# Coverage Policy Unit (CPU) - Monthly Policy Updates

## Effective July 15, 2024 (unless otherwise noted)

**Note – Log-in is needed for policy update sections marked with an asterisk *. Use this link to log-in, Cigna for Health Care Professionals > Resources > Reimbursement and Payment Policies.**

| Medical Coverage Policy | New, Updated, or Retired? | Comments |
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| Ambulatory External and Implantable Electrocardiographic Monitoring - (0547) | Update | Minor **changes** in coverage criteria/policy:<br>• Minor correction of implantable monitor criteria to align with American College of Cardiology. |
| Inhaled Nitric Oxide (INO) - (0453) | Update | Minor **changes** in coverage criteria/policy:<br>• Minor change in criteria to remove "an unrepaired" from policy statement section referencing congenital diaphragmatic hernia.<br>• Minor change to noncoverage rationale from "experimental, investigational, or unproven" to "not medically necessary". |
| Minimally Invasive Spine Surgery Procedures and Trigger Point Injections - (0139) | Update | Effective **10/15/2024**.<br>Important **changes** in coverage criteria:<br>• Limited coverage for trigger point injections to no more than ten (10) in a rolling 12-month period. |

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| | | • Added not covered statement for the use of ultrasound guidance (CPT code 76942) for trigger point injections. |
| Miscellaneous Musculoskeletal Procedures - (0515) | Update | Minor **changes** in coverage criteria/policy:<br>• Minor change to move noncoverage statement for thermal shrinkage from policy 0176 Thermal Shrinkage to this policy, as policy 0176 will be retired.<br>  • No change to coverage; thermal shrinkage is considered experimental, investigational or unproven. |
| Omnibus Codes – (0504) | Update | Important changes:<br>• No longer review/content being removed from 0504 (as of 7/15/2024):<br>  • Retinal prosthesis system (CPT 0100T, 0472T, 0473T).<br>  • Transtympanic Micropressure Device for Ménière's Disease (e.g., Meniett™ Device) (HCPCS Code E2120).<br>• Moved to a standalone policy/content being removed from 0504 (as of 7/15/2024):<br>  • Tympanostomy with iontophoresis local anesthesia (Tubes Under Local Anesthesia, TULA) (CP 0570, CPT 0583T)<br>  • Bioimpedance Spectroscopy to Measure Extracellular Fluid Differences Between Limbs (CP 0571, CPT Code 93702).<br>• PT OT Chiro Frequency edit content being removed from CP 0504. Is addressed by ASH CPGs 135, 155, 278 (as of 9/15/2024) |
| Phototherapy, Photochemotherapy, Excimer Laser, Dermabrasion and Chemical Peels for Dermatologic Conditions – (0505) | Update | Important **changes** in coverage criteria:<br>• Added a "continuation" of treatment statement for office-based phototherapy and photochemotherapy for the 6 listed covered indications to clarify that continued treatment is acceptable when there is a beneficial clinical response to treatment.<br>• Removed the requirement of an initial regimen of treatment for vitiligo in both the "Office-Based phototherapy and Photochemotherapy" and "Office-Based Excimer Laser Therapy" sections of the policy because allowing only 12 weeks of treatment may not be a long enough period of time to gauge treatment response.<br>• Added a "Plaque Psoriasis" Header beneath the "Office-Based Excimer Laser Therapy" section for improved readability.<br>• Added a "continuation" statement for office-based excimer laser therapy for plaque psoriasis to clarify that continued treatment is acceptable when there is a beneficial clinical response to treatment.<br>• Removed the "home phototherapy devices" section from the policy because the HCPCS codes associated with this section of the policy are not managed. |
| Tests for the Evaluation of Preterm Labor and Premature | Update | Important **changes** in coverage criteria:<br>• Added an example of a system that tests for salivary estriol for clarity. |

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| Rupture of Membranes – (0099) | | • Removed the policy statement "bacterial vaginosis (BV) testing in asymptomatic women" from the EIU statement for the screening of preterm labor because these codes are already managed with CP 0530 Nucleic Acid Pathogen Testing.<br>• Changed the policy statement for the evaluation of pregnant women at high risk for preterm birth from EIU to NMN because it didn't meet Cigna's definition of EIU. |
| Transcranial Magnetic Stimulation – (EN0383) | Update | Important **changes** in coverage criteria:<br>• Added an EIU policy statement for accelerated treatment protocols (e.g., Theta Burst Stimulation, Stanford Accelerated Intelligent Neuromodulation Therapy) because the safety and efficacy of these protocols are not supported by the existing peer reviewed literature. |
| Athletic Pubalgia Surgery - (0522) | Update | No change in coverage. |
| Bioimpedance Spectroscopy - (0571) | Update | No change in coverage. |
| Diaphragmatic/Phrenic Nerve Stimulation - (0391) | Update | No change in coverage. |
| Fetal Surgery - (0175) | Update | No change in coverage. |
| Lyme Disease Treatment - Antibiotic Treatment - (0400) | Update | No change in coverage. |
| Oncology Imaging Amendment to Cigna-eviCore General Oncology Imaging Guideline - (DV002) | Update | No change in coverage. |
| Tympanostomy with iontophoresis local anesthesia - (0570) | Update | No change in coverage. |
| Thermal Shrinkage - (0176) | Retired | Policy retired 7/15/2024.<br>• Statement and content consolidated into policy 0515 Miscellaneous Musculoskeletal Procedures. |

| ASH Guidelines | New, Updated, or Retired? | Comments |
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| Patient Assessments: Medical Necessity Decision Assist Guideline for Evaluations and Re-evaluations – (CPG 111) | Update | No change in coverage. |
| Cognitive Rehabilitation – (CPG 270) | Update | No change in coverage. |
| **eviCore Guidelines** | **New, Updated, or Retired?** | **Comments** |
| Cobranded Cigna-EviCore Peripheral Vascular Intervention Guidelines | New | Effective **11/1/2024**<br>**New** guidelines.<br>• New guidelines with coverage criteria for select arterial and venous interventional procedures. |
| Cobranded Cigna-EviCore Spine Surgery Guidelines | New | Effective **11/1/2024**<br>**New** guidelines.<br>• New guidelines with coverage criteria for select spine procedures:<br>  • CMM-401 Discography<br>  • CMM-600 Preface to the Spine Surgery Guidelines<br>  • CMM-601 Anterior Cervical Discectomy and Fusion<br>  • CMM-602 Cervical Total Disc Arthroplasty<br>  • CMM-603 Posterior Cervical Decompression (Laminectomy/Hemilaminectomy/Laminoplasty)<br>  • CMM-604 Posterior Cervical Fusion<br>  • CMM-605 Cervical Microdiscectomy<br>  • CMM-606 Lumbar Microdiscectomy (Laminotomy, Laminectomy, or Hemilaminectomy) |

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| | | • CMM-607 Primary Vertebral Augmentation (Percutaneous Vertebroplasty/Kyphoplasty) and Sacroplasty<br>• CMM-608 Lumbar Decompression<br>• CMM-609 Lumbar Fusion (Arthrodesis)<br>• CMM-610 Lumbar Total Disc Arthroplasty<br>• CMM-611 Sacroiliac Joint Fusion or Stabilization<br>• CMM-612 Grafts<br>• CMM-613 Thoracic Decompression/Discectomy<br>• CMM-614 Thoracic/Thoracolumbar Fusion (Arthrodesis)<br>• CMM-615 Electrical and Low Frequency Ultrasound Bone Growth Stimulation (Spine)<br>• CMM-616 Vertebral Body Tethering for Adolescent Idiopathic Scoliosis |
| Cobranded Cigna-EviCore High-Tech Imaging Guidelines | Update | Effective **10/15/2024**<br>Important **changes** in coverage criteria.<br>• Cardiac Imaging Guidelines<br>  • Guidelines underwent numerous revisions which both expand and limit coverage. |
| Cobranded Cigna-EviCore Ablations/Denervations of Facet Joints and Peripheral Nerves – (CMM-208) | Update | Effective **11/1/2024**<br>Important **change** in coverage criteria.<br>• Title changed<br>• Added not covered statement for radiofrequency ablation of the intraosseous basivertebral nerve for the treatment of vertebrogenic back pain.<br><br>Informational document updated, no change to coverage:<br>• Preface to the Comprehensive Musculoskeletal Management (CMM) Guidelines |
| **Administrative Policy** | **New, Updated, or Retired?** | **Comments** |
| | | No updates in July 2024 |
| **Drug & Biologic Coverage Policy** | **New, Updated, or Retired?** | **Comments**<br><br>**All policy changes effective July 1, 2024, unless otherwise stated** |
| Amyloidosis – Wainua - (IP0628) | New | Effective: 7/1/2024 |

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| | | • New coverage policy addressing utilization management of Wainua (eplontersen) subcutaneous injection |
| Antibiotics (inhaled) – Cayston – (IP0485) | Update | Effective: 7/1/2024<br>**Updated** coverage policy title from *Aztreonam Inhalation Solution* to *Antibiotics (Inhaled) – Cayston*. |
| Antibiotics – Linezolid (Zyvox), Sivextro - (IP0372) | Update | Effective: 7/1/2024<br>• **Linezolid and Zyvox**<br>  • Updated the authorization duration from 28 days to 1 month for Methicillin-Resistant Staphylococcus Species Infection, Treatment, Vancomycin-Resistant Enterococcus Species Infection, Treatment, Continuation of Linezolid Therapy and Treatment of an Infection that is Resistant to Other Antibiotics, but the Organism is Sensitive to Linezolid.<br>  • **Added coverage for** patients where there is Insufficient Information Available to Make a Determination Regarding Coverage and the Prescriber or Representative Cannot be Contacted<br>  • **Removed coverage for** Known or Suspected Multi-Drug Resistant Streptococcal Species Infection, Known or Suspected Multi-Drug Resistant Tuberculosis (MDR-TB) Infection, as Part of a Multi-Drug Regimen and Known or Suspected Nontuberculous Mycobacterial (or Atypical Mycobacterial) Infection - when prescribed by, or in consultation with, an infectious disease specialist.<br>• **Sivextro**<br>  • **Acute Bacterial Skin and Skin Structure Infections (ABSSSI)**<br>  • Removed the prerequisite step through an appropriate first-line therapy.<br>  • **Added coverage for** patients where there is Insufficient Information Available to Make a Determination Regarding Coverage and the Prescriber or Representative Cannot be Contacted.<br>  • **Added** a preferred product step through linezolid for IFP. |
| Antibiotics (Inhaled) – Tobramycin Inhalation Solution – (IP0094) | Update | Effective: 7/1/2024<br>**For all indications:**<br>  • Added medical necessity criteria, including preferred products, for Individual and Family Plans to the policy.<br>**Cystic Fibrosis**: Added TOBI podhaler as another preferred alternative option for Employer Plans. |

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| | | **Continuation of Tobramycin Inhalation Solution Therapy (for conditions other than Cystic Fibrosis or Bronchiectasis, Non-Cystic Fibrosis) :**<br>• Updated authorization duration to 1 month, was previously 12 months. |
| Apremilast – (IP0226) | Update | Effective 7/15/2024<br>**Plaque Psoriasis:**<br>• Expanded age requirement from > 18 to > 6 years of age. |
| Brands with Bioequivalent Generics – (IP0011) | Update | Effective: 7/15/2024<br>• **Updated** format of policy to remove Diagnosis column.<br>• **Removed** diagnosis requirement for the following products: Felbatol, Keppra, Keppra XR, Lamictal, Lamictal ODT, Lamictal XR, Qudexy XR, Topamax, Trileptal, Vimpat, and Zonegran and to now support both Employer and Individual and Family plans medical necessity review.<br>• **Added** the following products to the policy to support medical necessity review for Individual and Family Plans: Atralin, Differin 0.1% cream, Differin 0.3% gel pump, Retin-A cream, Retin-A gel, Retin-A Micro gel, Retin-A Micro Pump gel. |
| Parkinson's Disease - Duopa – (IP0303) | Update | Effective: 7/15/2024<br>**Parkinson's Disease:**<br>• **Updated** coverage policy title.<br>• **Removed** criterion screening for positive history of clinical response to treatment with oral levodopa.<br>• **Updated** criterion requiring failure, contraindication, or intolerance to immediate- or extended-release carbidopa/levodopa treatment to require intolerance or inadequate response to extended-release carbidopa/levodopa treatment.<br>• **Updated** criterion requiring two additional therapies for "off" episodes to require three additional therapies for "off" episodes.<br>• **Removed** reauthorization criteria. |
| Complement Inhibitors – Zilbrysq - (IP0622) | New | Effective: 7/1/2024<br>• New coverage policy addressing utilization management of Zilbrysq (zilucoplan) subcutaneous injection |
| Cushing's – Korlym - (IP0092) | Update | Effective: 7/1/2024<br>• **Mifepristone tablets added to the policy**<br>• **Endogenous Cushing's Syndrome:**<br>  • Added a standard of care prerequisite step.<br>• **Endogenous Cushing's Syndrome – Patient Awaiting Surgery:**<br>  ▪ Decreased the initial authorization duration from 6 to 4 months. |

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| | | ▪ Added a preferred product prerequisite step.<br>• **Endogenous Cushing's Syndrome – Patient Awaiting Response after Radiotherapy:**<br>• Decreased the initial authorization duration from 6 to 4 months.<br>• Added a preferred product prerequisite step.<br>• **Added preferred product criteria.**<br>• For Korlym on all Employer and IFP formularies. |
| Cystic Fibrosis – Kalydeco - (IP0431) | Update | Effective: 7/15/2024<br>• **Cystic Fibrosis (CF):** The criterion that the patient has at least one of the following mutations in the cystic fibrosis transmembrane conductance regulator gene, was modified to require that the mutation be considered pathogenic or likely pathogenic. A criterion was added to require that the patient has at least one of the following: positive cystic fibrosis newborn screening test, family history of cystic fibrosis, or a clinical presentation consistent with signs and symptoms of cystic fibrosis. A criterion was added to require that the patient has evidence of abnormal cystic fibrosis transmembrane conductance regulator function as demonstrated by at least one of the following: elevated sweat chloride test, two cystic fibrosis-causing cystic fibrosis transmembrane conductance regulator mutations, or an abnormal nasal potential difference.<br>• **Cystic Fibrosis (CF), Patient Homozygous for the F508del Mutation in the Cystic Fibrosis Transmembrane Regulator Gene.** Reference to Phe508del was removed from this condition not recommended for approval (this is the same as F508del).<br>• **Infertility:** This indication was added to conditions not recommended for approval |
| Cystic Fibrosis – Trikafta - (IP0434) | Update | Effective: 7/15/2024<br>• **Cystic Fibrosis.**<br>Updated 'Documented diagnosis of cystic fibrosis (CF) [i.e., a clinical presentation consistent with signs/symptoms of CF, a positive CF newborn screening test, or family history of CF AND evidence of abnormal CFTR function (as demonstrated by elevated sweat chloride, detection of two CF-causing CFTR mutations, or abnormal nasal potential differences)]' TO 'Clinical presentation consistent with signs and symptoms of cystic fibrosis; Note: Examples of clinical presentation of cystic fibrosis include but are not limited to meconium ileus, sino-pulmonary symptoms (e.g., persistent cough, wheezing, pulmonary function tests consistent with obstructive airway disease, excess sputum production), bronchiectasis, sinusitis, failure to thrive, pancreatic insufficiency'<br>• **Added** 'Patient has evidence of abnormal cystic fibrosis transmembrane conductance regulator function as demonstrated by at least ONE of the following (i, ii, or iii): (i)Elevated sweat chloride test; (ii) Two cystic fibrosis-causing cystic fibrosis |

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| | | transmembrane conductance regulator mutations; (iii) Abnormal nasal potential difference.<br>• **Conditions Not Covered.**<br>• **Removed** (1) CFTR-related disorder (for example, congenital absence of the vas deferens (CAVD), isolated pancreatitis, recurrent sinusitis or bronchitis), (2) CFTR-related metabolic syndrome, CF Screen Positive, Inconclusive Diagnosis (CRMS/CFSPID)<br>• **Added** Infertility |
| Dermatology – Filsuvez - (IP0635) | New | Effective 7/15/2024<br>• New coverage policy addressing pharmacy prior authorization of Filsuvez (birch triterpenes) topical gel. |
| Drugs/Biologics Not Covered Unless Approved Under Medical Necessity Review - Employer Group Plans: Value, Advantage, or Cigna Total Savings Prescription Drug List - (1602) | Update | Effective 7/1/2024<br>• Removed Tekturna from the policy. Tekturna relocated to MSB CP (IP0011) based on business decision brought through on 01/29/2024 HPCC Agenda |
| Drug and Biologic Medical Necessity (Injectables) – medical benefits - (2027) | Update | Effective: 7/1/2024<br>• **Added** DefenCath (heparin taurolidine) catheter lock solution) - J0911 |
| Eculizumab – (IP0549) | Update | Effective: 7/1/2024<br>• **Removed** criterion that required prior use with systemic therapy/ rituximab; Soliris is listed as a first-line treatment option in the Neuromyelitis Optica Study Group (NEMOS) recommendations for the treatment of NMOSD (2024); in-alignment with ESI PA & UM Medical standard policy. |
| Enzyme Replacement Therapy – Lamzede - (IP0563) | Update | Effective 7/1/2024<br>• Revised title from Velmanase<br>• No content change in criteria |
| Gaucher Disease – Substrate Reduction | Update | Effective: 7/1/2024<br>• Removed criterion related to age, monotherapy and individual's ability to take enzyme replacement therapy. |

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| Therapy – Miglustat - (IP0446) | | • **Updated Employer preferred product criteria** from the ESI standard Formulary Exception Criteria to a Multisource Brand approach |
| Hematology – Reblozyl for Non-Oncology Uses - (IP0115) | Update | Effective 7/1/2024<br>**Beta Thalassemia.**<br>• **Removed** 'Treatment of anemia with a documented diagnosis of beta-thalassemia'<br>• **Updated** 'Has not received Zynteglo (betibeglogene autotemcel intravenous infusion) in the past 12 months' TO 'Patient has not received a gene therapy for transfusion dependent beta-thalassemia in the past; Note: Examples include Zynteglo (betibeglogene autotemcel intravenous infusion) and Casgevy (exagamglogene autotemcel intravenous infusion).'<br>• **Added** criteria for 'Patient is Currently Receiving Reblozyl'<br>• **Added** dosing |
| Hepatology – Rezdiffra - (IP0642) | New | Effective 7/15/2024<br>• New coverage policy addressing utilization management of Rezdiffra (resmetirom tablets). |
| Human Immunodeficiency Virus – Sunlenca - (IP0546) | Update | Effective: 7/15/2024<br>• **Updated** the policy title to Human Immunodeficiency Virus – Sunlenca; previously it was Lenacapavir.<br><br>• **Human Immunodeficiency Virus (HIV)-1 Infection, Treatment:** Updated initial approval duration from 12 months to 6 months. Removed "History of multi-drug resistant Human Immunodeficiency Virus" and replaced with "According to the prescriber, the patient is failing a current antiretroviral regimen for HIV; AND According to the prescriber, the patient has resistance to two or more agents from at least THREE of the following antiviral classes: a)Nucleoside reverse transcriptase inhibitor; b)Non-nucleoside reverse transcriptase inhibitor; c)Protease inhibitor; d)Integrase strand transfer inhibitor"**.** Examples of agents from each antiviral class were also included. |
| Hypoactive Sexual Desire Disorder – Addyi – (IP0116) | Update | Effective: 7/15/2024<br>• **Updated** policy title was previously titled Flibanserin.<br>• **Hypoactive Sexual Desire Disorder (HSDD)/Female Sexual Interest/Arousal Disorder (FSIAD):** Removed "Female at birth"; updated "Not currently being treated for active depression" to "Patient does not have a diagnosis of depression"; added clarification to patient counseling requirement to specifically address the increased risk of hypotension and syncope with Addyi and alcohol. Added to Patient is Currently Receiving Addyi criteria the following: "Patient has not reported any |

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| | | serious or concerning adverse events (e.g., hypotension, syncope, dizziness) while taking Addyi". |
| Inebilizumab - (IP0062) | Update | Effective: 7/1/2024<br>• **Removed** criterion that required prior use with systemic therapy/ rituximab; Uplizna is listed as a first-line treatment option in the Neuromyelitis Optica Study Group (NEMOS) recommendations for the treatment of NMOSD (2024). |
| Infectious Disease – Livtencity - (IP0394) | Update | Effective: 7/1/2024<br>• IFP added to the policy.<br>• Added a weight restriction (≥ 35 kg) aligned to the FDA labeled indication.<br>• Updated the ganciclovir resistance statement to intolerance to ganciclovir or valganciclovir.<br>• Added a restriction prohibiting concurrent use of Livtencity with ganciclovir or valganciclovir. |
| Infectious Disease – Sirturo – (IP0494) | Update | Effective 7/1/2024<br>• Revised title from Bedaquiline<br>• No content change in criteria |
| Inflammatory Conditions – Cosentyx Intravenous - (IP0643) | New | Effective: 7/1/2024<br>• New coverage policy addressing utilization management of Cosentyx (secukinumab) intravenous infusion<br>• Policy will apply to Employer Plans and Individual and Family Plans and medical benefit clients only. |
| Inflammatory Conditions – Cosentyx Subcutaneous - (IP0223) | Update | Effective: 7/15/2024<br>• **Added** Otezla as an Employer Plans preferred product option for Plaque Psoriasis - Pediatric and Adolescent.<br>• **Added** Rinvoq as an Employer Plans preferred product option for Psoriatic Arthritis - Pediatric and Adolescent. |
| Inflammatory Conditions – Ilaris – (IP0235) | Update | Effective: 7/1/2024<br>• Updated policy title, previously was Canakinumab<br>• **For All Indications:** Added clarification throughout the policy for all indications that for a Patient Currently Receiving Ilaris. "Patient has been established on this medication for at least 6 months; |

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| | | • Note: For a patient who has not received 6 months of therapy or who is restarting therapy with this medication, refer to Initial Therapy criteria"<br>• **Cryopyrin-Associated Periodic Syndromes (CAPS)** - Added patient is ≥ 4 years of age<br>• **Stills Disease, Adult Onset and Systemic Juvenile Idiopathic Arthritis (SJIA)** - Added requirements for ONE of the following: trial of ONE other biologic; OR patient was started on Ilaris in the hospital.<br>• **Conditions Not Covered:** Removed Behcet's Disease, Cardiovascular risk reduction and disorder prevention, Majeed Syndrome, Schnitzler Syndrome, Type 1 or 2 Diabetes. All continue to be considered experimental, investigational, or unproven. This was list maintenance and does not imply any updates to coverage status. |
| Inflammatory Conditions – Spevigo Intravenous – (IP0501) | Update | Effective: 7/15/2024<br>• Updated policy title to Inflammatory Conditions – Spevigo Intravenous. Previously it was titled Spesolimab.<br>• **Generalized Pustular Psoriasis Flare**: The word "flare" was added to the condition of approval. The age requirement was changed from ≥ 18 years of age to ≥ 12 years of age. The weight requirement of ≥ 40 kilogram (kg) was added. Clarification was added that the following criteria apply to a patient who is not currently taking Spevigo subcutaneous: patient has Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) total score of ≥ 3 points; and patient has a GPPGA pustulation subscore of ≥ 2 points; and patient has new or worsening pustules; and patient has erythema and pustules which affects ≥ 5% of body surface area. Criteria was added for patient currently taking Spevigo subcutaneous which are: patient has had an increase in GPPGA total score of ≥ 2 points and patient has GPPGA pustulation subscore of ≥ 2 points. Reference to Spevigo was reworded to Spevigo intravenous in the following criterion "if patient has already received Spevigo intravenous (IV), patient has not already received two doses of Spevigo IV for treatment of the current flare". The following criterion was reworded from "if this is a new flare" to state "if patient has previously received two doses of Spevigo IV" at least 12 weeks have elapsed since the last dose of Spevigo. The authorization duration was updated to be up to two doses, it was previously 3 months. |
| Ixekizumab - (IP0224) | Update | Effective: 7/15/2024<br>• **Added** Otezla as an Employer Plans preferred product option for Plaque Psoriasis - Pediatric and Adolescent.<br>• **Removed** Cimzia an Employer Plans preferred product option for Plaque Psoriasis - Pediatric and Adolescent. |

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| Lumacaftor/Ivacaftor - (IP0432) | Update | Effective: 7/15/2024<br>• **Cystic Fibrosis.**<br>• **Updated** 'Documented diagnosis of cystic fibrosis (CF) [i.e., a clinical presentation consistent with signs/symptoms of CF, a positive CF newborn screening test, or family history of CF AND evidence of abnormal CFTR function (as demonstrated by elevated sweat chloride, detection of two CF-causing CFTR mutations, or abnormal nasal potential differences)]' TO 'Patient meets at least ONE of the following (i, ii, or iii): (i) Positive cystic fibrosis newborn screening test, (ii) Family history of cystic fibrosis, (iii)Clinical presentation consistent with signs and symptoms of cystic fibrosis; Note: Examples of clinical presentation of cystic fibrosis include but are not limited to meconium ileus, sino-pulmonary symptoms (e.g., persistent cough, wheezing, pulmonary function tests consistent with obstructive airway disease, excess sputum production), bronchiectasis, sinusitis, failure to thrive, pancreatic insufficiency.' AND 'Patient has evidence of abnormal cystic fibrosis transmembrane conductance regulator function as demonstrated by at least ONE of the following (i, ii, or iii): (i)Elevated sweat chloride test; (ii) Two cystic fibrosis-causing cystic fibrosis transmembrane conductance regulator mutations; (iii) Abnormal nasal potential difference'<br>• Updated 'Documentation the individual is homozygous for the F508del variant in the CFTR gene (i.e., 2 copies of the F508del variant)' to 'Patient has TWO copies of the F508del mutation in the CFTR gene'<br>• **Conditions Not Covered.**<br>• **Removed** (1) CFTR-related disorder (for example, congenital absence of the vas deferens (CAVD), isolated pancreatitis, recurrent sinusitis or bronchitis), (2) CFTR-related metabolic syndrome, CF Screen Positive, Inconclusive Diagnosis (CRMS/CFSPID)<br>• **Added** Infertility |
| Lupus – Saphnelo – (IP0280) | Update | Effective: 7/1/2024<br>• **No** changes to clinical criteria. |
| Metabolic Disorders – Cysteamine Ophthalmic Solution - (IP0082) | Update | Effective 07/15/2024<br>• **Policy Name Change:** Updated Policy Name from "Cysteamine Ophthalmic Solution" to "Metabolic Disorders – Cysteamine Ophthalmic Solution."<br>• No criteria changes |
| Migraine – Calcitonin Gene-Related Peptide Inhibitors – Aimovig – (IP0503) | Update | Effective: 7/15/2024<br>• **Updated** coverage policy title from *Erenumab* to *Migraine – Calcitonin Gene-Related Peptide Inhibitors – Aimovig*.<br>• **Migraine Headache Prevention:** |

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| | | • **Removed** the criteria requiring a patient to have tried either Botox or at least two standard prophylactic (preventive) pharmacologic therapies, each from a different pharmacologic class, and requiring that a patient has had inadequate efficacy or adverse event(s) severe enough to warrant discontinuation of those therapies.<br>• **Added** preferred product table with criteria to support non-formulary use of Aimovig for IFP plans.<br>• **Authorization Duration:**<br>• **Updated** initial approval duration updated from 6 months to 1 year. |
| Migraine – Calcitonin Gene-Related Peptide Inhibitors – Ajovy – (IP0504)<br><br>Brand | Update | Effective: 7/15/2024<br>• **Updated** coverage policy title from *Fremanezumab* to *Migraine – Calcitonin Gene-Related Peptide Inhibitors – Ajovy*.<br>• **Migraine Headache Prevention:**<br>• **Removed** the criteria requiring a patient to have tried either Botox or at least two standard prophylactic (preventive) pharmacologic therapies, each from a different pharmacologic class, and requiring that a patient has had inadequate efficacy or adverse event(s) severe enough to warrant discontinuation of those therapies have been removed.<br>• **Added** preferred product table with criteria to support non-formulary use of Ajovy for IFP plans.<br>• **Authorization Duration:**<br>• **Updated** the initial approval duration updated from 6 months to 1 year. |
| Migraine – Calcitonin Gene-Related Peptide Inhibitors – Emgality - (IP0505)<br><br>Dike | Update | Effective 07/15/2024<br>• **Policy Name Change: Updated** Policy Name from "Galcanezumab" to "Migraine – Calcitonin Gene-Related Peptide Inhibitors – Emgality."<br>• **Episodic Cluster Headache Treatment:**<br>• **Added** preferred product requirement criteria for both Employer Plans and Individual and Family Plans.<br>• **Migraine Headache Prevention:**<br>• The criteria requiring a patient to have tried botox or at least two standard prophylactic (preventive) pharmacologic therapies, each from a different pharmacologic class, and requiring that a patient has had inadequate efficacy or adverse event(s) severe enough to warrant discontinuation of those therapies have been removed. |

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| | | • **Updated** the requirement from "prior to initiating Emgality" to "prior to initiating a migraine-preventive medication," regarding patients needing to have 4 or more migraine headache days per month.<br>• **Authorization Duration:**<br>  • **Updated** initial approval duration for Episodic Cluster Headache Treatment to 6 months from 3 months and for Migraine Headache Prevention to 12 months from 6 months. |
| Migraine – Calcitonin Gene-Related Peptide Inhibitors – Vyepti - (IP0506) | Update | Effective 07/15/2024<br>• **Policy Name Change: Updated** Policy Name from "Eptinezumab" to "Migraine – Calcitonin Gene-Related Peptide Inhibitors – Vyepti."<br>• **Migraine Headache Prevention:**<br>  • The criteria requiring a patient to have tried botox or at least two standard prophylactic (preventive) pharmacologic therapies, each from a different pharmacologic class, and requiring that a patient has had inadequate efficacy or adverse event(s) severe enough to warrant discontinuation of those therapies have been removed.<br>  • **Updated** the requirement from "prior to initiating Vyepti" to "prior to initiating a migraine-preventive medication," regarding patients needing to have 4 or more migraine headache days per month.<br>  • **Removed** Aimovig and Ajovy as a preferred product step requirement for Individual and Family Plans.<br>• **Authorization Duration:**<br>  • **Updated** initial approval duration for Migraine Headache Prevention to 12 months from 6 months. |
| Migraine – Nurtec ODT – (IP0147) | Update | Effective: 7/15/2024<br>• **Migraine Headache Prevention:**<br>  • **Removed** the criteria requiring a patient to have tried at least two standard prophylactic (preventive) pharmacologic therapies, each from a different pharmacologic class, and requiring that a patient has had inadequate efficacy or adverse event(s) severe enough to warrant discontinuation of those therapies. |
| Migraine – Qulipta - (IP0377) | Update | Effective 7/15/2024 |

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| | | • **Policy Name Change: Updated** Policy Name from "Atogepant" to "Migraine – Qulipta."<br>• **Migraine Headache Prevention:**<br>  • The criteria requiring a patient to have tried botox or at least two standard prophylactic (preventive) pharmacologic therapies, each from a different pharmacologic class, and requiring that a patient has had inadequate efficacy or adverse event(s) severe enough to warrant discontinuation of those therapies have been removed.<br>  • **Updated** the requirement from "prior to initiating Qulipta" to "prior to initiating a migraine-preventive medication," regarding patients needing to have 4 or more migraine headache days per month.<br>  • **Added** preferred product criteria for Individual and Family Plans. |
| Muscular Dystrophy – Agamree - (IP0624) | New | Effective: 7/15/2024<br>• New coverage policy addressing utilization management of Agamree (vamorolone) oral suspension. |
| Non-Oncology – Everolimus - (IP0408) | Update | Effective: 7/1/2024<br>• **Updated** coverage policy title.<br>**Tuberous Sclerosis Complex-Associated Renal Angiomyolipoma.**<br>• **Removed** criterion screening for age.<br>• **Removed** criterion requiring confirmation of angiomyolipoma greater than or equal to 3 cm diagnosed on radiographic imaging.<br>**Tuberous Sclerosis Complex-Associated Partial Onset Seizures.**<br>• **Removed** criterion screening for age.<br>• **Removed** criteria requiring failure, contraindication, or intolerance to two antiepileptic drugs.<br>• **Removed** criterion requiring use as adjunctive therapy to other antiepileptic drugs.<br>• **Removed** criterion requiring consultation with specialist. |
| Northera – (IP0110) | Update | Effective 7/15/2024<br>• **Neurogenic Orthostatic Hypotension:** Removed "Documented diagnosis of Neurogenic Orthostatic Hypotension (NOH) is confirmed by a sustained decrease in systolic blood pressure of at least 20 mmHg or diastolic blood pressure of at least 10 mmHg within 3 minutes of standing OR during a head-up tilt-table test" and nephrologist from list of specialist prescribers. |

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| Oncology (Injectable – CAR-T) – Abecma - (IP0168) | Update | Effective: 7/1/2024<br>**Multiple Myeloma.**<br>• **Removed** (1) 'Documentation of an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 1', (2) 'Does not have central nervous system involvement with myeloma', (3) Does not have presence or history of plasma cell leukemia, (4) Removed Hematologist from specialist, (5) Documented diagnosis of multiple myeloma<br>**Conditions Not Covered.**<br>• **Removed** 'Repeat administration of Idecabtagene vicleucel (Abecma)', note that it was added to approve as a single dose in the medical necessity criteria section |
| Oncology (Injectable – CAR-T) – Kymriah - (IP0197) | Update | Effective: 7/1/2024<br>**Acute Lymphoblastic Leukemia, B-Cell Precursor**<br>• **Removed** (1) 'Individual is not being treated for primary central nervous system lymphoma, (2) 'Individual has an Eastern Cooperative Oncology Group (ECOG) performance status of 0-1', (3) Individual has an Eastern Cooperative Oncology Group (ECOG) performance status of 0-1, (4) 'Individual does not have active or latent hepatitis B, active hepatitis C or other active uncontrolled infection', (5) 'Individual does not have an active inflammatory disorder', (6) 'Individual does not have active graft versus host disease, (7) Hematologist as allowable specialist<br>**B-Cell Lymphoma.**<br>• **Removed** (1) 'Individual is not being treated for primary central nervous system lymphoma', (2) 'Individual has an Eastern Cooperative Oncology Group (ECOG) performance status of 0-1', (3) 'Individual does not have active or latent hepatitis B, active hepatitis C or other active uncontrolled infection', (4) 'Individual does not have an active inflammatory disorder' (5) Hematologist as allowable specialist<br>• **Updated** the following: "follicular" was changed to "indolent" in the option for approval "diffuse large B-cell lymphoma arising from indolent lymphoma." The option of approval of diffuse large B-cell lymphoma arising from nodal marginal zone lymphoma was removed. |
| Oncology (Injectable) – Cosela – (IP0150) | Update | Effective 07/15/2024<br>• **Policy Name Change: Updated** Policy Name from "Trilaciclib Injection" to "Oncology (Injectable) – Cosela."<br>• **Small Cell Lung Cancer: Added** dosing information. |

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| Oncology Medications - (1403) | Update | Effective: 7/1/2024<br>• **Alunbrig/Zykadia**<br>  • Non-Small Cell Lung Cancer – anaplastic lymphoma kinase (*ALK*)-positive: **Added** preferred product step requirement through Alecensa for Employer and Individual and Family Plans<br>• **Votrient:**<br>  • **Added** preferred product step requirement through generic pazopanib for Employer Plans<br>• **Braftovi**<br>  • Melanoma, unresectable or metastatic, treatment of *BRAF* V600 mutation-positive: **Added** preferred product step requirement through Tafinlar or Zelboraf on Employer plans<br>• **Mektovi**<br>  • Melanoma, unresectable or metastatic, treatment of *BRAF* V600 mutation-positive: **Added** preferred product step requirement through Cotellic or Mekinist for Employer plans<br>• **Bosulif**<br>  • Chronic Myeloid Leukemia (CML), Philadelphia Chromosome Positive: **Updated** preferred product criteria to add Scemblix and Tasigna as step requirement options, **Updated** preferred product step requirement exceptions<br>• **Gleevec:**<br>  • **Updated** preferred product step through generic imatinib requirement criteria<br>• **Iclusig**<br>  • Chronic Myeloid Leukemia, Philadelphia Chromosome Positive: **Updated** preferred product criteria to add Scemblix and Tasigna as step requirement options, **Updated** step requirement from requiring "ONE" to requiring "TWO" preferred products for Employer and Individual and Plans, **Updated** exceptions to the step requirement for Employer plans and Individual and Family Plans<br>  • Acute Lymphoblastic Leukemia, Philadelphia Chromosome Positive: **Added** preferred product step requirement through generic imatinib or Sprycel for Iclusig<br>• **Scemblix** |

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| | | • Chronic Myeloid Leukemia (CML), Philadelphia Chromosome Positive: **Removed** Scemblix preferred product step requirement on Employer Plans, **Updated** step requirement from requiring "ONE" to requiring "TWO" preferred products for Individual and Plans, **Updated** exceptions to the step requirement for Individual and Family Plans<br>• **Tasigna**<br>• Chronic Myeloid Leukemia (CML), Philadelphia Chromosome Positive: **Updated** exceptions to the step requirement for Employer and Individual and Family Plans |
| Ophthalmology – Dry Eye Disease – Xiidra for Individual and Family Plans – (IP0644) | New | Effective 7/15/2024<br>New coverage policy addressing medical necessity review for Xiidra for Individual and Family Plans. |
| Ophthalmology – Gene Therapy – Luxturna - (IP0160) | Update | Effective 07/15/2024<br>• **Policy Name Change: Updated** Policy Name from "Voretigene Neparvovec-rzyl" to "Ophthalmology – Gene Therapy – Luxturna.<br>• **Biallelic Human Retinal Pigment Epithelial 65 kDa Protein (RPE65) Mutation-Associated Retinal Dystrophy:**<br>• **Removed** the requirement for the presence of sufficiently viable retinal cells determined by optical coherence tomography (OCT) and/or ophthalmoscopy, evidenced by either area of retina within the posterior pole of greater than 100 µm thickness per OCT, or at least 3 disc areas of retina without atrophy or pigmentary degeneration within the posterior pole, or remaining visual field within 30 degrees of fixation as measured by a III4e isopter or equivalent. |
| Parkinson's Disease – Carbidopa - (IP0523) | Update | Effective: 7/1/2024<br>• **Parkinson's disease, Postencephalitic Parkinsonism or Symptomatic Parkinsonism.**<br>• **Updated** 'Currently receiving levodopa-based treatment' to 'Patient is currently receiving carbidopa/levodopa therapy'<br>• **Preferred Product table.**<br>• **Updated** step thru generic criteria (MSB) from medical necessity criteria to preferred product table. |

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| Parkinson's Disease – Inbrija - (IP0522) | Update | Effective 7/1/2024<br>• **Parkinson's Disease.**<br>  • **Updated** 'Currently receiving levodopa-based treatment' to 'Patient is currently taking carbidopa-levodopa'<br>  • **Added** 'Patient does not have asthma, chronic obstructive pulmonary disease, or other chronic underlying lung disease' for alignment<br>• **Preferred Product Table.**<br>  • **Added** 'Patients already started on Inbrija' |
| Parkinson's Disease – Nourianz - (IP0524) | Update | Effective: 7/1/2024<br>• **Policy Name Change: Updated** Policy Name from "Istradefylline" to "Parkinson's Disease – Nourianz."<br>• **Parkinson's Disease:**<br>  • **Removed** the age requirement of 18 years or older for Parkinson's disease treatment.<br>  • **Updated** criterion from "currently receiving levodopa-based treatment" to "currently taking carbidopa/levodopa."<br>  • **Moved** preferred product requirement criteria to preferred product table. |
| Parkinson's Disease – Nuplazid - (IP0145) | Update | Effective: 7/1/2024<br>• **Parkinson's Disease Psychosis.**<br>  • **Added** 'Patient does not have dementia-related psychosis unrelated to the hallucinations and delusions associated with Parkinson's disease psychosis'<br>• **Preferred Product table.**<br>  • **Updated** to move step thru criteria to preferred product table.<br>  • **Updated** preferred product table to include (1) patient is unable to use either quetiapine (Seroquel, generics) or clozapine (Clozaril, generics) and (2) patient is currently taking Nuplazid or has taken Nuplazid at any time in the past. |
| Parkinson's Disease – Ongentys – (IP0532) | Update | Effective: 7/1/2024<br>• **Parkinson's disease:**<br>  • **Updated** coverage policy title from *Opicapone* to *Parkinson's Disease – Ongentys*<br>  • **Removed** criterion requiring patient experience "off" episodes. |
| Pharmacy Prior Authorization - (1407) | Update | Effective: 7/15/2024<br>• **Added** IFP product specific criteria as follows:<br>  • Kiprofen<br>  • Sovuna<br>  • Ermeza |

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| | | • levothyroxine<br>• Thyquidity<br>• Tirosint<br>• Tirosint-SOL<br>• Glucose Test Strips<br>• Lancets<br>• Altreno<br>• Retin-A Micro Pump 0.06% gel<br>• tretinoin 0.025%, 0.05%, 0.1% cream<br>• tretinoin 0.01%, 0.025%, 0.05% gel<br>• tretinoin gel micro 0.04%, 0.08%, 0.1% pump<br>• tretinoin gel micro 0.04%, 0.1% tube<br>• adapalene 0.1% cream<br>• adapalene 0.1% lotion<br>• adapalene 0.1% solution<br>• adapalene 0.1% swab<br>• adapalene 0.3% gel<br>• adapalene 0.3% gel pump<br>• Differin 0.1% lotion<br>• adapalene-benzoyl peroxide 0.1-2.5% gel pump<br>• adapalene-benzoyl peroxide 0.3-2.5% gel pump<br>• Epiduo Forte 0.3-2.5% gel pump<br>• **Removed** IFP product specific criteria as follows:<br>• Blue Link glucose test strips |
| Qbrexza – (IP0074) | Update | Effective 7/1/2024<br>• **Hyperhidrosis, Primary Axillary:** Updated "Documentation of failure, contraindication or intolerance to at least ONE prescription aluminum chloride-containing topical antiperspirant applied for at least 4 weeks." to now read, "Patient meets one of the following (i or ii): i. Patient has tried one prescription aluminum chloride-containing topical antiperspirant for at least 4 weeks and experienced inadequate efficacy; OR ii. According to the prescriber, the patient has experienced significant intolerance with an aluminum-containing topical antiperspirant. Added "The prescriber has excluded secondary causes of hyperhidrosis". |
| Satralizumab – (IP0078) | Update | Effective: 7/1/2024<br>• **Removed** criterion that required prior use with systemic therapy/ rituximab; Enspryng is listed as a first-line treatment option in the Neuromyelitis Optica Study Group (NEMOS) recommendations for the treatment of NMOSD (2024). |
| Secukinumab Intravenous for | Update | Effective: 7/1/2024 |

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| Employer Plans - (IP0594) | | • Policy will only apply to Employer Plans and pharmacy benefit clients only. |
| Sickle Cell Disease – Endari for IFP – (IP0475) | Update | Effective: 7/15/2024<br>• **Updated** coverage policy title from *L-glutamine Oral Powder for Individual and Family Plans* to *Sickle Cell Disease – Endari for Individual and Family Plans.*<br>• **Added** *Preferred Product Criterion* for *the patient who is not a candidate for a hydroxyurea product.* |
| Thrombocytopenia – Eltrombopag Products - (IP0153) | Update | Effective 7/15/2024<br>• Alvaiz (eltrombopag choline tablets) added to the policy.<br>• Promacta (Aplastic Anemia)<br>  • Added examples of a beneficial response to the Patient is Currently Receiving Eltrombopag approach.<br>• Promacta (Immune Thrombocytopenia)<br>  • Removed the age restriction.<br>  • Removed contraindication or intolerance to ALL therapies.<br>  • Added examples of a beneficial response to the Patient is Currently Receiving Eltrombopag approach.<br>• Promacta (Thrombocytopenia in a Patient with Myelodysplastic Syndrome)<br>  • Added examples of a beneficial response to the Patient is Currently Receiving Eltrombopag approach.<br>• Added Promacta coverage for Thrombocytopenia in a Patient Post-Allogeneic Transplantation. |
| Tocilizumab Intravenous - (IP0228) | Update | Effective 7/15/2024<br>• **Added** Tyenne (biosimilar to Actemra Intravenous) to the policy with the same criteria as Actemra Intravenous.<br>• Throughout the policy, wording was changed from Actemra to tocilizumab. |
| Unassigned Drug Or Biologic Code Medical Precertification - (1701) | Update | Effective: 7/1/2024<br>• **Removed** DefenCath (heparin taurolidine) catheter lock solution) – J3490 |
| Upadacitinib - (IP0229) | Update | Effective: 7/15/2024 |

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| | | • **Added** Otezla as an Employer Plans preferred product option for Plaque Psoriasis - Pediatric and Adolescent.<br>• **Removed** Cimzia an Employer Plans preferred product option for Plaque Psoriasis - Pediatric and Adolescent. |
| Weight Loss – Glucagon-Like Peptide-1 Agonists - (IP0206) | Update | Effective: 7/15/2024<br>**Wegovy and Zepbound added to the policy.**<br>*Saxenda*<br>• **Initial Therapy (Adult):**<br>• Examples of comorbidities updated.<br>• **Patient is Continuing on Therapy (Adult):**<br>• Examples of comorbidities updated.<br>• Updated the body weight decrease requirement by removing "only required once"<br>• Added a requirement for the patient to tolerate a maintenance dose.<br>• **Initial Therapy (Pediatric)**<br>• Removed the option for the patient to alternatively have a BMI ≥ 85th percentile and < 95th percentile for age and sex (overweight) if the patient had at least one comorbidity.<br>• **Patient is Continuing on Therapy (Pediatric):**<br>• Removed the option for the patient to alternatively have a BMI ≥ 85th percentile and < 95th percentile for age and sex (overweight) if the patient had at least one comorbidity.<br>• Added a requirement for the patient to tolerate a maintenance dose of.<br>*Wegovy*<br>• **Initial Therapy (Adult):**<br>  • Examples of comorbidities updated.<br>• **Patient is Continuing on Therapy (Adult):**<br>  • Examples of comorbidities updated.<br>  • Updated the body weight decrease requirement by removing "only required once"<br>  • Added a requirement for the patient to tolerate a maintenance dose.<br>• **Initial Therapy (Pediatric)**<br>  • Removed the option for the patient to alternatively have a BMI ≥ 85th percentile and < 95th percentile for age and sex (overweight) if the patient had at least one comorbidity.<br>• **Patient is Continuing on Therapy (Pediatric):**<br>  • Removed the option for the patient to alternatively have a BMI ≥ 85th percentile and < 95th percentile for age and sex (overweight) if the patient had at least one comorbidity. |

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| | | • Updated the requirement of a reduction in body weight to a reduction in BMI and by removing "only required once"<br>• A requirement for the patient to tolerate a maintenance dose added.<br>• **Major Adverse Cardiovascular Event(s) Risk Reduction in a Patient with Established Cardiovascular Disease who is Either Obese or Overweight.**<br>• Added a new condition of coverage to FDA-approved indications for Wegovy.<br>*Zepbound*<br>• **Initial Therapy (Adult):**<br>• Examples of comorbidities updated.<br>• **Patient is Continuing on Therapy (Adult):**<br>• Documentation required added to the approach for adult patients with a BMI ≥ 30 kg/m$^2$ or a BMI ≥ 27 kg/m$^2$<br>• Examples of comorbidities updated.<br>• Updated the body weight decrease requirement by removing "only required once"<br>• Added a requirement for the patient to tolerate a maintenance dose. |
| Weight Loss – Semaglutide (Wegovy™) – (IP0521) | Retired | Policy to be retired effective 7/15/2024<br>• Product moved into CP IP0206 |
| **CareAllies Medical Necessity Guideline** | **New, Updated, or Retired?** | **Comments** |
| | | Updates made for CareAllies - see above policies |
| **Precertification Policy*** | **New, Updated, or Retired?** | **Comments** |
| | | No updates in July 2024 |
| **Reimbursement Policy*** | **New, Updated, or Retired?** | **Comments** |
| Emergency Room Services - (R36) | Update | Updates made to policy. |

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| Unacceptable Primary/Principal Diagnosis - (R38) | Update | Effective 06/16/2024<br>• Updates made to policy. |
| Diagnosis Coding Guidelines - (R47) | New | Effective 06/16/2024<br>• Updates made to policy. |
| Diagnosis Coding Guidelines - (R47) | Update | Effective 07/14/2024<br>• Updates made to policy. |
| **ClaimsXten Documents*** | **New, Updated, or Retired?** | **Comments** |
| Code Editing Policy and Guidelines | Update | Effective 08/17/2024<br>• Updates made. |