

# UnitedHealthcare Commercial Medical Policy Update Bulletin: July 2023

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## Take Note

### Quarterly CPT® and HCPCS Code Updates

Effective **Jul. 1, 2023**, 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 Quarterly Update](#)

Policy Title	Policy Type	Summary of Changes
Assisted Administration of Clotting Factors, Coagulant Blood Products & Other Hemostatics (for Oxford Only)	Medical Benefit Drug Policy	<ul style="list-style-type: none"> <li>• Added HCPCS code J7213</li> </ul>
Cardiovascular Disease Risk Tests	Medical Policy	<ul style="list-style-type: none"> <li>• Revised description for CPT code 0308U</li> </ul>
Carrier Testing for Genetic Diseases	Medical Policy	<ul style="list-style-type: none"> <li>• Added CPT code 0400U</li> </ul>
Category III Codes	Medical Policy	<ul style="list-style-type: none"> <li>• Added CPT codes 0791T, 0792T, 0793T, 0794T, 0795T, 0796T, 0797T, 0798T, 0799T, 0800T, 0801T, 0802T, 0803T, 0804T, 0805T, 0806T, 0807T, 0808T, 0809T, and 0810T</li> </ul>
Clotting Factors, Coagulant Blood Products & Other Hemostatics	Medical Benefit Drug Policy	<ul style="list-style-type: none"> <li>• Added HCPCS code J7213</li> </ul>
Genetic Testing for Cardiac Disease	Medical Policy	<ul style="list-style-type: none"> <li>• Added CPT code 0401U</li> </ul>
Immune Globulin (IVIG and SCIG)	Medical Benefit Drug Policy	<ul style="list-style-type: none"> <li>• Added HCPCS code J1576</li> </ul>
Long-Acting Injectable Antiretroviral Agents for HIV	Medical Benefit Drug Policy	<ul style="list-style-type: none"> <li>• Replaced HCPCS codes C9399, J3490, and J3590 with J1961</li> </ul>
Molecular Oncology Testing for Cancer Diagnosis, Prognosis, and Treatment Decisions	Medical Policy	<ul style="list-style-type: none"> <li>• Added CPT codes 0388U, 0391U, and 0397U</li> </ul>
Pharmacogenetic Panel Testing	Medical Policy	<ul style="list-style-type: none"> <li>• Added CPT code 0392U</li> </ul>
Preimplantation Genetic Testing and Related Services	Medical Policy	<ul style="list-style-type: none"> <li>• Added CPT code 0396U</li> </ul>
Provider Administered Drugs – Site of Care	Medical Benefit Drug Policy	<ul style="list-style-type: none"> <li>• Added HCPCS code J9381</li> <li>• Replaced HCPCS code J1599 with J1576</li> </ul>
Sacroiliac Joint Interventions	Medical Policy	<ul style="list-style-type: none"> <li>• Added CPT code 0809T</li> </ul>

## Take Note

Policy Title	Policy Type	Summary of Changes
Syfovre™ (Pegcetacoplan Injection)	Medical Benefit Drug Policy	<ul style="list-style-type: none"> <li>Replaced HCPCS code C9399 with C9151</li> </ul>
Tziel™ (Teplizumab-Mzwv)	Medical Benefit Drug Policy	<ul style="list-style-type: none"> <li>Removed C9149</li> <li>Replaced J3490 and J3590 with J9381</li> </ul>

## Medical Policy Updates

Updated		
Policy Title	Effective Date	Summary of Changes
Genetic Testing for Hereditary Cancer	Sep. 1, 2023	<p><b>Documentation Requirements</b></p> <ul style="list-style-type: none"> <li>Updated list of CPT codes with associated documentation requirements; removed 81165, 81166, 81167, and 81216</li> </ul> <p><b>Applicable Codes</b></p> <ul style="list-style-type: none"> <li>Removed CPT codes 81165, 81166, 81167, and 81216</li> </ul>
Infertility Diagnosis, Treatment and Fertility Preservation	Sep. 1, 2023	<p><b>Applicable Codes</b></p> <ul style="list-style-type: none"> <li>Removed CPT code 81224</li> </ul>
Intrauterine Fetal Surgery	Jul. 1, 2023	<p><b>Coverage Rationale</b></p> <ul style="list-style-type: none"> <li>Replaced reference to “congenital cystic adenomatoid malformation (CCAM)” with “congenital cystic adenomatoid malformation (CCAM)/congenital pulmonary airway malformation (CPAM)”</li> </ul> <p><b>Supporting Information</b></p> <ul style="list-style-type: none"> <li>Updated <i>Clinical Evidence</i> and <i>References</i> sections to reflect the most current information</li> <li>Removed <i>Benefit Considerations</i> section</li> </ul>
Outpatient Surgical Procedures – Site of Service	Jul. 1, 2023	<p><b>Coverage Rationale</b></p> <ul style="list-style-type: none"> <li>Updated list of conditions in which a planned surgical procedure performed in a hospital outpatient department is considered medically necessary if there is an inability to access an ambulatory surgical center (ASC); replaced “an ASC’s specific guideline regarding the individual’s weight or health conditions <i>prevents the use of an ASC</i>” with “an ASC’s specific guideline regarding the individual’s health conditions or weight <i>precludes management of an individual within an ASC setting</i>”</li> </ul> <p><b>Supporting Information</b></p> <ul style="list-style-type: none"> <li>Updated <i>References</i> section to reflect the most current information</li> </ul>
Surgery of the Ankle	Aug. 1, 2023	<p><b>Applicable Codes</b></p> <ul style="list-style-type: none"> <li>Revised description for CPT code 27685</li> </ul> <p><b>Supporting Information</b></p> <ul style="list-style-type: none"> <li>Updated <i>Clinical Evidence</i> and <i>References</i> sections to reflect the most current information</li> </ul>
Surgery of the Hand or Wrist	Sep. 1, 2023	<p><b>Documentation Requirements</b></p> <ul style="list-style-type: none"> <li>Updated list of CPT codes with associated documentation requirements; removed 25447</li> </ul> <p><b>Applicable Codes</b></p> <ul style="list-style-type: none"> <li>Removed CPT codes 25332 and 25447</li> </ul>

## Medical Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Abnormal Uterine Bleeding and Uterine Fibroids	Aug. 1, 2023	<p><b>Coverage Rationale</b></p> <ul style="list-style-type: none"> <li>Removed language indicating ultrasound-guided radiofrequency ablation (e.g., Acessa™, Sonata®) is unproven and not medically necessary for treating uterine fibroids due to insufficient evidence of efficacy</li> </ul> <p><b>Applicable Codes</b></p> <ul style="list-style-type: none"> <li>Removed CPT codes 0404T and 58674</li> </ul> <p><b>Supporting Information</b></p> <ul style="list-style-type: none"> <li>Updated <i>Description of Services</i>, <i>Clinical Evidence</i>, <i>FDA</i>, and <i>References</i> sections to reflect the most current information</li> </ul>	<p><b>Endometrial Ablation</b></p> <p>Endometrial ablation is proven and medically necessary for treating abnormal uterine bleeding in premenopausal women. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Hysteroscopy, Operative, Endometrial ablation for abnormal bleeding in premenopausal women.</p> <p>Click <a href="#">here</a> to view the InterQual® criteria.</p> <p><b>Levonorgestrel-Releasing Intrauterine Device</b></p> <p>Levonorgestrel-releasing intrauterine devices (LNG-IUD) (e.g., Mirena®, Skyla®, Liletta® or Kyleena™) are proven and medically necessary for treating menorrhagia. Refer to the U.S. Food and Drug Administration (FDA) section of the policy for additional information.</p> <p><b>Uterine Fibroids</b></p> <p>Uterine artery embolization (UAE) is proven and medically necessary for treating symptomatic uterine fibroids when there is documentation of evaluation of abnormal uterine bleeding (AUB) including endometrial biopsy for individuals &gt; 40 years of age and a pap smear screening consistent with current guidelines. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Uterine Artery Embolization (UAE).</p> <p>Click <a href="#">here</a> to view the InterQual® criteria.</p> <p>UAE is unproven and not medically necessary for the purpose of preserving childbearing potential for women with symptomatic uterine fibroids due to insufficient evidence of efficacy.</p> <p>Magnetic resonance-guided focused ultrasound ablation (MRgFUS) is unproven and not medically necessary for treating uterine fibroids due to insufficient evidence of efficacy.</p>

## Medical Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Ambulance Services	Aug. 1, 2023	<p><b>Template Update</b></p> <ul style="list-style-type: none"> <li>Changed policy type classification from “Coverage Determination Guideline” to “Medical Policy”</li> </ul> <p><b>Coverage Rationale</b></p> <ul style="list-style-type: none"> <li>Revised language to indicate:           <p><b>Emergency Air Ambulance Services</b></p> <ul style="list-style-type: none"> <li>Emergency Air Ambulance services are considered Medically Necessary when <b>all</b> of the following criteria are present:               <ul style="list-style-type: none"> <li>The member’s medical condition requires immediate transportation that cannot be provided by ground ambulance and a delay in transportation time may endanger the member’s life or seriously endanger the member’s health including:                   <ul style="list-style-type: none"> <li>When ground transport times are excessive (i.e., 30-60 minutes or longer)</li> <li>When weather or traffic conditions make ground ambulance transportation impractical,</li> </ul> </li> </ul> </li> </ul> </li> </ul>	<p><b>Emergency Air Ambulance services are considered Medically Necessary when all of the following criteria are present:</b></p> <ul style="list-style-type: none"> <li>The member’s medical condition requires immediate transportation that cannot be provided by ground ambulance and a delay in transportation time may endanger the member’s life or seriously endanger the member’s health including:           <ul style="list-style-type: none"> <li>When ground transport times are excessive (i.e., 30 - 60 minutes or longer); or</li> <li>When weather or traffic conditions make ground ambulance transportation impractical, impossible, or overly time consuming; or</li> <li>When the pickup point is inaccessible by ground ambulance</li> </ul> </li> <li>The member’s destination is the nearest acute care hospital that can meet the member’s needs; and</li> <li>One of the following conditions exist:           <ul style="list-style-type: none"> <li>Services requested by police or medical authorities at the site of an Emergency; or</li> <li>Advanced or basic life support is required during transportation</li> </ul> </li> </ul> <p><b>Emergency Air Ambulance services are not considered Medically Necessary for all other indications.</b></p> <p><b>Emergency ground ambulance services are considered Medically Necessary when all of the following criteria are present:</b></p> <ul style="list-style-type: none"> <li>The member’s medical condition requires immediate transportation:           <ul style="list-style-type: none"> <li>To the nearest acute hospital that can provide services appropriate to the covered person’s illness or injury; or</li> <li>To the nearest neonatal special care unit for newborn infants’ treatment of illness, injuries, congenital birth defects, or complications of premature birth that require that level of care; or</li> <li>To a hospital that provides a required higher level of care that was not available at the original hospital</li> </ul> </li> <li>A delay in transportation time may endanger the member’s life or seriously endanger the member’s health; and</li> </ul>

## Medical Policy Updates

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Ambulance Services (continued)	Aug. 1, 2023	<ul style="list-style-type: none"> <li>impossible, or overly time consuming               <ul style="list-style-type: none"> <li>- When the pickup point is inaccessible by ground ambulance</li> </ul> </li> <li>▪ The member's destination is the nearest acute care hospital that can meet the member's needs</li> <li>▪ <b>One</b> of the following conditions exist:               <ul style="list-style-type: none"> <li>- Services requested by police or medical authorities at the site of an emergency</li> <li>- Advanced or basic life support is required during transportation</li> </ul> </li> <li>○ Emergency Air Ambulance services are not considered Medically Necessary for all other indications [not listed above]</li> </ul> <p><b><i>Emergency Ground Ambulance Services</i></b></p> <ul style="list-style-type: none"> <li>○ Emergency ground ambulance services are considered Medically Necessary when <b>all</b> of the following criteria are present:               <ul style="list-style-type: none"> <li>▪ The member's medical condition requires immediate transportation:</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Advanced or basic life support is required during transportation</li> </ul> <p><b>Emergency ground ambulance services without ground transportation are considered Medically Necessary when treatment is rendered by the emergency ground ambulance personnel at the scene. Emergency ground ambulance transportation is not considered Medically Necessary for all other indications.</b></p>



## Medical Policy Updates

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Ambulance Services (continued)	Aug. 1, 2023	<ul style="list-style-type: none"> <li>- To the nearest acute hospital that can provide services appropriate to the covered person's illness or injury</li> <li>- To the nearest neonatal special care unit for newborn infants' treatment of illness, injuries, congenital birth defects, or complications of premature birth that require that level of care</li> <li>- To a hospital that provides a required higher level of care that was not available at the original hospital               <ul style="list-style-type: none"> <li>▪ A delay in transportation time may endanger the member's life or seriously endanger the member's health</li> </ul> </li> <li>○ Advanced or basic life support is required during transportation</li> <li>○ Emergency ground ambulance services without ground transportation are considered</li> </ul>	

## Medical Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Ambulance Services (continued)	Aug. 1, 2023	<p>Medically Necessary when treatment is rendered by the emergency ground ambulance personnel at the scene</p> <ul style="list-style-type: none"> <li>Emergency ground ambulance transportation is not considered Medically Necessary for all other indications [not listed above]</li> </ul> <p><b>Applicable Codes</b></p> <ul style="list-style-type: none"> <li>Revised description for:               <ul style="list-style-type: none"> <li>Modifier G</li> <li>Revenue code 0546</li> </ul> </li> </ul> <p><b>Supporting Information</b></p> <ul style="list-style-type: none"> <li>Added <i>Description of Services</i>, <i>Benefit Considerations</i> (previously located in <i>Coverage Rationale</i> section), <i>Clinical Evidence</i>, and <i>FDA</i> sections</li> <li>Updated <i>References</i> section to reflect the most current information</li> </ul>	
Category III Codes	Aug. 1, 2023	<p><b>Coverage Rationale</b></p> <ul style="list-style-type: none"> <li>Added language to clarify Category III codes are considered experimental, investigational, or unproven and not medically necessary due to insufficient evidence of efficacy <i>unless otherwise specified in another applicable UnitedHealthcare Policy</i></li> </ul> <p><b>Applicable Codes</b></p> <ul style="list-style-type: none"> <li>Updated list of experimental, investigational, or unproven and</li> </ul>	<p>Unless otherwise specified in another applicable UnitedHealthcare Policy, category III codes are considered experimental, investigational, or unproven and not medically necessary due to insufficient evidence of efficacy. Refer to the <i>Category III CPT Codes List</i> in the <i>Applicable Codes</i> section of the policy for specific information surrounding a Category III code.</p>

## Medical Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Category III Codes (continued)	Aug. 1, 2023	<p>not medically necessary Category III codes:</p> <ul style="list-style-type: none"> <li>○ Added CPT code 0779T and corresponding reference link to the Medical Policy titled <i>Gastrointestinal Motility Disorders, Diagnosis and Treatment</i></li> <li>○ Removed CPT code 0404T and corresponding reference link to the Medical Policy titled <i>Abnormal Uterine Bleeding and Uterine Fibroids</i></li> <li>○ Added reference link to the Medical Policy titled <i>Macular Degeneration Treatment Procedures</i> for CPT codes 0378T and 0379T</li> </ul>	
Cell-Free Fetal DNA Testing	Aug. 1, 2023	<p><b>Related Policies</b></p> <ul style="list-style-type: none"> <li>● Added reference link to the Medical Policy titled <i>Preimplantation Genetic Testing and Related Services</i></li> </ul> <p><b>Coverage Rationale</b> <b>DNA-Based Noninvasive Prenatal Tests</b></p> <ul style="list-style-type: none"> <li>● Replaced language indicating “DNA-based noninvasive prenatal tests of fetal aneuploidy are proven and medically necessary as screening tools for trisomy 21 (Down syndrome), trisomy 18 (Edwards syndrome) or trisomy 13</li> </ul>	<p><b>DNA-based noninvasive prenatal tests of fetal Aneuploidy are proven and medically necessary as screening tools for Trisomy 21 (Down syndrome), Trisomy 18 (Edwards syndrome) or Trisomy 13 (Patau syndrome), with or without fetal sex chromosomes, for individuals with a singleton or twin pregnancy in any one of the following circumstances:</b></p> <ul style="list-style-type: none"> <li>● Birthing person aged 35 years or older at delivery and/or donor oocyte aged 35 years or older; or</li> <li>● Fetal ultrasound findings indicating an increased risk of Aneuploidy; or</li> <li>● History of a prior pregnancy with a trisomy due to translocation; or</li> <li>● Positive first- or second-trimester screening test results for Aneuploidy; or</li> <li>● Parental balanced Robertsonian translocation with an increased risk of fetal Trisomy 13 or Trisomy 21; or</li> <li>● Screening after pre-test counseling from a board-certified genetic counselor or from the prenatal care physician or healthcare professional using Shared Decision-Making (SDM)</li> </ul>

## Medical Policy Updates

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Cell-Free Fetal DNA Testing (continued)	Aug. 1, 2023	<p>(Patau syndrome) for individuals with a singleton pregnancy in any one of the [listed] circumstances” with “DNA-based noninvasive prenatal tests of fetal Aneuploidy are proven and medically necessary as screening tools for Trisomy 21 (Down syndrome), Trisomy 18 (Edwards syndrome) or Trisomy 13 (Patau syndrome), <i>with or without fetal sex chromosomes</i>, for individuals with a singleton <i>or twin</i> pregnancy in any one of the [listed] circumstances</p> <ul style="list-style-type: none"> <li>• Revised list of circumstances in which DNA-based noninvasive prenatal tests of fetal Aneuploidy are proven and medically necessary; replaced: <ul style="list-style-type: none"> <li>○ “<i>Maternal age or oocyte age of 35 years or older at delivery</i>” with “<i>birthing person aged 35 years or older at delivery and/or donor oocyte aged 35 years or older</i>”</li> <li>○ “<i>History of a prior pregnancy with a trisomy</i>” with “<i>history of a prior pregnancy with a trisomy due to translocation</i>”</li> </ul> </li> <li>• Revised list of unproven and not medically necessary indications: <ul style="list-style-type: none"> <li>○ Added:</li> </ul> </li> </ul>	<p><b>Due to insufficient evidence of efficacy, DNA-based noninvasive prenatal tests are unproven and not medically necessary for any of the following:</b></p> <ul style="list-style-type: none"> <li>• For the sole purpose of determining the sex of the fetus unless the determination of fetal sex is essential to the diagnosis of a condition</li> <li>• For the sole purpose of determining twin zygosity</li> <li>• Conditions including, but not limited to, the following: <ul style="list-style-type: none"> <li>○ Pregnancies involving one or more of the following: <ul style="list-style-type: none"> <li>▪ Three or more fetuses</li> <li>▪ Fetal demise in a multiple gestation pregnancy</li> <li>▪ Vanishing twin syndrome</li> </ul> </li> <li>○ Repeat testing due to low fetal fraction</li> <li>○ Missed abortion/fetal demise in a single gestation pregnancy</li> <li>○ Screening for the following: <ul style="list-style-type: none"> <li>▪ Aneuploidy other than trisomies 21, 18, 13 or sex chromosomes</li> <li>▪ Microdeletions</li> <li>▪ Single gene disorders (e.g., Vistara™, PreSeek™, Unity™ Carrier Testing)</li> <li>▪ Fetal RhD status</li> </ul> </li> </ul> </li> </ul> <p><b>Due to insufficient evidence of efficacy, the following DNA-based noninvasive prenatal test is unproven and not medically necessary:</b></p> <ul style="list-style-type: none"> <li>• Vanadis®</li> </ul> <p><b>Genetic Counseling</b></p> <p>Genetic counseling is strongly recommended prior to fetal screening or prenatal diagnosis in order to inform persons being tested about the advantages and limitations of the test as applied to a unique person.</p>

## Medical Policy Updates

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Cell-Free Fetal DNA Testing (continued)	Aug. 1, 2023	<ul style="list-style-type: none"> <li>▪ For the sole purpose of determining the sex of the fetus unless the determination of fetal sex is essential to the diagnosis of a condition</li> <li>▪ Missed abortion/fetal demise in a single gestation pregnancy</li> <li>▪ Pregnancies involving one or more of the following:               <ul style="list-style-type: none"> <li>- Three or more fetuses</li> <li>- Fetal demise in a multiple gestation pregnancy</li> <li>- Vanishing twin syndrome</li> </ul> </li> <li>○ Removed “multiple gestation pregnancies”</li> <li>○ Replaced:               <ul style="list-style-type: none"> <li>▪ “Twin zygosity” with “<i>for the sole purpose of determining twin zygosity</i>”</li> <li>▪ “Screening for Aneuploidy other than trisomies 21, 18, or 13” with “screening for Aneuploidy other than trisomies 21, 18, 13, or sex chromosomes”</li> <li>▪ “Screening for single gene disorders” with “screening for single gene disorders”</li> </ul> </li> </ul>	

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Cell-Free Fetal DNA Testing (continued)	Aug. 1, 2023	<p>(e.g., Vistara™, PreSeek™, Unity™ Carrier Testing)”</p> <p><b>Documentation Requirements</b></p> <ul style="list-style-type: none"> <li>• Updated list of CPT codes with associated documentation requirements; added 0060U</li> <li>• Updated list of Required Clinical Information: <ul style="list-style-type: none"> <li>○ Added: <ul style="list-style-type: none"> <li>▪ Number of fetuses in current pregnancy</li> <li>▪ Purpose of test</li> </ul> </li> <li>○ Replaced “maternal age” with “age of birthing person and/or donor oocyte”</li> </ul> </li> </ul> <p><b>Definitions</b></p> <ul style="list-style-type: none"> <li>• Added definition of “Twin Zygoty”</li> <li>• Updated definition of: <ul style="list-style-type: none"> <li>○ Aneuploidy</li> <li>○ Cell Free Fetal DNA (cffDNA or cfDNA)</li> </ul> </li> </ul> <p><b>Applicable Codes</b></p> <ul style="list-style-type: none"> <li>• Added ICD-10 diagnosis codes O30.001, O30.002, O30.003, O30.009, O30.011, O30.012, O30.013, O30.019, O30.021, O30.022, O30.023, O30.029, O30.031, O30.032, O30.033, O30.039, O30.041, O30.042, O30.043, O30.049, O30.091, O30.092, O30.093, and O30.099</li> </ul>	

## Medical Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Cell-Free Fetal DNA Testing (continued)	Aug. 1, 2023	<ul style="list-style-type: none"> <li>Revised description for ICD-10 diagnosis codes O09.10, O09.11, O09.12, and O09.13</li> </ul> <p><b>Supporting Information</b></p> <ul style="list-style-type: none"> <li>Updated <i>Clinical Evidence</i> and <i>References</i> sections to reflect the most current information</li> </ul>	
Chromosome Microarray Testing (Non-Oncology Conditions)	Aug. 1, 2023	<p><b>Related Policies</b></p> <ul style="list-style-type: none"> <li>Added reference link to the Medical Policy titled <i>Whole Exome and Whole Genome Sequencing</i></li> </ul> <p><b>Coverage Rationale</b></p> <ul style="list-style-type: none"> <li>Added language to indicate pre-test genetic counseling is strongly recommended in order to inform persons being tested about the advantages and limitations of the test as applied to a unique person</li> <li>Replaced reference to “<i>genome-wide</i> comparative genomic hybridization/microarray testing or single-nucleotide polymorphism (SNP) chromosomal <i>microarray analysis</i>” with “chromosome microarray testing using array comparative genomic hybridization (aCGH) and/or single-nucleotide polymorphism (SNP) array”</li> <li>Revised list of proven and medically necessary indications; replaced: <ul style="list-style-type: none"> <li>“Evaluation of an embryo/fetus in <i>women</i> undergoing invasive</li> </ul> </li> </ul>	<p><b>Pre-test genetic counseling is strongly recommended in order to inform persons being tested about the advantages and limitations of the test as applied to a unique person.</b></p> <p><b>Chromosome microarray testing using array comparative genomic hybridization (aCGH) and/or single-nucleotide polymorphism (SNP) array is proven and medically necessary for the following:</b></p> <ul style="list-style-type: none"> <li>Evaluation of an embryo/fetus in the following cases: <ul style="list-style-type: none"> <li>Intrauterine Fetal Demise or Stillbirth</li> <li>Testing the products of conception following pregnancy loss</li> <li>Individuals undergoing invasive prenatal testing (i.e., amniocentesis, chorionic villus sampling or fetal tissue sampling)</li> </ul> </li> <li>Evaluation of individuals with one or more of the following: <ul style="list-style-type: none"> <li>Autism spectrum disorder</li> <li>Isolated severe congenital heart disease</li> <li>Multiple anomalies that are not specific to a Well-Delineated Genetic Syndrome and cannot be identified by a clinical evaluation alone</li> <li>Developmental Delay/Intellectual Disability where a specific syndrome is not suspected</li> </ul> </li> <li>Evaluation of biological parent of a fetus or child with an abnormal or equivocal finding on chromosome microarray testing results</li> </ul> <p><b>Chromosome microarray testing using aCGH or SNP array is unproven and not medically necessary for all other populations and conditions due to insufficient evidence of efficacy.</b></p>

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Chromosome Microarray Testing (Non-Oncology Conditions) (continued)	Aug. 1, 2023	<p>prenatal testing” with “evaluation of an embryo/fetus in <i>individuals</i> undergoing invasive prenatal testing”</p> <ul style="list-style-type: none"> <li>○ “Evaluation of individuals with <i>non-syndromic</i> Developmental Delay/Intellectual Disability” with “evaluation of individuals with Developmental Delay/Intellectual Disability <i>where a specific syndrome is not suspected</i>”</li> <li>○ “Evaluation of biological parent of a fetus or child with an equivocal chromosome microarray result” with “evaluation of biological parent of a fetus or child with an <i>abnormal or equivocal finding on chromosome microarray testing results</i>”</li> <li>● Removed list of examples of unproven and not medically necessary conditions</li> <li>● Removed reference link to the Medical Policy titled <i>Molecular Oncology Testing for Cancer Diagnosis Prognosis, and Treatment Decisions</i> for genome-wide comparative genomic hybridization microarray testing or SNP chromosomal microarray</li> </ul>	<p><b>Note:</b> Preimplantation genetic testing (PGT) is addressed in the Medical Policy titled Preimplantation Genetic Testing and Related Services.</p>



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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Chromosome Microarray Testing (Non-Oncology Conditions) (continued)	Aug. 1, 2023	<p>analysis for the evaluation of cancer</p> <p><b>Definitions</b></p> <ul style="list-style-type: none"> <li>Updated definition of: <ul style="list-style-type: none"> <li>Intellectual Disability</li> <li>Well-Delineated Genetic Syndrome</li> </ul> </li> </ul> <p><b>Supporting Information</b></p> <ul style="list-style-type: none"> <li>Updated <i>Description of Services</i>, <i>Clinical Evidence</i>, and <i>References</i> sections to reflect the most current information</li> </ul>	
Cosmetic and Reconstructive Procedures	Aug. 1, 2023	<p><b>Coverage Rationale</b></p> <p><b>Cosmetic Procedures</b></p> <ul style="list-style-type: none"> <li>Added language to indicate cosmetic procedures are procedures or services that change or improve appearance without significantly improving physiological function; a procedure is considered to be a cosmetic procedure when it does not meet the reconstructive criteria in the <i>Reconstructive Procedures</i> section [of the policy]</li> <li>Removed list of unproven and not medically necessary cosmetic procedures</li> <li>Added instruction to refer to the <i>Benefit Considerations</i> section [of the policy] for additional information on cosmetic services and exclusions</li> </ul>	<p><b>Reconstructive Procedures</b></p> <p>A procedure is considered reconstructive and medically necessary when all of the following criteria are met:</p> <ul style="list-style-type: none"> <li>There is documentation that the physical abnormality and/or physiological abnormality is causing a Functional Impairment that requires correction; and</li> <li>The proposed treatment is of proven efficacy and is deemed likely to significantly improve or restore the individual's physiological function.</li> </ul> <p><b>Note:</b> Microtia repair is considered Reconstructive although no Functional Impairment may be documented.</p> <p><b>Tissue Transfer (Flap) Repair</b></p> <p>Flap repair is considered reconstructive and medically necessary in certain circumstances. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Tissue Transfer (Flap).</p> <p>Click <a href="#">here</a> to view the InterQual® criteria.</p>

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Cosmetic and Reconstructive Procedures (continued)	Aug. 1, 2023	<p><b>Documentation Requirements</b></p> <ul style="list-style-type: none"> <li>Updated list of CPT codes with associated documentation requirements; removed 15731, 15736, 36468, 36470, and 36471</li> <li>Updated list of <i>Required Clinical Information</i>; removed reference link to the Medical Policy titled <i>Outpatient Surgical Procedures – Site of Service</i> for CPT codes 15731 and 15736</li> </ul> <p><b>Definitions</b></p> <ul style="list-style-type: none"> <li>Updated definition of: <ul style="list-style-type: none"> <li>Cosmetic Surgery</li> <li>Microtia</li> <li>Reconstructive Surgery</li> </ul> </li> <li>Removed definition of: <ul style="list-style-type: none"> <li>Adjacent Tissue Transfer</li> <li>Congenital Anomaly</li> <li>Cosmetic Procedures</li> <li>Cosmetic Procedures (California only)</li> <li>Injury</li> <li>Medically Necessary</li> <li>Reconstructive Procedures</li> <li>Reconstructive Procedures (California only)</li> <li>Sickness</li> </ul> </li> </ul> <p><b>Applicable Codes</b></p> <ul style="list-style-type: none"> <li>Removed coding clarifications and CPT coding tips</li> </ul> <p><b>Benefit Considerations</b></p> <ul style="list-style-type: none"> <li>Added language to indicate:</li> </ul>	<p><b>Cosmetic Procedures</b></p> <p>Cosmetic procedures are procedures or services that change or improve appearance without significantly improving physiological function. A procedure is considered to be a cosmetic procedure when it does not meet the reconstructive criteria in the reconstructive procedures section above.</p> <p>Procedures that correct an anatomical congenital anomaly without improving or restoring physiologic function are considered cosmetic procedures. The fact that a covered person may suffer psychological consequences or socially avoidant behavior as a result of an Injury, sickness or congenital anomaly does not classify surgery (or other procedures done to relieve such consequences or behavior) as a reconstructive procedure.</p> <p><b>Note:</b> Refer to the <i>Benefit Considerations</i> section of the policy for additional information on cosmetic services and exclusions.</p>

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Cosmetic and Reconstructive Procedures (continued)	Aug. 1, 2023	<ul style="list-style-type: none"> <li>○ Cosmetic Procedures are excluded from coverage</li> <li>○ In most benefit plans, the following cosmetic procedures are specifically excluded from coverage:               <ul style="list-style-type: none"> <li>▪ Pharmacological regimens, nutritional procedures, or treatments</li> <li>▪ Scar or tattoo removal or revision procedures (such as salabrasion, chemosurgery, and other such skin abrasion procedures)</li> <li>▪ Skin abrasion procedures performed as a treatment for acne</li> <li>▪ Liposuction or removal of fat deposits considered undesirable, including fat accumulation under the male breast and nipple; this exclusion does not apply to reconstructive liposuction</li> <li>▪ Treatment for skin wrinkles or any treatment to improve the appearance of the skin</li> <li>▪ Treatment for spider veins</li> <li>▪ Sclerotherapy treatment of veins</li> </ul> </li> </ul>	

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Cosmetic and Reconstructive Procedures (continued)	Aug. 1, 2023	<ul style="list-style-type: none"> <li>▪ Hair removal or replacement by any means, except for hair removal as part of genital reconstruction prescribed by a Physician for the treatment of gender dysphoria; for laser or electrolysis hair removal in advance of genital reconstruction, refer to the Medical Policy titled Gender Dysphoria Treatment</li> <li>○ Benefits for reconstructive procedures include breast reconstruction following a mastectomy and reconstruction of the non-affected breast to achieve symmetry; other services required by the Women's Health and Cancer Rights Act of 1998, including breast prostheses and treatment of complications, are provided in the same manner and at the same level as those for any other covered health care service</li> <li>○ If the original service was not a covered benefit under the contract or UnitedHealthcare</li> </ul>	

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Cosmetic and Reconstructive Procedures (continued)	Aug. 1, 2023	<p>guidelines (e.g., cosmetic, investigational, not a covered health service, etc.), then benefits are limited to the treatment of the complication</p> <ul style="list-style-type: none"> <li>▪ Examples include, but are not limited to, removal of a leaking or defective silicone breast prosthesis is a covered health care service</li> <li>▪ However, benefits for replacement of the breast prosthesis are only available if the original prosthesis was considered “reconstructive”</li> </ul> <p><b>Supporting Information</b></p> <ul style="list-style-type: none"> <li>• Updated <i>Description of Services</i> and <i>References</i> sections to reflect the most current information</li> </ul>	
Epidural Steroid Injections for Spinal Pain	Aug. 1, 2023	<p><b>Coverage Rationale</b></p> <ul style="list-style-type: none"> <li>• Revised coverage criteria:               <ul style="list-style-type: none"> <li>○ Added criterion requiring “evidence of structural and/or functional nerve root involvement”</li> <li>○ Removed criterion requiring:                   <ul style="list-style-type: none"> <li>▪ Evidence of nerve impingement by imaging or electromyography (EMG)</li> </ul> </li> </ul> </li> </ul>	<p><b>Epidural Steroid Injections (ESI) are proven and medically necessary when all of the following criteria are met:</b></p> <ul style="list-style-type: none"> <li>• The injection is intended for the management of Radicular Pain as evidenced by history and physical exam; and</li> <li>• The Radicular Pain is unresponsive to the following conservative treatment for ≥ 4 weeks:               <ul style="list-style-type: none"> <li>○ Pharmacotherapy such as NSAIDs or acetaminophen; or</li> <li>○ Activity modification (including but not limited to heavy lifting, bending, spinal torsion activities); or</li> <li>○ PT or home exercise; and</li> </ul> </li> <li>• There is evidence of structural and/or functional nerve root involvement; and</li> <li>• The injection is performed under fluoroscopic or CT guidance.</li> </ul>

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Epidural Steroid Injections for Spinal Pain (continued)	Aug. 1, 2023	<ul style="list-style-type: none"> <li>No evidence of a condition that would contraindicate Epidural Steroid Injections (ESIs)</li> <li>Updated list of examples of conditions that would contraindicate ESIs; removed “infection at the site of injection”</li> </ul> <p><b>Epidural Steroid Injection Limitations</b></p> <ul style="list-style-type: none"> <li>Replaced language indicating “subsequent ESIs may be provided if pain has returned or deterioration in function has occurred” with “subsequent ESIs may be provided if <i>Radicular</i> Pain has returned <i>and/or</i> deterioration in function has occurred”</li> </ul> <p><b>Supporting Information</b></p> <ul style="list-style-type: none"> <li>Updated <i>Clinical Evidence</i> and <i>References</i> sections to reflect the most current information</li> </ul>	<p>Conditions that would contraindicate ESIs include but are not limited to:</p> <ul style="list-style-type: none"> <li>Spinal neoplasm</li> <li>Rapidly progressing neurological deficit</li> <li>Epidural abscess</li> </ul> <p><b>The following are unproven and not medically necessary due to insufficient evidence of efficacy:</b></p> <ul style="list-style-type: none"> <li>The use of ultrasound guidance for ESIs</li> <li>ESI for all other indications of the spine not included above</li> </ul> <p><b>Epidural Steroid Injection Limitations</b></p> <ul style="list-style-type: none"> <li>A maximum of four (4) ESI sessions (per region, regardless of level, location, or side) per year <ul style="list-style-type: none"> <li>A session is defined as one date of service in which ESI injection(s) are performed</li> <li>A region is defined by either the region of the cervical, thoracic or lumbosacral</li> <li>A year is defined as the 12-month period starting from the date of service of the first approved injection</li> </ul> </li> <li>Subsequent ESIs may be provided only if: <ul style="list-style-type: none"> <li>Radicular pain has returned and/or deterioration in function has occurred; and</li> <li>The previous injection resulted in <math>\leq 50\%</math> pain relief or functional improvement for less than three months as measured by validated measurement tools and there has been a reassessment of the individual and the injection site and technique; or</li> <li>The previous injection resulted in <math>\geq 50\%</math> pain relief or functional improvement for three or more months as measured by validated measurement tools</li> </ul> </li> </ul>
Gender Dysphoria Treatment (for Commercial Only)	Jul. 1, 2023	<p><b>Notice of Revision:</b> The following summary of changes has been modified. Revisions to the previous policy update announcement are outlined in red below.</p>	<p><b>Notes:</b></p> <ul style="list-style-type: none"> <li>This Medical Policy does not apply to individuals with ambiguous genitalia or disorders of sexual development.</li> </ul>

## Medical Policy Updates

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Gender Dysphoria Treatment (for Commercial Only) (continued)	Jul. 1, 2023	<p><b>Please take note of the amended updates to be applied on Jul. 1, 2023.</b></p> <p><b>Related Policies</b></p> <ul style="list-style-type: none"> <li>Added reference link to the Medical Policy titled <i>Infertility Diagnosis, Treatment and Fertility Preservation</i></li> </ul> <p><b>Coverage Rationale</b></p> <ul style="list-style-type: none"> <li>Revised list of indications for surgical treatment for Gender Dysphoria; replaced “breast mastectomy/breast reduction surgery” with “breast surgery (mastectomy, breast reduction or <i>breast augmentation</i>)”</li> <li>Replaced references to:               <ul style="list-style-type: none"> <li>“<i>Psychological assessment</i>” with “<i>clinical assessment</i>”</li> <li>“Qualified Behavioral Health Provider” with “Qualified Healthcare Professional”</li> </ul> </li> <li>Revised criteria that must be met and documented in the written clinical assessment for:               <p><b>Breast Surgery</b></p> <ul style="list-style-type: none"> <li>Replaced criterion requiring the individual “must be 18 years of age (<i>age of majority</i>)” with “must be 18 years of age”</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>This Medical Policy does not apply to fully-insured group plans in California. Refer to the Benefit Interpretation Policy titled <i>Gender Dysphoria (Gender Identity Disorder) Treatment: CA</i>.</li> <li>This Medical Policy does not apply to fully-insured group plans in the state of Washington. Refer to the Benefit Interpretation Policy titled <i>Gender Dysphoria (Gender Identity Disorder) Treatment: WA</i>.</li> </ul> <p><b>Surgical treatment for Gender Dysphoria may be indicated for individuals who provide the following documentation:</b></p> <ul style="list-style-type: none"> <li>For breast surgery (mastectomy, breast reduction or breast augmentation), a written clinical assessment from at least one Qualified Healthcare Professional experienced in treating Gender Dysphoria is required. The assessment must document that an individual meets <b>all</b> of the following criteria:               <ul style="list-style-type: none"> <li>Persistent, well-documented Gender Dysphoria</li> <li>Capacity to make a fully informed decision and to consent for treatment</li> <li>Must be at least 18 years of age</li> <li>Favorable psychosocial-behavioral evaluation to provide screening and identification of risk factors or potential postoperative challenges</li> <li>For breast augmentation, continued Gender Dysphoria following the completion of 12 months of continuous hormone therapy prior to the breast procedure is required</li> </ul> </li> <li>For thyroid cartilage reduction and/or voice modification surgery (e.g., laryngoplasty, glottoplasty or shortening of the vocal cords), a written clinical assessment from at least one Qualified Healthcare Professional experienced in treating Gender Dysphoria is required. The assessment must document that an individual meets all of the following criteria:               <ul style="list-style-type: none"> <li>Persistent, well-documented Gender Dysphoria</li> <li>Capacity to make a fully informed decision and to consent for treatment</li> <li>Must be at least 18 years of age</li> <li>Favorable psychosocial-behavioral evaluation to provide screening and identification of risk factors or potential postoperative challenges</li> <li>Completion of 6 months of continuous hormone therapy prior to surgery</li> </ul> </li> </ul>

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Gender Dysphoria Treatment (for Commercial Only) (continued)	Jul. 1, 2023	<p><b><i>Thyroid Cartilage Reduction and/or Voice Modification Surgery</i></b></p> <ul style="list-style-type: none"> <li>○ Added criterion requiring:           <ul style="list-style-type: none"> <li>▪ Completion of 6 months of continuous hormone therapy prior to surgery is required for voice masculinization</li> <li>▪ For voice modification surgery, documentation of presurgical voice lessons and/or therapy</li> </ul> </li> <li>○ Replaced criterion requiring the individual “must be 18 years of age (<i>age of majority</i>)” with “must be 18 years of age”</li> </ul> <p><b><i>Genital Surgery</i></b></p> <ul style="list-style-type: none"> <li>○ Replaced criterion requiring an individual must:           <ul style="list-style-type: none"> <li>▪ “Be at least 18 years of age (<i>age of majority</i>)” with “be at least 18 years of age”</li> <li>▪ “Complete at least 12 months of successful continuous full-time real-life involvement in the <i>experienced</i> gender” with “complete at least 12 months of successful continuous full-time real-</li> </ul> </li> </ul>	<p>is required for voice masculinization</p> <ul style="list-style-type: none"> <li>○ For voice modification surgery, documentation of presurgical voice lessons and/or therapy</li> <li>● For genital surgery, a written clinical assessment from at least two Qualified Healthcare Professional experienced in treating Gender Dysphoria, who have independently assessed the individual, is required. The assessment must document that an individual meets <b>all</b> of the following criteria:           <ul style="list-style-type: none"> <li>○ Persistent, well-documented Gender Dysphoria</li> <li>○ Capacity to make a fully informed decision and to consent for treatment</li> <li>○ Must be at least 18 years of age</li> <li>○ Favorable psychosocial-behavioral evaluation to provide screening and identification of risk factors or potential postoperative challenges</li> <li>○ Complete at least 12 months of successful continuous full-time real-life involvement in the identified gender</li> <li>○ Complete 12 months of continuous hormone therapy appropriate for the experienced gender (unless medically contraindicated or not indicated for gender)</li> <li>○ Treatment plan that includes ongoing follow-up and care by a Qualified Healthcare Professional experienced in treating Gender Dysphoria</li> </ul> </li> </ul> <p><b>When the <a href="#">above criteria</a> are met, the following surgical procedures and/or therapies to treat Gender Dysphoria are medically necessary and covered as a proven benefit:</b></p> <ul style="list-style-type: none"> <li>● Bilateral mastectomy or breast reduction</li> <li>● Breast augmentation with breast implants or fat transfer</li> <li>● Clitoroplasty (creation of clitoris)</li> <li>● Hysterectomy (removal of uterus)</li> <li>● Labiaplasty (creation of labia)</li> <li>● Laser or electrolysis hair removal in advance of genital reconstruction prescribed by a physician for the treatment of Gender Dysphoria</li> <li>● Metoidioplasty (creation of penis, using clitoris)</li> <li>● Orchiectomy (removal of testicles)</li> <li>● Penectomy (removal of penis)</li> </ul>



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Gender Dysphoria Treatment (for Commercial Only) (continued)	Jul. 1, 2023	<p>life involvement in the <i>identified gender</i>”</p> <p><b>Medically Necessary and Covered as a Proven Benefit</b></p> <ul style="list-style-type: none"> <li>• Revised list of procedures and/or therapies that are medically necessary and covered as a proven benefit; added:               <ul style="list-style-type: none"> <li>○ Breast augmentation with breast implants or fat transfer</li> <li>○ Thyroid cartilage reduction/reduction thyroid chondroplasty/tracheal shave (removal or reduction of the Adam’s apple)</li> <li>○ Voice lessons and/or voice therapy</li> <li>○ Voice modification surgery (e.g., laryngoplasty, glottoplasty, or shortening of the vocal cords)</li> </ul> </li> </ul> <p><b>Cosmetic and Not Medically Necessary</b></p> <ul style="list-style-type: none"> <li>• Revised list of ancillary procedures that are considered cosmetic and not medically necessary when performed as part of surgical treatment for Gender Dysphoria; removed:               <ul style="list-style-type: none"> <li>○ Breast enlargement, including augmentation mammoplasty and breast implants</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Penile prosthesis</li> <li>• Phalloplasty (creation of penis)</li> <li>• Salpingo-oophorectomy (removal of fallopian tubes and ovaries)</li> <li>• Scrotoplasty (creation of scrotum)</li> <li>• Testicular prostheses</li> <li>• Thyroid cartilage reduction/reduction thyroid chondroplasty/tracheal shave (removal or reduction of the Adam’s apple)</li> <li>• Urethroplasty (reconstruction of female urethra)</li> <li>• Urethroplasty (reconstruction of male urethra)</li> <li>• Vaginectomy (removal of vagina)</li> <li>• Vaginoplasty (creation of vagina)</li> <li>• Voice lessons and/or voice therapy</li> <li>• Voice modification surgery (e.g., laryngoplasty, glottoplasty or shortening of the vocal cords)</li> <li>• Vulvectomy (removal of vulva)</li> </ul> <p><b>Certain ancillary procedures, including but not limited to the following, are considered cosmetic and not medically necessary when performed as part of surgical treatment for Gender Dysphoria:</b></p> <p>Refer to the <i>Benefit Considerations</i> section of the policy as member specific benefit plan language may vary.</p> <p><b>Note:</b> For fully insured group policies in New York, refer to the Benefit Considerations section for more information.</p> <ul style="list-style-type: none"> <li>• Abdominoplasty (also refer to the Medical Policy titled Panniculectomy and Body Contouring Procedures)</li> <li>• Blepharoplasty (also refer to the Medical Policy titled Brow Ptosis and Eyelid Repair)</li> <li>• Body contouring (e.g., fat transfer, lipoplasty, panniculectomy) (also refer to the Medical Policy titled Panniculectomy and Body Contouring Procedures)</li> <li>• Brow lift</li> <li>• Calf implants</li> </ul>

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Gender Dysphoria Treatment (for Commercial Only) (continued)	Jul. 1, 2023	<ul style="list-style-type: none"> <li>○ Thyroid cartilage reduction/reduction thyroid chondroplasty/trachea shave (removal or reduction of the Adam’s apple)</li> <li>○ Voice lessons and voice therapy</li> <li>○ Voice modification surgery (e.g., laryngoplasty, glottoplasty, or shortening of the vocal cords)</li> </ul> <p><b>Documentation Requirements</b></p> <ul style="list-style-type: none"> <li>● Updated list of CPT codes with associated documentation requirements; removed 14000, 19340, and 19342</li> <li>● Updated list of <i>Required Clinical Information</i> to reflect/include: <ul style="list-style-type: none"> <li>○ <del>When requested, high quality color photographs of the physical and/or physiological abnormality</del> <ul style="list-style-type: none"> <li>▪ <del>Note: All images must be labeled with the:</del> <ul style="list-style-type: none"> <li>- <del>Date taken</del></li> <li>- <del>Applicable case number obtained at time of notification, or member’s name and ID number</del></li> </ul> </li> <li>▪ <del>Submission of photographs can be submitted via the external</del></li> </ul> </li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>● Cheek, chin and nose implants</li> <li>● Injection of fillers or neurotoxins (also refer to the Medical Benefit Drug Policy titled Botulinum Toxins A and B)</li> <li>● Face/forehead lift and/or neck tightening</li> <li>● Facial bone remodeling for facial feminization</li> <li>● Laser or electrolysis hair removal not related to genital reconstruction</li> <li>● Hair transplantation</li> <li>● Lip augmentation</li> <li>● Lip reduction</li> <li>● Liposuction (suction-assisted lipectomy) (also refer to the Medical Policy titled Panniculectomy and Body Contouring Procedures)</li> <li>● Mastopexy</li> <li>● Pectoral implants for chest masculinization</li> <li>● Rhinoplasty (also refer to the Medical Policy titled Rhinoplasty and Other Nasal Surgeries)</li> <li>● Skin resurfacing (e.g., dermabrasion, chemical peels, laser)</li> </ul>

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Gender Dysphoria Treatment (for Commercial Only) (continued)	Jul. 1, 2023	<p><del>portal at</del> <del>uhprovider.com/paan;</del> <del>faxes will not be accepted</del></p> <ul style="list-style-type: none"> <li>○ The number of months member has completed continuous hormone therapy or reason for medical contraindication or non-indication</li> <li>○ A written clinical assessment from a Qualified Healthcare Professional experienced in treating Gender Dysphoria, who has independently assessed the individual; the assessment should include all of the following:               <ul style="list-style-type: none"> <li>▪ Persistent, well-documented gender dysphoria</li> <li>▪ The member is capable to make a fully informed decision and to consent for treatment</li> <li>▪ Member's age</li> <li>▪ Results of psychosocial-behavioral evaluation including management of coexisting mental health condition</li> </ul> </li> <li>○ Treatment plan that includes ongoing and follow-up care by a Qualified Healthcare</li> </ul>	

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Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Gender Dysphoria Treatment (for Commercial Only) (continued)	Jul. 1, 2023	<p>Professional experienced in treating Gender Dysphoria, and whether request is part of a staged procedure</p> <ul style="list-style-type: none"> <li>○ For voice modification surgery, in addition to the above, also include documentation of presurgical voice lessons and/or therapy</li> <li>○ For genital surgery, in addition to the above, also include:               <ul style="list-style-type: none"> <li>▪ Clinical written assessment from a second Qualified Healthcare Professional experienced in treating Gender Dysphoria, who has independently assessed the individual</li> <li>▪ Documentation the member has completed at least 12 months of successful continuous full-time real-life experience in identified gender</li> </ul> </li> </ul> <p><b>Definitions</b></p> <ul style="list-style-type: none"> <li>● Added definition of “Qualified Healthcare Professional”</li> <li>● Removed definition of “Qualified Behavioral Health Provider”</li> </ul> <p><b>Applicable Codes</b></p> <ul style="list-style-type: none"> <li>● Removed CPT codes 19340 and 19342</li> </ul> <p><b>Supporting Information</b></p>	

## Medical Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Gender Dysphoria Treatment (for Commercial Only) (continued)	Jul. 1, 2023	<ul style="list-style-type: none"> <li>Updated <i>Description of Services</i>, <i>Clinical Evidence</i>, and <i>References</i> sections to reflect the most current information</li> </ul>	
Glaucoma Surgical Treatments	Sep. 1, 2023	<p><b>Coverage Rationale</b></p> <ul style="list-style-type: none"> <li>Revised list of unproven and not medically necessary indications for treating any type of glaucoma; replaced:               <ul style="list-style-type: none"> <li>“Canaloplasty (ab interno) and gonioscopy-assisted transluminal trabeculotomy (e.g., OMNI® Surgical System) with “combined canaloplasty (ab interno) and gonioscopy-assisted transluminal trabeculotomy (e.g., OMNI® Surgical System)”</li> <li>“Goniotomy or gonioscopy-assisted transluminal trabeculotomy (for all other conditions not [listed in the policy as proven or medically necessary])” with “goniotomy or gonioscopy-assisted transluminal trabeculotomy (for all other indications [not listed in the policy as proven or medically necessary])”</li> </ul> </li> </ul> <p><b>Applicable Codes</b></p> <ul style="list-style-type: none"> <li>Removed CPT codes 66184 and 66185</li> </ul>	<p><b>The following are proven and medically necessary:</b></p> <ul style="list-style-type: none"> <li>Goniotomy or Gonioscopy-assisted transluminal trabeculotomy for pediatric glaucoma (age 18 years or less)</li> <li>iStent®, iStent Inject®, or the Hydrus® Microstent when used in combination with cataract surgery for treating mild to moderate open-angle glaucoma (OAG) and a cataract in adults currently being treated with ocular hypotensive medication</li> <li>Some glaucoma drainage devices (specifically: XEN System, EX-PRESS, Molteno Implant, Baerveldt Tube Shunt, Ahmed Glaucoma Valve Implant and Krupin-Denver Valve Implant) for treating refractory glaucoma when medical or surgical treatments have failed or are inappropriate</li> </ul> <p><b>The following are unproven and not medically necessary for treating any type of glaucoma due to insufficient evidence of efficacy and/or safety:</b></p> <ul style="list-style-type: none"> <li>Canaloplasty (ab interno)</li> <li>Combined Canaloplasty (ab interno) and gonioscopy-assisted transluminal trabeculotomy (e.g., OMNI® Surgical System)</li> <li>Glaucoma drainage devices that are not FDA approved</li> <li>Goniotomy or Gonioscopy-Assisted Transluminal Trabeculotomy (for all other indications)</li> </ul>

## Medical Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Glaucoma Surgical Treatments (continued)	Sep. 1, 2023	<p><b>Supporting Information</b></p> <ul style="list-style-type: none"> <li>Updated <i>Description of Services</i>, <i>Clinical Evidence</i>, <i>FDA</i>, and <i>References</i> sections to reflect the most current information</li> </ul>	
Macular Degeneration Treatment Procedures	Aug. 1, 2023	<p><b>Coverage Rationale</b></p> <ul style="list-style-type: none"> <li>Added language to indicate: <ul style="list-style-type: none"> <li>Home visual field monitoring (e.g., ForeseeHome) for detection of age-related macular degeneration (AMD)-associated choroidal neovascularization (CNV) is proven and medically necessary when <b>all</b> of the following criteria are met: <ul style="list-style-type: none"> <li>The individual is at risk for developing CNV with <b>one</b> of the following: <ul style="list-style-type: none"> <li>Bilateral large drusen; or</li> <li>Large drusen in one eye and advanced AMD in the fellow eye</li> </ul> </li> <li>Best corrected visual acuity of 20/60 or better in the affected eye(s)</li> <li>The individual is able to operate the device</li> <li>The individual does not have <b>any</b> of the following: <ul style="list-style-type: none"> <li>Medial opacities that prevent quality fundus</li> </ul> </li> </ul> </li> </ul> </li> </ul>	<p><b>The following is proven and medically necessary:</b></p> <ul style="list-style-type: none"> <li>The Implantable Miniature Telescope (IMT) when used according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings and precautions for treating individuals with end-stage, age-related macular degeneration</li> </ul> <p><b>Home visual field monitoring (e.g., ForeseeHome) for detection of age-related macular degeneration (AMD)-associated choroidal neovascularization (CNV) is proven and medically necessary when all of the following criteria are met:</b></p> <ul style="list-style-type: none"> <li>The individual is at risk for developing CNV with one of the following: <ul style="list-style-type: none"> <li>Bilateral large drusen; or</li> <li>Large drusen in one eye and advanced AMD in the fellow eye; and</li> </ul> </li> <li>Best corrected visual acuity of 20/60 or better in the affected eye(s); and</li> <li>The individual is able to operate the device; and</li> <li>The individual does not have any of the following: <ul style="list-style-type: none"> <li>Medial opacities that prevent quality fundus photographs</li> <li>Other retinal disorders (e.g., diabetic retinopathy)</li> </ul> </li> </ul> <p><b>Home visual field monitoring is unproven and not medically necessary due to insufficient evidence of efficacy for all other indications not listed as proven.</b></p> <p><b>The following are unproven and not medically necessary due to insufficient evidence of efficacy:</b></p> <ul style="list-style-type: none"> <li>Conjunctival incision with posterior extrascleral placement of a pharmacologic agent for treating ocular disorders including age-related macular degeneration</li> <li>Laser photocoagulation for treating macular drusen</li> </ul>

## Medical Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Macular Degeneration Treatment Procedures (continued)	Aug. 1, 2023	<ul style="list-style-type: none"> <li>photographs</li> <li>- Other retinal disorders (e.g., diabetic retinopathy)</li> <li>o Home visual field monitoring is unproven and not medically necessary due to insufficient evidence of efficacy for <b>all</b> other indications not listed as proven</li> </ul> <p><b>Applicable Codes</b></p> <ul style="list-style-type: none"> <li>• Added CPT codes 0378T and 0379T</li> </ul> <p><b>Supporting Information</b></p> <ul style="list-style-type: none"> <li>• Updated <i>Description of Services</i>, <i>Clinical Evidence</i>, <i>FDA</i>, and <i>References</i> sections to reflect the most current information</li> </ul>	<ul style="list-style-type: none"> <li>• Radiation therapy for AMD (i.e., epimacular and/or epiretinal brachytherapy and stereotactic radiotherapy and/or radiosurgery)</li> </ul>
Skin and Soft Tissue Substitutes	Sep. 1, 2023	<p><b>Coverage Rationale</b></p> <ul style="list-style-type: none"> <li>• Revised list of skin and soft tissue substitutes that are unproven and not medically necessary for any indication; added: <ul style="list-style-type: none"> <li>o Complete™ FT</li> <li>o Complete™ SL</li> <li>o Kerecis® Omega3 MariGen® Shield</li> <li>o NeoMatriX</li> <li>o NeoStim Membrane</li> <li>o NeoStim TL Membrane</li> <li>o NeoStimDL</li> <li>o SurGraft® FT</li> <li>o SurGraft® XT</li> </ul> </li> </ul>	Refer to the policy for complete details.

## Medical Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Skin and Soft Tissue Substitutes (continued)	Sep. 1, 2023	<p><b>Applicable Codes</b></p> <ul style="list-style-type: none"> <li>Added HCPCS codes A2021, Q4265, Q4266, Q4267, Q4268, Q4269, Q4270, and Q4271</li> </ul> <p><b>Supporting Information</b></p> <ul style="list-style-type: none"> <li>Updated <i>Clinical Evidence</i> section to reflect the most current information</li> </ul>	
Retired			
Policy Title	Effective Date	Summary of Changes	
Environmental Allergen Immunotherapy	Jul. 1, 2023	<ul style="list-style-type: none"> <li>Policy retired; environmental allergen immunotherapy no longer requires clinical review</li> </ul>	
Vitamin D Testing	Jul. 1, 2023	<ul style="list-style-type: none"> <li>Policy retired; vitamin D testing no longer requires clinical review</li> </ul>	



## Medical Benefit Drug Policy Updates

New		
Policy Title	Effective Date	Coverage Rationale
Briumvi® (Ublituximab-Xiiy)	Jul. 1, 2023	<p>Briumvi (ublituximab-xiiy) has been added to the Review at Launch program. Some members may not be eligible for coverage of this medication at this time. Refer to the Medical Benefit Drug Policy titled Review at Launch for New to Market Medications for additional details.</p> <p>Briumvi (ublituximab-xiiy) is proven for the treatment of:</p> <p><b>Relapsing Forms of Multiple Sclerosis</b></p> <p>Briumvi is medically necessary for the treatment of relapsing forms of multiple sclerosis (MS) when all of the following criteria are met:</p> <ul style="list-style-type: none"> <li>• For <b>initial therapy</b>, all of the following: <ul style="list-style-type: none"> <li>○ Diagnosis of relapsing forms of multiple sclerosis (MS) (e.g., relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses); <b>and</b></li> <li>○ Patient is <b>not</b> receiving Briumvi in combination with <b>any</b> of the following: <ul style="list-style-type: none"> <li>▪ Disease modifying therapy (e.g., interferon beta preparations, glatiramer acetate, natalizumab, fingolimod, cladribine, siponimod, or teriflunomide).</li> <li>▪ B cell targeted therapy (e.g., rituximab, belimumab, ofatumumab, ocrelizumab).</li> <li>▪ Lymphocyte trafficking blockers (e.g., alemtuzumab, mitoxantrone).</li> </ul> </li> </ul> <p><b>and</b></p> <ul style="list-style-type: none"> <li>○ Briumvi dosing is in accordance with the United States Food and Drug Administration approved labeling; <b>and</b></li> <li>○ Initial authorization is for no more than 6 months.</li> </ul> </li> <li>• For continuation of therapy, all of the following: <ul style="list-style-type: none"> <li>○ Patient has previously received treatment with Briumvi; <b>and</b></li> <li>○ Documentation of positive clinical response to Briumvi therapy; <b>and</b></li> <li>○ Patient is <b>not</b> receiving Briumvi in combination with <b>any</b> of the following: <ul style="list-style-type: none"> <li>▪ Disease modifying therapy (e.g., interferon beta preparations, dimethyl fumarate, glatiramer acetate, natalizumab, fingolimod, cladribine, siponimod, or teriflunomide).</li> <li>▪ B cell targeted therapy (e.g., rituximab, belimumab, ofatumumab, ocrelizumab).</li> <li>▪ Lymphocyte trafficking blockers (e.g., alemtuzumab, mitoxantrone).</li> </ul> </li> </ul> <p><b>and</b></p> <ul style="list-style-type: none"> <li>○ Briumvi dosing is in accordance with the United States Food and Drug Administration approved labeling; <b>and</b></li> <li>○ Authorization is for no more than 12 months.</li> </ul> </li> </ul>

## Medical Benefit Drug Policy Updates

New		
Policy Title	Effective Date	Coverage Rationale
Qalsody™ (Tofersen)	Jul. 1, 2023	<p>Qalsody™ (tofersen) has been added to the Review at Launch program. Some members may not be eligible for coverage of this medication at this time. Refer to the Medical Benefit Drug Policy titled Review at Launch for New to Market Medications for additional details.</p> <p>Qalsody (tofersen) is proven and medically necessary for the treatment of amyotrophic lateral sclerosis (ALS) in patients who meet all of the following criteria:</p> <ul style="list-style-type: none"> <li>• For <b>initial therapy</b>, all of the following:               <ul style="list-style-type: none"> <li>○ Submission of medical records (e.g., chart notes, previous medical history, diagnostic testing including: imaging, nerve conduction studies, laboratory values) to support the diagnosis of ALS; <b>and</b></li> <li>○ Submission of medical records confirming mutation in the superoxide dismutase 1 (SOD1) gene; <b>and</b></li> <li>○ Provider attestation that the patient's baseline functional ability has been documented prior to initiating treatment (e.g., speech, walking, climbing stairs, etc.); <b>and</b></li> <li>○ Patient is <b>not</b> dependent on invasive ventilation or tracheostomy; <b>and</b></li> <li>○ Qalsody is prescribed by, or in consultation with, a neurologist with expertise in the diagnosis of ALS; <b>and</b></li> <li>○ Qalsody dosing for ALS is in accordance with the United States Food and Drug Administration approved labeling; <b>and</b></li> <li>○ Initial authorization will be for no more than 6 months.</li> </ul> </li> <li>• For <b>continuation of therapy</b>, all of the following:               <ul style="list-style-type: none"> <li>○ Diagnosis of ALS; <b>and</b></li> <li>○ Patient is currently receiving Qalsody therapy; <b>and</b></li> <li>○ Provider attestation that the patient has slowed disease progression from baseline; <b>and</b></li> <li>○ Patient is <b>not</b> dependent on invasive ventilation or tracheostomy; <b>and</b></li> <li>○ Qalsody is prescribed by, or in consultation with, a neurologist with expertise in the diagnosis of ALS; <b>and</b></li> <li>○ Qalsody dosing for ALS is in accordance with the United States Food and Drug Administration approved labeling; <b>and</b></li> <li>○ Authorization will be for no more than 6 months.</li> </ul> </li> </ul>
Updated		
Policy Title	Effective Date	Summary of Changes
Antiemetics for Oncology	Aug. 1, 2023	<p><b>Applicable Codes</b></p> <ul style="list-style-type: none"> <li>• Added HCPCS code J1456</li> </ul> <p><b>Supporting Information</b></p> <ul style="list-style-type: none"> <li>• Updated <i>Clinical Evidence</i> and <i>References</i> sections to reflect the most current information</li> </ul>

## Medical Benefit Drug Policy Updates

Updated			
Policy Title	Effective Date	Summary of Changes	
Ophthalmologic Policy: Vascular Endothelial Growth Factor (VEGF) Inhibitors	Jul. 1, 2023	<b>Coverage Rationale</b> <ul style="list-style-type: none"> <li>Removed reference link to the Medical Benefit Drug policy titled <i>Review at Launch for New to Market Medications</i> for Cimerli™ (ranibizumab-eqrn) and Vabysmo™ (faricimab-svoa)</li> </ul>	
Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
17-Alpha-Hydroxyprogesterone Caproate (Makena® and 17P)	Aug. 1, 2023	<b>Coverage Rationale</b> <ul style="list-style-type: none"> <li>Changed coverage status for intramuscular and subcutaneous injection of 17P from “proven and medically necessary when [listed] criteria are met” to “unproven and not medically necessary” <ul style="list-style-type: none"> <li>Added language to indicate: <ul style="list-style-type: none"> <li>On April 6, 2023, the FDA announced the final decision to withdraw approval of Makena because Makena and its generics (i.e., generic versions of Makena) are not shown to be effective for reducing the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth</li> <li>Makena and its generics are no longer approved and cannot lawfully be distributed in interstate</li> </ul> </li> </ul> </li> </ul>	<p>On April 6, 2023, the FDA announced the final decision to withdraw approval of Makena because Makena and its generics (i.e., generic versions of Makena) are not shown to be effective for reducing the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth. Makena and its generics are no longer approved and cannot lawfully be distributed in interstate commerce. Lack of adequate data supporting effectiveness implicates compounded products as well.</p> <p>This policy provides coverage information about the use of injectable (both intramuscular and subcutaneous) 17-alpha-hydroxyprogesterone caproate, commonly called 17P, may also be referred to as 17-OHP, 17-OHPC, 17Pc, Makena®, 17-alpha hydroxyprogesterone, hydroxyprogesterone, hydroxyprogesterone, and hydroxy progesterone. Hereafter, it will be referred to as 17P. <b>Intramuscular and subcutaneous injection of 17P, including but not limited to compounded 17P, is not proven nor medically necessary for prevention of spontaneous preterm birth due to the approval for the drug being withdrawn by the FDA.</b></p> <p><b>Note:</b> Oral and intravaginal formulations of progesterone are <b>not</b> addressed in this policy and should be obtained through the member’s pharmacy benefit.</p>

## Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
17-Alpha-Hydroxyprogesterone Caproate (Makena® and 17P) (continued)	Aug. 1, 2023	<p>commerce; lack of adequate data supporting effectiveness implicates compounded products as well</p> <ul style="list-style-type: none"> <li>▪ Intramuscular and subcutaneous injection of 17P, including but not limited to compounded 17P, is not proven nor medically necessary for prevention of spontaneous preterm birth due to the approval for the drug being withdrawn by the FDA</li> <li>○ Removed language pertaining to:               <ul style="list-style-type: none"> <li>▪ Coverage criteria and limitations for intramuscular and subcutaneous injection of 17P</li> <li>▪ Additional information regarding compounded 17P</li> </ul> </li> </ul> <p><b>Supporting Information</b></p> <ul style="list-style-type: none"> <li>• Updated <i>Background, Clinical Evidence, FDA, and References</i> sections to reflect the most current information</li> </ul>	

## Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Gonadotropin Releasing Hormone Analogs	Aug. 1, 2023	<p><b>Coverage Rationale</b></p> <ul style="list-style-type: none"> <li>Revised list of applicable gonadotropin releasing hormone analog (GnRH analog) drug products; added:               <ul style="list-style-type: none"> <li>Eligard® (leuprolide acetate)</li> <li>Leuprolide acetate depot</li> </ul> </li> </ul> <p><b>Applicable Codes</b></p> <ul style="list-style-type: none"> <li>Added HCPCS code J1954</li> </ul> <p><b>Supporting Information</b></p> <ul style="list-style-type: none"> <li>Updated <i>Background</i>, <i>FDA</i>, and <i>References</i> sections to reflect the most current information</li> </ul>	<p>Refer to the Medical Benefit Drug Policy titled Oncology Medication Clinical Coverage for updated information based on the National Comprehensive Cancer Network (NCCN) Drugs &amp; Biologics Compendium® (NCCN Compendium®) for oncology indications.</p> <p>This policy refers to the following gonadotropin releasing hormone analog (GnRH analog) drug products:</p> <ul style="list-style-type: none"> <li>Camcevi™ (leuprolide mesylate)</li> <li>Eligard® (leuprolide acetate)</li> <li>Fensolvi® (leuprolide acetate)</li> <li>Firmagon® (degarelix)</li> <li>Leuprolide acetate depot</li> <li>Lupron Depot® (leuprolide acetate)</li> <li>Lupron Depot-PED® (leuprolide acetate)</li> <li>Supprelin® LA (histrelin acetate)</li> <li>Trelstar® (triptorelin pamoate)</li> <li>Triptodur® (triptorelin)</li> <li>Zoladex® (goserelin acetate)</li> </ul> <p>Refer to the policy for complete details.</p>
Medical Therapies for Enzyme Deficiencies	Aug. 1, 2023	<p><b>Coverage Rationale</b></p> <ul style="list-style-type: none"> <li>Revised list of applicable medical therapies for enzyme deficiency products; added Elfabrio® (pegunigalsidase alfa-iwxj)</li> <li>Added language to indicate:               <ul style="list-style-type: none"> <li>Elfabrio® (pegunigalsidase alfa-iwxj) has been added to the Review at Launch program                   <ul style="list-style-type: none"> <li>Some members may not be eligible for coverage of this medication at this time</li> </ul> </li> </ul> </li> </ul>	<p>Elfabrio® (pegunigalsidase alfa-iwxj) and Lamzede® (velmanase alfa-tycv) have been added to the Review at Launch program. Some members may not be eligible for coverage of this medication at this time. Refer to the Medical Benefit Drug Policy titled Review at Launch for New to Market Medications for additional details.</p> <p>This policy refers to the following medical therapies for enzyme deficiency products:</p> <ul style="list-style-type: none"> <li>Aldurazyme® (laronidase)</li> <li>Elapraxe® (idursulfase)</li> <li>Elfabrio® (pegunigalsidase alfa-iwxj)</li> <li>Fabrazyme® (agalsidase beta)</li> <li>Kanuma® (sebelipase alfa)</li> </ul>

## Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Medical Therapies for Enzyme Deficiencies (continued)	Aug. 1, 2023	<ul style="list-style-type: none"> <li>▪ Refer to the Medical Benefit Drug Policy titled <i>Review at Launch for New to Market Medications</i> for additional details</li> <li>○ Elfabrio<sup>®</sup> (pegunigalsidase alfa-iwxj) is proven for the treatment of adults with confirmed Fabry disease; Elfabrio is medically necessary when the following additional criteria are met: <ul style="list-style-type: none"> <li><b>Initial Therapy</b></li> <li>▪ Diagnosis of Fabry disease as confirmed by one the following: <ul style="list-style-type: none"> <li>– Absence or deficiency (&lt; 5% of mean) of normal alpha-galactosidase A (<math>\alpha</math>-Gal A) enzyme activity in leukocytes, dried blood spots, or serum analysis</li> <li>– Molecular genetic testing for deletion or mutations in the galactosidase alpha gene</li> </ul> </li> <li>▪ Presence of clinical signs and symptoms of the disease (e.g., acroparesthesias, angiokeratomas, whorls,</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Lamzedo<sup>®</sup> (velmanase alfa-tycv)</li> <li>• Lumizyme<sup>®</sup> (alglucosidase alfa)</li> <li>• Mepsevii<sup>®</sup> (vestronidase alfa-vjbk)</li> <li>• Naglazyme<sup>®</sup> (galsulfase)</li> <li>• Nexviazyme<sup>™</sup> (avalglucosidase alfa-ngpt)</li> <li>• Nulibry<sup>™</sup> (fosdenopterin)</li> <li>• Revcovi<sup>®</sup> (elapegademase-lvr)</li> <li>• Vimizim<sup>®</sup> (elosulfase alfa)</li> <li>• Xenpozyme<sup>™</sup> (olipudase alfa-rpcp)</li> </ul> <p>Refer to the policy for complete details.</p>

## Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Medical Therapies for Enzyme Deficiencies (continued)	Aug. 1, 2023	<p>anhidrosis/hypohidrosis, renal disease, exercise/heat/cold intolerance, etc.)</p> <ul style="list-style-type: none"> <li>▪ Dosing is in accordance with the United States Food and Drug Administration (U.S. FDA) approved labeling</li> <li>▪ Initial authorization will be for no more than 12 months</li> </ul> <p><b><i>Continuation of Therapy</i></b></p> <ul style="list-style-type: none"> <li>▪ Patient has previously received treatment with pegunigalsidase alfa-iwxj therapy</li> <li>▪ Patient has experienced a positive clinical response to pegunigalsidase alfa-iwxj therapy (e.g., improved renal function, reduction in mean plasma GL-3 levels, decreased GL-3 inclusions, etc.)</li> <li>▪ Dosing is in accordance with the U.S. FDA approved labeling</li> <li>▪ Reauthorization will be for no more than 12 months</li> </ul> <ul style="list-style-type: none"> <li>• Revised medical necessity criteria for <b>Nulibry</b>:</li> </ul>	

## Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Medical Therapies for Enzyme Deficiencies (continued)	Aug. 1, 2023	<p><b>Initial Therapy</b></p> <ul style="list-style-type: none"> <li>○ Updated list of conditions that confirm the diagnosis of molybdenum cofactor deficiency (MoCD) Type A:           <ul style="list-style-type: none"> <li>▪ Added “absence or deficiency of sulfite oxidase enzyme activity in fibroblasts”</li> <li>▪ Replaced:               <ul style="list-style-type: none"> <li>– “Documentation of confirmed MOCS1 gene mutation” with “Molecular genetic testing for mutations in the MOCS1 gene”</li> <li>– “Documentation of onset of clinical and/or laboratory signs and symptoms consistent with MoCD Type A [e.g., seizures, exaggerated startle response, high-pitched cry, axial hypotonia, limb hypertonia, feeding difficulties, elevated urinary sulfite and/or S-sulpho-cysteine (SSC), elevated xanthine in urine or blood, or low or absent uric acid in</li> </ul> </li> </ul> </li> </ul>	



## Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Medical Therapies for Enzyme Deficiencies (continued)	Aug. 1, 2023	<p>the urine or blood] within the first 28 days after birth” with “<i>presence of clinical signs and symptoms of the disease</i> [e.g., seizures, exaggerated startle response, high-pitched cry, axial hypotonia, limb hypertonia, feeding difficulties, elevated urinary sulfite and/or S-sulphocysteine (SSC), elevated xanthine in urine or blood, or low or absent uric acid in the urine or blood] within the first 28 days after birth”</p> <p><b>Continuation of Therapy</b></p> <ul style="list-style-type: none"> <li>Removed criterion requiring confirmation of MOCS1 gene mutation</li> </ul> <p><b>Applicable Codes</b></p> <p><b>Elfabrio</b></p> <ul style="list-style-type: none"> <li>Added HCPCS codes C9399, J3490, and J3590</li> <li>Added ICD-10 diagnosis code E75.21</li> </ul> <p><b>Supporting Information</b></p> <ul style="list-style-type: none"> <li>Updated <i>Background, Clinical Evidence, FDA, and References</i></li> </ul>	

## Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Medical Therapies for Enzyme Deficiencies (continued)	Aug. 1, 2023	sections to reflect the most current information	
Ocrevus® (Ocrelizumab)	Aug. 1, 2023	<p><b>Coverage Rationale</b></p> <ul style="list-style-type: none"> <li>Replaced references to “ocrelizumab” with “Ocrevus”</li> <li>Updated list of examples of B cell targeted therapy; added “ublituximab-xiyy”</li> <li>Removed specific dosage requirements for the use of Ocrevus; refer to the applicable U.S. FDA approved labeling</li> <li>Revised medical necessity criteria for continuation of therapy:           <p><b>Primary Progressive Multiple Sclerosis</b></p> <ul style="list-style-type: none"> <li>Removed criterion requiring diagnosis of primary progressive multiple sclerosis (PPMS)</li> </ul> <p><b>Relapsing Forms of Multiple Sclerosis</b></p> <ul style="list-style-type: none"> <li>Removed criterion requiring diagnosis of relapsing forms of multiple sclerosis (MS) (e.g., relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses)</li> </ul> </li> </ul>	<p>Ocrevus (ocrelizumab) is proven for:</p> <p><b>Primary Progressive Multiple Sclerosis</b></p> <p>Ocrevus is medically necessary for the treatment of primary progressive multiple sclerosis (PPMS) when all of the following criteria are met:</p> <ul style="list-style-type: none"> <li>For <b>initial therapy</b>, all of the following:           <ul style="list-style-type: none"> <li>Diagnosis of primary progressive multiple sclerosis (PPMS); <b>and</b></li> <li>Patient is <b>not</b> receiving Ocrevus in combination with <b>any</b> of the following:               <ul style="list-style-type: none"> <li>Disease modifying therapy (e.g., interferon beta preparations, dimethyl fumarate, glatiramer acetate, natalizumab, fingolimod, cladribine, siponimod, or teriflunomide)</li> <li>B cell targeted therapy (e.g., rituximab, belimumab, ofatumumab, ublituximab-xiyy)</li> <li>Lymphocyte trafficking blockers (e.g., alemtuzumab, mitoxantrone)</li> </ul> </li> </ul> </li> <li><b>and</b></li> <li>Ocrevus dosing is in accordance with the United States Food and Drug Administration approved labeling; <b>and</b></li> <li>Initial authorization is for no more than 6 months</li> <li>For <b>continuation of therapy</b>, all of the following:           <ul style="list-style-type: none"> <li>Patient has previously received treatment with Ocrevus; <b>and</b></li> <li>Documentation of positive clinical response to Ocrevus therapy; <b>and</b></li> <li>Patient is <b>not</b> receiving Ocrevus in combination with <b>any</b> of the following:               <ul style="list-style-type: none"> <li>Disease modifying therapy (e.g., interferon beta preparations, dimethyl fumarate, glatiramer acetate, natalizumab, fingolimod, cladribine, siponimod, or teriflunomide)</li> <li>B cell targeted therapy (e.g., rituximab, belimumab, ofatumumab, ublituximab-xiyy)</li> <li>Lymphocyte trafficking blockers (e.g., alemtuzumab, mitoxantrone)</li> </ul> </li> </ul> </li> </ul>

## Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Ocrevus® (Ocrelizumab) (continued)	Aug. 1, 2023	<p><b>Supporting Information</b></p> <ul style="list-style-type: none"> <li>Updated <i>References</i> section to reflect the most current information</li> </ul>	<p><b>and</b></p> <ul style="list-style-type: none"> <li>Ocrevus dosing is in accordance with the United States Food and Drug Administration approved labeling; <b>and</b></li> <li>Authorization is for no more than 12 months</li> </ul> <p>Ocrevus (ocrelizumab) is proven for:</p> <p><b>Relapsing Forms of Multiple Sclerosis</b></p> <p>Ocrevus is medically necessary for the treatment of relapsing forms of multiple sclerosis (MS) when all of the following criteria are met:</p> <ul style="list-style-type: none"> <li>For <b>initial therapy</b>, all of the following: <ul style="list-style-type: none"> <li>Diagnosis of relapsing forms of multiple sclerosis (MS) (e.g., relapsing-remitting MS, secondary-progressive MS with relapses, progressive-relapsing MS with relapses); <b>and</b></li> <li>Patient is <b>not</b> receiving Ocrevus in combination with <b>any</b> of the following: <ul style="list-style-type: none"> <li>Disease modifying therapy (e.g., interferon beta preparations, glatiramer acetate, natalizumab, fingolimod, cladribine, siponimod, or teriflunomide)</li> <li>B cell targeted therapy (e.g., rituximab, belimumab, ofatumumab, ublituximab-xiiy)</li> <li>Lymphocyte trafficking blockers (e.g., alemtuzumab, mitoxantrone)</li> </ul> </li> </ul> </li> <li><b>and</b></li> <li>Ocrevus dosing is in accordance with the United States Food and Drug Administration approved labeling; <b>and</b></li> <li>Initial authorization is for no more than 6 months</li> <li>For <b>continuation of therapy</b>, all of the following: <ul style="list-style-type: none"> <li>Patient has previously received treatment with Ocrevus ; <b>and</b></li> <li>Documentation of positive clinical response to Ocrevus therapy; <b>and</b></li> <li>Patient is <b>not</b> receiving Ocrevus in combination with <b>any</b> of the following: <ul style="list-style-type: none"> <li>Disease modifying therapy (e.g., interferon beta preparations, dimethyl fumarate, glatiramer acetate, natalizumab, fingolimod, cladribine, siponimod, or teriflunomide)</li> </ul> </li> </ul> </li> </ul>

## Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Ocrevus® (Ocrelizumab) (continued)	Aug. 1, 2023		<ul style="list-style-type: none"> <li>▪ B cell targeted therapy (e.g., rituximab, belimumab, ofatumumab, ublituximab-xiyy)</li> <li>▪ Lymphocyte trafficking blockers (e.g., alemtuzumab, mitoxantrone)</li> </ul> <p><b>and</b></p> <ul style="list-style-type: none"> <li>○ Ocrevus dosing is in accordance with the United States Food and Drug Administration approved labeling; <b>and</b></li> <li>○ Authorization is for no more than 12 months</li> </ul> <p><b>Ocrevus is unproven and not medically necessary for the treatment of:</b></p> <ul style="list-style-type: none"> <li>● Lupus nephritis</li> <li>● Rheumatoid arthritis</li> <li>● Systemic lupus erythematosus</li> </ul>
Provider Administered Drugs – Preferred Products	Aug. 1, 2023	<p><b>Coverage Rationale</b></p> <ul style="list-style-type: none"> <li>● Revised list of brand/generic alternative <b>non-preferred</b> drug products; added: <ul style="list-style-type: none"> <li>○ Treprostinil 20mg/20mL Solution for Injection (43598-0649-11) (Dr. Reddy’s Laboratories, Inc.)</li> <li>○ Treprostinil 50mg/20mL Solution for Injection (43598-0646-11) (Dr. Reddy’s Laboratories, Inc.)</li> <li>○ Treprostinil 100mg/20mL Solution for Injection (43598-0647-11) (Dr. Reddy’s Laboratories, Inc.)</li> <li>○ Treprostinil 200mg/20mL Solution for Injection (43598-0648-11) (Dr. Reddy’s Laboratories, Inc.)</li> </ul> </li> </ul>	<p>This policy provides parameters for coverage of preferred medications covered under the medical benefit.</p> <p><b>Medical Necessity Plans</b></p> <p>The <a href="#">Preferred Drug Products</a> table below lists the UnitedHealthcare preferred products and respective non-preferred products. Coverage will be provided for the UnitedHealthcare preferred product contingent on the coverage criteria in the <a href="#">Diagnosis-Specific Criteria</a> section.</p> <p>Coverage for any respective non-preferred product will be provided contingent on the criteria in the <a href="#">Preferred Drug Products Criteria</a> and the <a href="#">Diagnosis-Specific Criteria</a> sections. Members new to therapy will be required to utilize the UnitedHealthcare preferred product unless they meet the criteria in this section.</p> <p><b>Preferred Product Criteria</b></p> <p>Treatment with the respective non-preferred product specified in the <a href="#">Non-Preferred Drug Products</a> table below is medically necessary for proven indications when both of the following are met:</p> <ul style="list-style-type: none"> <li>● History of intolerance or contraindication to one of the UnitedHealthcare’s preferred products; and</li> </ul>

## Medical Benefit Drug Policy Updates

Revised							
Policy Title	Effective Date	Summary of Changes	Coverage Rationale				
Provider Administered Drugs – Preferred Products (continued)	Aug. 1, 2023	<ul style="list-style-type: none"> <li>○ Treprostinil 20mg/20mL Solution for Injection (42023-0206-01) (Par Sterile Products)</li> <li>○ Treprostinil 50mg/20mL Solution for Injection (42023-0207-01) (Par Sterile Products)</li> <li>○ Treprostinil 100mg/20mL Solution for Injection (42023-0208-01) (Par Sterile Products)</li> <li>○ Treprostinil 200mg/20mL Solution for Injection (42023-0209-01) (Par Sterile Products)</li> </ul>	<ul style="list-style-type: none"> <li>● 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.</li> </ul> <p><b>Medical Drug Products</b></p> <p>Below are UnitedHealthcare preferred medical drug products with a brand/generic alternative non-preferred products:</p> <table border="1"> <thead> <tr> <th>UnitedHealthcare Preferred Drug Products</th> <th>UnitedHealthcare Non-Preferred Drug Products</th> </tr> </thead> <tbody> <tr> <td> <ul style="list-style-type: none"> <li>● Treprostinil 20mg/20mL Solution for Injection (00781-3420) (Sandoz Inc. a Novartis Company)</li> <li>● Treprostinil 50mg/20mL Solution for Injection (00781-3425) (Sandoz Inc. a Novartis Company)</li> <li>● Treprostinil 100mg/20mL Solution for Injection (00781-3427) (Sandoz Inc. a Novartis Company)</li> <li>● Treprostinil 200mg/20mL Solution for Injection (00781-3430) (Sandoz Inc. a Novartis Company)</li> </ul> </td> <td> <ul style="list-style-type: none"> <li>● Remodulin (treprostinil) 1mg/mL Solution for Injection (66302-0101) (United Therapeutics Corporation)</li> <li>● Remodulin (treprostinil) 2.5mg/mL Solution for Injection (66302-0102) (United Therapeutics Corporation)</li> <li>● Remodulin (treprostinil) 5mg/mL Solution for Injection (66302-0105) (United Therapeutics Corporation)</li> <li>● Remodulin (treprostinil) 10mg/mL Solution for Injection (66302-0110) (United Therapeutics Corporation)</li> <li>● Treprostinil 20mg/20mL Solution for Injection (00703-0666) (Teva Pharmaceuticals USA)</li> <li>● Treprostinil 50mg/20mL Solution for Injection (00703-0676) (Teva Pharmaceuticals USA)</li> <li>● Treprostinil 100mg/20mL Solution for Injection (00703-0686) (Teva Pharmaceuticals USA)</li> <li>● Treprostinil 200mg/20mL Solution for Injection (00703-0696) (Teva Pharmaceuticals USA)</li> </ul> </td> </tr> </tbody> </table>	UnitedHealthcare Preferred Drug Products	UnitedHealthcare Non-Preferred Drug Products	<ul style="list-style-type: none"> <li>● Treprostinil 20mg/20mL Solution for Injection (00781-3420) (Sandoz Inc. a Novartis Company)</li> <li>● Treprostinil 50mg/20mL Solution for Injection (00781-3425) (Sandoz Inc. a Novartis Company)</li> <li>● Treprostinil 100mg/20mL Solution for Injection (00781-3427) (Sandoz Inc. a Novartis Company)</li> <li>● Treprostinil 200mg/20mL Solution for Injection (00781-3430) (Sandoz Inc. a Novartis Company)</li> </ul>	<ul style="list-style-type: none"> <li>● Remodulin (treprostinil) 1mg/mL Solution for Injection (66302-0101) (United Therapeutics Corporation)</li> <li>● Remodulin (treprostinil) 2.5mg/mL Solution for Injection (66302-0102) (United Therapeutics Corporation)</li> <li>● Remodulin (treprostinil) 5mg/mL Solution for Injection (66302-0105) (United Therapeutics Corporation)</li> <li>● Remodulin (treprostinil) 10mg/mL Solution for Injection (66302-0110) (United Therapeutics Corporation)</li> <li>● Treprostinil 20mg/20mL Solution for Injection (00703-0666) (Teva Pharmaceuticals USA)</li> <li>● Treprostinil 50mg/20mL Solution for Injection (00703-0676) (Teva Pharmaceuticals USA)</li> <li>● Treprostinil 100mg/20mL Solution for Injection (00703-0686) (Teva Pharmaceuticals USA)</li> <li>● Treprostinil 200mg/20mL Solution for Injection (00703-0696) (Teva Pharmaceuticals USA)</li> </ul>
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## Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Provider Administered Drugs – Preferred Products (continued)	Aug. 1, 2023		<ul style="list-style-type: none"> <li>Treprostinil 20mg/20mL Solution for Injection (43598-0649-11) (Dr. Reddy’s Laboratories, Inc.)</li> <li>Treprostinil 50mg/20mL Solution for Injection (43598-0646-11) (Dr. Reddy’s Laboratories, Inc.)</li> <li>Treprostinil 100mg/20mL Solution for Injection (43598-0647-11) (Dr. Reddy’s Laboratories, Inc.)</li> <li>Treprostinil 200mg/20mL Solution for Injection (43598-0648-11) (Dr. Reddy’s Laboratories, Inc.)</li> <li>Treprostinil 20mg/20mL Solution for Injection (42023-0206-01) (Par Sterile Products)</li> <li>Treprostinil 50mg/20mL Solution for Injection (42023-0207-01) (Par Sterile Products)</li> <li>Treprostinil 100mg/20mL Solution for Injection (42023-0208-01) (Par Sterile Products)</li> <li>Treprostinil 200mg/20mL Solution for Injection (42023-0209-01) (Par Sterile Products)</li> </ul> <p><b>Diagnosis-Specific Criteria</b> Refer to the drug-specific coverage policy if noted in the <i>Related Policies</i> section of the policy.</p>
Provider Administered Drugs - Site of Care	Aug. 1, 2023	<p><b>Coverage Rationale</b></p> <ul style="list-style-type: none"> <li>Revised coverage criteria for outpatient hospital facility-based intravenous medication infusion; replaced criterion requiring “initial</li> </ul>	<p>This policy addresses the criteria for consideration of allowing hospital outpatient facility infusion services for specialty medications and intravenous Immune Globulin (IVIG) and subcutaneous Immune Globulin (SCIG) therapy. This includes claim submission for hospital-based services with the following CMS/AMA Place of Service codes:</p>

## Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Provider Administered Drugs - Site of Care (continued)	Aug. 1, 2023	<p>infusion or re-initiation of therapy after more than 6 months” with “initial infusion or re-initiation of therapy after more than 6 months <i>for a short duration of time (e.g., 4 weeks)</i>”</p> <ul style="list-style-type: none"> <li>Revised list of medications that require healthcare provider administration; added Elfabrio® (pegunigalsidase alfa-iwxj)</li> </ul> <p><b>Documentation Requirements</b></p> <ul style="list-style-type: none"> <li>Updated list of specialty medications with associated documentation requirements; added Elfabrio® (pegunigalsidase alfa-iwxj) (HCPCS codes C9399, J3490, and J3590)</li> </ul>	<ul style="list-style-type: none"> <li>19 Off Campus-Outpatient Hospital; and</li> <li>22 On Campus-Outpatient Hospital</li> </ul> <p>Alternative Sites of Care, such as non-hospital outpatient infusion, physician office, ambulatory infusion suites or home infusion services are well accepted places of service for medication infusion therapy. If an individual does not meet criteria for outpatient hospital facility infusion, alternative sites of care may be used.</p> <p><b>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):</b></p> <ul style="list-style-type: none"> <li>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: <ul style="list-style-type: none"> <li>The individual’s complex medical status or therapy requires enhanced monitoring and potential intervention above and beyond the capabilities of the alternate Site of Care; or</li> <li>The individual’s documented history of a significant comorbidity (e.g., cardiopulmonary disorder or fluid overload) status that precludes treatment at an alternate Site of Care; or</li> <li>Treatment at an alternate Site of Care setting presents a health risk due to a clinically significant physical or cognitive impairment; or difficulty establishing and maintaining patent vascular access</li> </ul> </li> <li>or</li> <li>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), not including the first or second infusion and, while receiving requested therapy 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 at an alternate Site of Care; or</li> </ul>

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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Provider Administered Drugs - Site of Care (continued)	Aug. 1, 2023		<ul style="list-style-type: none"> <li>Initial infusion or re-initiation of therapy after more than 6 months for a short duration of time (e.g., 4 weeks); or</li> <li><b>For IVIG or SCIG only:</b> Individual has immunoglobulin A (IgA) deficiency with anti-IgA antibodies; or</li> <li>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:               <ul style="list-style-type: none"> <li>The prescriber is unable to infuse in the office setting</li> <li>There are no ambulatory infusion suite options available for this member</li> </ul> </li> </ul> <p>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.</p> <p><b>Note:</b> If more than one of the above criteria are met, then the greatest of the applicable approval time periods will be allowed.</p> <p>This policy applies to these medications that require healthcare provider administration:</p> <ul style="list-style-type: none"> <li>Actemra® (tocilizumab)</li> <li>Adakveo® (crizanlizumab-tmca)</li> <li>Aldurazyme® (laronidase)</li> <li>Amondys 45™ (casimersen)</li> <li>Amvuttra™ (vutrisiran)</li> <li>Apretude™ (cabotegravir)</li> <li>Aralast NP® (A1-PI)</li> <li>Asceniv™ (IV)</li> <li>Avsola™ (infliximab-axxq)</li> <li>Benlysta® (belimumab)</li> <li>Bivigam® (IV)</li> <li>Cabenuva (cabotegravir; rilpiverine)</li> <li>Carimune® NF (IV)</li> <li>Cerezyme® (imiglucerase)</li> </ul>



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Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Provider Administered Drugs - Site of Care (continued)	Aug. 1, 2023		<ul style="list-style-type: none"> <li>• Cimzia® (certolizumab pegol)</li> <li>• Cinqair® (reslizumab)</li> <li>• Crysvida® (burosumab-twza)</li> <li>• Cutaquig® (SC)</li> <li>• Cuvitru® (SC)</li> <li>• Elaprase® (idursulfase)</li> <li>• Elelyso® (taliglucerase)</li> <li>• Enjaymo™ (sutimlimab-jome)</li> <li>• Elfabrio® (pegunigalsidase alfa-iwxj)</li> <li>• Entyvio® (vedolizumab)</li> <li>• Evkeeza™ (evinacumab)</li> <li>• Exondys 51® (eteplirsen)</li> <li>• Fabrazyme® (agalsidase beta)</li> <li>• Fasenra® (benralizumab)</li> <li>• Flebogamma® DIF (IV)</li> <li>• Gammagard® Liquid (IV, SC)</li> <li>• Gammagard® S/D (IV)</li> <li>• Gammaked™ (IV, SC)</li> <li>• Gammaplex® (IV)</li> <li>• Gamunex®C (IV, SC)</li> <li>• Givlaari® (givosiran)</li> <li>• Glassia® (A1-PI)</li> <li>• Hizentra® (SC)</li> <li>• HyQvia® (SC)</li> <li>• Ilaris® (canakinumab)</li> <li>• Ilumya™ (tildrakizumab-asmn)</li> <li>• Inflectra® (infliximab-dyyb)</li> <li>• Kanuma® (sebelipase alfa)</li> <li>• Lamzedo® (velmanase alfa-tycv)</li> <li>• Lumizyme® (alglucosidase alfa)</li> <li>• Mepsevii™ (vestronidase alfa-vj bk)</li> <li>• Naglazyme® (galsulfase)</li> <li>• Nexviazyme™ (avalglucosidase alfa-ngpt)</li> </ul>

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Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Provider Administered Drugs - Site of Care (continued)	Aug. 1, 2023		<ul style="list-style-type: none"> <li>• Nucala<sup>®</sup> (mepolizumab)</li> <li>• Nulibry<sup>™</sup> (fosdenopterin)</li> <li>• Octagam<sup>®</sup> (IV)</li> <li>• Onpattro<sup>®</sup> (patisiran)</li> <li>• Orencia<sup>®</sup> (abatacept)</li> <li>• Oxlumo<sup>™</sup> (lumasiran)</li> <li>• Panzyga<sup>®</sup> (IV)</li> <li>• Privigen<sup>®</sup> (IV)</li> <li>• Prolastin<sup>®</sup>-C<sup>™</sup> (A1-PI)</li> <li>• Radicava<sup>®</sup> (edaravone)</li> <li>• Remicade<sup>®</sup> (infliximab)</li> <li>• Revcovi<sup>®</sup> (elapegademase-ivlr)</li> <li>• Ryplazim<sup>®</sup> (plasminogen, human-tvmh)</li> <li>• Saphnelo<sup>™</sup> (anifrolumab-fnia)</li> <li>• Simponi Aria<sup>®</sup> (golimumab)</li> <li>• Skyrizi<sup>®</sup> (risankizumab-rzaa)</li> <li>• Soliris<sup>®</sup> (eculizumab)</li> <li>• Stelara<sup>®</sup> (ustekinumab)</li> <li>• Tepezza<sup>®</sup> (teprotumumab-trbw)</li> <li>• Tezspire<sup>™</sup> (tezepelumab-ekko)</li> <li>• Trogarzo<sup>®</sup> (ibalizumab-uiyk)</li> <li>• Tziel<sup>™</sup> (teplizumab-mzww)</li> <li>• Ultomiris<sup>®</sup> (ravulizumab-cwvz)</li> <li>• Uplizna<sup>™</sup> (inebilizumab-cdon)</li> <li>• Viltepso<sup>™</sup> (viltolarsen)</li> <li>• Vimizim<sup>®</sup> (elosulfase alfa)</li> <li>• VPRIV<sup>®</sup> (velaglucerase)</li> <li>• Vyep<sup>®</sup> (eptinezumab-jjmr)</li> <li>• Vyondys 53<sup>™</sup> (golodirsen)</li> <li>• Vyvgart<sup>™</sup> (efgartigimod)</li> <li>• Xembify<sup>®</sup> (SC)</li> <li>• Xenpozyme<sup>™</sup> (olipudase alfa-rpcp)</li> <li>• Zemaira<sup>®</sup> (A1-PI)</li> </ul>

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Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Syfovre™ (Pegcetacoplan Injection)	Jul. 1, 2023	<p><b>Coverage Rationale</b></p> <ul style="list-style-type: none"> <li>• Revised coverage criteria to reflect/include:               <ul style="list-style-type: none"> <li>○ For <b>initial therapy</b>, all of the following:                   <ul style="list-style-type: none"> <li>▪ Diagnosis of geographic atrophy (GA) secondary to age-related macular degeneration (AMD)</li> <li>▪ Diagnosis has been confirmed by geographic atrophy secondary to age-related macular degeneration sensitive tests [e.g., optical coherence tomography (OCT), fundus autofluorescence (FAF) imaging]</li> <li>▪ Macular atrophy is not secondary to any conditions other than AMD (e.g., Stargardt disease, cone rod dystrophy, toxic maculopathies)</li> <li>▪ Prescribed by or in consultation with an ophthalmologist experienced in treatment of retinal diseases</li> <li>▪ Dosing is in accordance with the United States Food and Drug</li> </ul> </li> </ul> </li> </ul>	<p>Syfovre™ (pegcetacoplan injection) has been added to the Review at Launch program. Some members may not be eligible for coverage of this medication at this time. Refer to the Medical Benefit Drug Policy titled Review at Launch for New to Market Medications for additional details.</p> <p>Syfovre is proven for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD).</p> <p>Syfovre is medically necessary when the following criteria are met:</p> <ul style="list-style-type: none"> <li>• For <b>initial therapy</b>, all of the following:               <ul style="list-style-type: none"> <li>○ Diagnosis of geographic atrophy (GA) secondary to age-related macular degeneration (AMD); <b>and</b></li> <li>○ Diagnosis has been confirmed by geographic atrophy secondary to age-related macular degeneration sensitive tests (e.g., optical coherence tomography [OCT], fundus autofluorescence [FAF] imaging); <b>and</b></li> <li>○ Macular atrophy is not secondary to any conditions other than AMD (e.g., Stargardt disease, cone rod dystrophy, toxic maculopathies).</li> <li>○ Prescribed by or in consultation with an ophthalmologist experienced in treatment of retinal diseases; <b>and</b></li> <li>○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; <b>and</b></li> <li>○ Authorization is for no more than 12 months.</li> </ul> </li> <li>• For continuation of therapy, all of the following:               <ul style="list-style-type: none"> <li>○ Physician attestation that patient would benefit from continued administration; <b>and</b></li> <li>○ For long term treatment, documentation of titration to the minimum dosing frequency to achieve maximum benefit; <b>and</b></li> <li>○ Dosing is in accordance with the United States Food and Drug Administration approved labeling; <b>and</b></li> <li>○ Authorization is for no more than 12 months.</li> </ul> </li> </ul>

## Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Syfovre™ (Pegcetacoplan Injection) (continued)	Jul. 1, 2023	<ul style="list-style-type: none"> <li>Administration (U.S. FDA) approved labeling               <ul style="list-style-type: none"> <li>▪ Authorization is for no more than 12 months</li> </ul> </li> <li>○ For <b>continuation of therapy</b>, <b>all</b> of the following:               <ul style="list-style-type: none"> <li>▪ Physician attestation that patient would benefit from continued administration</li> <li>▪ For long term treatment, documentation of titration to the minimum dosing frequency to achieve maximum benefit</li> <li>▪ Dosing is in accordance with the U.S. FDA approved labeling</li> <li>▪ Authorization is for no more than 12 months</li> </ul> </li> </ul> <p><b>Applicable Codes</b></p> <ul style="list-style-type: none"> <li>● Updated list of applicable HCPCS codes to reflect quarterly edits; replaced C9399 with C9151</li> </ul>	
Tepezza® (Teprotumumab-Trbw)	Aug. 1, 2023	<p><b>Coverage Rationale</b></p> <ul style="list-style-type: none"> <li>● Added language to clarify Tepezza is proven for the treatment of thyroid eye disease <i>regardless of activity or duration</i></li> <li>● Revised coverage criteria; added criterion requiring a history of intolerance, failure, or contraindication to intravenous</li> </ul>	<p><b>Thyroid Eye Disease</b></p> <p><b>Tepezza is proven for the treatment of thyroid eye disease regardless of activity or duration. Tepezza is medically necessary when all of the following criteria are met:</b></p> <ul style="list-style-type: none"> <li>● Diagnosis of Graves' disease associated with active thyroid eye disease (TED) with a Clinical Activity Score (CAS) ≥ 4 in the most severely affected eye; <b>and</b></li> <li>● Presence of moderately to severely active TED, associated with at least <b>one</b> of the following:           <ul style="list-style-type: none"> <li>○ Lid retraction ≥ 2 mm</li> </ul> </li> </ul>

## Medical Benefit Drug Policy Updates

Revised			
Policy Title	Effective Date	Summary of Changes	Coverage Rationale
Tepezza® (Teprotumumab-Trbw) (continued)	Aug. 1, 2023	glucocorticoids (e.g., methylprednisolone)  <b>Supporting Information</b> <ul style="list-style-type: none"> <li>Added <i>CMS</i> section</li> <li>Updated <i>Clinical Evidence</i>, <i>FDA</i>, and <i>References</i> sections to reflect the most current information</li> </ul>	<ul style="list-style-type: none"> <li>Moderate or severe soft tissue involvement</li> <li>Exophthalmos <math>\geq 3</math> mm above normal for race and gender</li> <li>Diplopia</li> </ul> <b>and</b> <ul style="list-style-type: none"> <li>History of intolerance, failure, or contraindication to intravenous glucocorticoids (e.g., methylprednisolone) (for Medicare reviews, refer to the CMS section*)</li> </ul> <b>and</b> <ul style="list-style-type: none"> <li><b>One</b> of the following:               <ul style="list-style-type: none"> <li>Patient is euthyroid [defined as free triiodothyronine (T3) and thyroxine (T4) levels within the normal limits]; <b>or</b></li> <li>Presence of mild hypo- or hyperthyroidism [defined as free T3 and T4 levels less than 50% above or below the normal limits] and patient is undergoing treatment to correct the mild hypo- or hyperthyroidism to maintain a euthyroid state</li> </ul> </li> </ul> <b>and</b> <ul style="list-style-type: none"> <li>Tepezza is prescribed by an endocrinologist or ophthalmologist; <b>and</b></li> <li>Tepezza will not be used in combination with another biologic immunomodulator [e.g., rituximab (Rituxan®, Ruxience®, Truxima®, Riabni™), Actemra® (tocilizumab), Kevzara® (sarilumab)]; <b>and</b></li> <li>Dosing is in accordance with the United States Food and Drug Administration approved labeling; <b>and</b></li> <li>Authorization will be issued for a maximum of 8 doses per lifetime</li> </ul> <b>Reauthorization/Continuation of Care Criteria</b> The clinical benefit of Tepezza has not been demonstrated beyond 8 infusions in phase 3 clinical trials. The continued use of Tepezza beyond 8 infusions in the patient's lifetime is unproven and not medically necessary.

## General Information

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

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

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

## Policy Update Classifications

### *New*

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

### *Updated*

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

### *Revised*

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

### *Replaced*

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

### *Retired*

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



The complete library of UnitedHealthcare Medical Policies, Medical Benefit Drug Policies, Coverage Determination Guidelines, and Utilization Review Guidelines is available at [UHCprovider.com](https://UHCprovider.com) > Policies and Protocols > Commercial Policies > [Medical & Drug Policies and Coverage Determination Guidelines](#).