide the [listed] documentation" ○ "When the [documentation] criteria are met, the [listed] surgical procedures to treat Gender Dysphoria are medically necessary and covered as a proven benefit" with "when the [documentation] criteria are met, the [listed] *Gender Confirmation* surgical procedures to treat Gender Dysphoria are medically necessary and covered as a proven benefit" ○ "Certain ancillary procedures, including but not limited to [those listed in the policy], *are* considered cosmetic and not medically necessary when performed as	individual, is required. The assessment must document that an individual meets all of the following criteria: ○ Persistent, well-documented Gender Dysphoria ○ Capacity to make a fully informed decision and to consent for treatment ○ Must be at least 18 years of age (age of majority) ○ Favorable psychosocial-behavioral evaluation to provide screening and identification of risk factors or potential postoperative challenges ○ Complete at least 12 months of successful continuous full-time real-life experience in the desired gender ○ Complete 12 months of continuous cross-sex hormone therapy appropriate for the desired gender (unless medically contraindicated) • Treatment plan that includes ongoing follow-up and care by a Qualified Behavioral Health Provider experienced in treating Gender Dysphoria When the above criteria are met, the following Gender Confirmation surgical procedures to treat Gender Dysphoria are medically necessary and covered as a proven benefit: • Bilateral mastectomy or breast reduction* • Breast enlargement, including augmentation mammaplasty and breast implants, in male to female members • Clitoroplasty (creation of clitoris) • Hysterectomy (removal of uterus) • Labiaplasty (creation of labia) • Laser or electrolysis hair removal in advance of genital reconstruction prescribed by a physician for the treatment of Gender Dysphoria • Mastopexy in male to female members • Metoidioplasty (creation of penis, using clitoris) • Orchiectomy (removal of testicles)

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Gender Dysphoria Treatment (for Pennsylvania Only) (continued)	Aug. 1, 2022	part of surgical treatment for Gender Dysphoria *(please check the federal, state or contractual requirements for benefit coverage)*" with "certain ancillary procedures, including but not limited to [those listed in the policy], *may be* considered cosmetic and not medically necessary when performed as part of surgical treatment for Gender Dysphoria *(items identified as cosmetic must be reviewed on a case-by-case basis as they could be considered medically necessary for individuals with severe gender dysphoria)*" • Revised list of Gender Confirmation surgical procedures that are medically necessary and covered as a proven benefit to treat Gender Dysphoria; added: ○ Breast enlargement, including augmentation mammaplasty and breast implants in male-to-female members ○ Mastopexy in male-to-female members • Revised list of ancillary procedures that may be considered cosmetic and not medically necessary when performed as part of surgical treatment for Gender Dysphoria; removed: ○ Breast enlargement, including augmentation mammaplasty and breast implants ○ Mastopexy Supporting Information • Updated *References* section to reflect the	• Penectomy (removal of penis) • Penile prosthesis • Phalloplasty (creation of penis) • Salpingo-oophorectomy (removal of fallopian tubes and ovaries) • Scrotoplasty (creation of scrotum) • Testicular prostheses • Urethroplasty (reconstruction of female urethra) • Urethroplasty (reconstruction of male urethra) • Vaginectomy (removal of vagina) • Vaginoplasty (creation of vagina) • Vulvectomy (removal of vulva) *When bilateral mastectomy or breast reduction is performed as a stand-alone procedure, without genital reconstruction procedures, completion of hormone therapy prior to the breast procedure is not required. Certain ancillary procedures, including but not limited to the following, may be considered cosmetic and not medically necessary when performed as part of surgical treatment for Gender Dysphoria (Items identified as cosmetic must be reviewed on a case by case basis as they could be considered medically necessary for individuals with severe gender dysphoria): • Abdominoplasty (also refer to the Coverage Determination Guideline titled Panniculectomy and Body Contouring Procedures (for Pennsylvania Only)) • Blepharoplasty (also refer to the Coverage Determination Guideline titled Blepharoplasty, Blepharoptosis, and Brow Ptosis Repair (for Pennsylvania Only)) • Body contouring (e.g., fat transfer, lipoplasty, panniculectomy) (also refer to the Coverage Determination Guideline titled Panniculectomy and Body Contouring Procedures (for Pennsylvania Only))

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Gender Dysphoria Treatment (for Pennsylvania Only) (continued)	Aug. 1, 2022	most current information	• Brow lift • Calf implants • Cheek, chin and nose implants • Face/forehead lift and/or neck tightening • Facial bone remodeling for facial feminization • Hair transplantation • Injection of fillers or neurotoxins (also refer to the Medical Benefit Drug Policy titled Botulinum Toxins A and B) • Laser or electrolysis hair removal not related to genital reconstruction • Lip augmentation • Lip reduction • Liposuction (suction-assisted lipectomy) (also refer to the Coverage Determination Guideline titled Panniculectomy and Body Contouring Procedures (for Pennsylvania Only)) • Pectoral implants for chest masculinization • Rhinoplasty (also refer to the Coverage Determination Guideline titled Rhinoplasty and Other Nasal Surgeries (for Pennsylvania Only) • Skin resurfacing (e.g., dermabrasion, chemical peels, laser) • Thyroid cartilage reduction/reduction thyroid chondroplasty/trachea shave (removal or reduction of the Adam's apple) • Voice modification surgery (e.g., laryngoplasty, glottoplasty or shortening of the vocal cords) • Voice lessons and voice therapy
Genitourinary Pathogen Nucleic Acid Detection Panel Testing (for Pennsylvania Only)	Aug. 1, 2022	Application • Added language to indicate any requests for services that do not meet criteria set in the Prior Authorization Review Panel (PARP) will be evaluated on a case-by-case basis; refer to *Pennsylvania Exceptions, Pennsylvania Code, Title 55, Chapter 1101*	The following are proven and medically necessary to evaluate symptomatic individuals for Vaginitis: • Direct and amplified DNA probe testing for Trichomoniasis vaginalis • Direct probe testing for Candida sp. Due to insufficient evidence of efficacy, the following are unproven and not medically necessary:

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Genitourinary Pathogen Nucleic Acid Detection Panel Testing (for Pennsylvania Only) (continued)	Aug. 1, 2022	**Coverage Rationale** • Added language to indicate screening of asymptomatic individuals for vaginitis is unproven and not medically necessary • Replaced language indicating "[the listed indications are] proven and medically necessary to evaluate symptomatic *women* for Vaginitis" with "[the listed indications are] proven and medically necessary to evaluate symptomatic *individuals* for Vaginitis" **Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information	• Amplified DNA probe testing for vulvovaginitis due to Candida sp. • Direct and amplified DNA probe testing for bacterial Vaginosis (i.e., Gardnerella vaginalis) • Multiplex polymerase chain reaction (PCR) panel testing of genitourinary pathogens, including but not limited to pathogens commonly associated with Vaginitis • Screening of asymptomatic individuals for vaginitis Note: This policy does not apply to tests for gonorrhea and chlamydia.

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.

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
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	**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-

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

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		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: ○ 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.)
Tezspire™ (Tezepelumab-Ekko)	Aug. 1, 2022	Title Change • Previously titled *Tezspire™ (Tezepelumab)* Coverage Rationale • Revised coverage criteria; added	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

Medical Benefit Drug Policy Updates

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

Medical Benefit Drug Policy Updates

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

Utilization Review Guideline Updates

Revised

Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Provider Administered Drugs – Site of Care (for Pennsylvania Only)	Aug. 1, 2022	**Application** • Added language to indicate any requests for services that do not meet criteria set in the Prior Authorization Review Panel (PARP) will be evaluated on a case-by-case basis; refer to *Pennsylvania Exceptions, Pennsylvania Code, Title 55, Chapter 1101* • Revised list of applicable medications; added Nexviazyme™ (avalglucosidase alfa-ngpt) **Coverage Rationale** • Revised medical necessity criteria: ○ Removed criterion requiring [outpatient hospital facility-based intravenous medication infusion] is used to initiate or re-initiate products for a short duration (e.g., 4 weeks) ○ Replaced criterion requiring "homecare or infusion provider has deemed that the individual, home caregiver, or home environment is not suitable for home infusion therapy *if* the prescriber *cannot* infuse in the office setting" with "homecare or infusion provider has deemed that the individual, home caregiver, or home environment is not suitable for home infusion therapy *[when]*	This guideline addresses the criteria for consideration of allowing hospital outpatient facility medication infusion services. This includes claim submission for hospital based services with the following CMS/AMA Place of Service codes: • 22 On Campus-Outpatient Hospital; and • 19 Off Campus-Outpatient Hospital Alternative sites of care, such as non-hospital outpatient infusion, physician office, ambulatory infusion or home infusion services are well accepted places of service for medication infusion therapy. If a patient does not meet criteria for outpatient hospital facility infusion, alternative sites of care may be used. Outpatient hospital facility-based intravenous medication infusion is medically necessary for individuals who meet at least one of the following criteria (submission of medical records is required): • Documentation that the individual is medically unstable for administration of the prescribed medication at the alternative sites of care as determined by any of the following: ○ The individual's complex medical status or therapy requires enhanced monitoring and potential intervention above and beyond the capabilities of the office or home infusion setting; or ○ The individual's documented history of a significant comorbidity (e.g., cardiopulmonary disorder) or fluid overload status that precludes treatment at an alternative Site of Care; or ○ Outpatient treatment in the home or office setting presents a health risk due to a clinically significant physical or cognitive impairment; or ○ Difficulty establishing and maintaining patent vascular access; or • Documentation (e.g., infusion records, medical records) of episodes of severe or potentially life-threatening adverse events (e.g., anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure) that have not been responsive to acetaminophen, steroids, diphenhydramine, fluids, infusion rate reductions, or other pre-medications, thereby increasing risk to the individual when administration is in the home or office setting;

Utilization Review Guideline Updates

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Provider Administered Drugs – Site of Care (for Pennsylvania Only) (continued)	Aug. 1, 2022	the prescriber *is unable to* infuse in the office setting *and there are no ambulatory infusion suite options available for this member*" • Revised list of medications that require healthcare provider administration; added Nexviazyme™ (avalglucosidase alfa-ngpt) **Applicable Codes** • Added HCPCS code J0219 **Supporting Information** • Updated *References* section to reflect the most current information	or • Initial infusion or re-initiation of therapy after more than 6 months; or • Homecare or infusion provider has deemed that the individual, home caregiver, or home environment is not suitable for home infusion therapy and both of the following ○ The prescriber is unable to infuse in the office setting ○ There are no ambulatory infusion suite options available for this member Ongoing outpatient hospital facility-based infusion duration of therapy will be no more than 6 months to allow for reassessment of the individual's ability to receive therapy at an alternative Site of Care. This policy applies to these medications that require healthcare provider administration: • Actemra® (Tocilizumab) • Aldurazyme® (laronidase) • Amondys 45™ (casimersen) • Asceniv™ (IV) • Avsola™ (Infliximab-axxq) • Bivigam® (IV) • Carimune® NF (IV) • Cutaquig® (SC) • Cuvitru® (SC) • Elaprase® (idursulfase) • Entyvio® (Vedolizumab) • Exondys 51® (eteplirsen) • Fabrazyme® (agalsidase beta) • Flebogamma® DIF (IV) • Gammagard® Liquid (IV, SC) • Gammagard® S/D (IV) • Gammaked™ (IV, SC)

Utilization Review Guideline Updates

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Policy Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Provider Administered Drugs – Site of Care (for Pennsylvania Only) (continued)	Aug. 1, 2022		• Gammaplex® (IV) • Gamunex®-C (IV, SC) • Hizentra® (SC) • HyQvia® (SC) • Ilumya™ (Tildrakizumab-asmn) • Inflectra® (Infliximab-dyyb) • Kanuma® (sebelipase alfa) • Lumizyme® (alglucosidase alfa) • Mepsevii™ (vestronidase alfa-vjbk) • Naglazyme® (galsulfase) • Nexviazyme™ (avalglucosidase alfa-ngpt) • Octagam® (IV) • Orencia® (Abatacept) • Panzyga® (IV) • Privigen® (IV) • Remicade® (Infliximab) • Renflexis® (Infliximab-abda) • Revcovi® (elapegademase-lvlr) • Simponi Aria® (Golimumab) • Vimizim® (elosulfase alfa) • Viltepso™ (viltolarsen) • Vyondys 53™ (golodirsen) • Xembify® (SC)

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