

Coverage Policy Unit (CPU) - Monthly Policy Updates

Effective October 15, 2024 (unless otherwise noted)

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

| Medical Coverage Policy | New, Updated, or Retired? | Comments |
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| <u>Airway Clearance</u> <u>Devices in the</u> <u>Ambulatory Setting –</u> (CP 0069) | Update | Posting 10/15/2024; Effective 1/15/2025 Important changes in coverage criteria: Removed the following devices from the policy because they're not managed: acoustical percussor, positive expiratory pressure and aerosol drug delivery system combination devices (e.g., Vibralung®; E0480) mechanical percussors (HCPCS E0480) oscillatory (vibratory) positive expiratory pressure devices (HCPCS E0484; S8185) Added medical necessity criteria back into the policy for positive expiratory pressure devices because the associated code, E1399, is being added back to precertification (this is also noted in a separate entry below regarding all of the policies impacted by E1399 being added to precertification). |

| Diabetes Equipment and Supplies - (CP0106) Infertility Services - (CP 0089) | Update Update | Posted and Effective 10/18/2024. Minor changes in coverage criteria/policy: Added Freestyle Libre 2 Plus and Freestyle Libre 3 Plus sensors to therapeutic/non-adjunctive continuous glucose monitoring statemen04ts Important change: Revised coverage policy definition of infertility to reflect the current American Society of Reproductive Medicine (ASRM) definition. This change will increase inclusivity and equitable access to infertility/reproductive care. |
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| <u>Atrial Fibrillation:</u> <u>Nonpharmacological</u> <u>Treatments - (CP</u> <u>0469)</u> | Update | Important changes in coverage criteria: Added coverage for CPT 33258 (extensive Maze/ablation procedure, performed at the time of other cardiac procedure[s], but without cardiopulmonary bypass - List separately in addition to code for primary procedure). |
| Cardiac Omnibus Codes - (CP 0574) | New / Update | Important changes in coverage criteria: Added new topic, new policy statement for carotid sinus baroreflex activation device (i.e., BAROSTIM[™] NEO[®] System) No clinical policy statement changes for these topics that have been moved from CP 0504 Omnibus Codes into CP 0574: Endovascular repair of iliac artery at the time of aorto-iliac artery endograft placement by deployment of an iliac branched endograft (i.e., GORE[®] EXCLUDER[®] Iliac Branch Endoprosthesis [IBE] device Pulmonary artery pressure sensor (e.g., CardioMEMS[™] HF system, Cordella[™] Pulmonary Artery Sensor System) Cardiac contractility modulation (CCM[®]) therapy (i.e., OPTIMIZER Smart System) Coronary Intravascular Lithotripsy (IVL) (i.e., Shockwave C2 Coronary IVL System) |
| <u>Cervical Cancer</u> <u>Screening Visualization</u> <u>Technologies – (CP</u> <u>0127)</u> | Update | Minor change in coverage criteria: Removed the verbiage "but not limited to" from the coverage statement in preparation for automation. |
| Electrical Stimulation Therapy and Devices in a Home Setting - (CP 0160) | Update | Posting 10/15/2024 ; Effective 1/15/2025 Important changes in coverage criteria: |

| | | Removed the following devices/technologies from the policy, as the corresponding codes are not managed: auricular electroacupuncture cranial electrical stimulation pelvic floor electrical stimulation transcutaneous afferent patterned stimulation neuromodulation therapy transcutaneous electrical joint stimulation Added the following devices/treatments to the policy statement as experimental, investigational or unproven; the associated HCPCS code (E1399) is being added to precertification (this is also noted in a separate entry below regarding all of the policies impacted by E1399 being added to precertification).: bioelectric nerve block combination therapy electrotherapeutic point stimulation H-WAVE electrical stimulation high-voltage galvanic stimulation thigh-voltage galvanic stimulation threshold/therapeutic electrical stimulation |
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| <u>Gender Dysphoria</u> <u>Treatment - (CP 0266)</u> | Update | Minor change in coverage criteria/policy: Minor change to clarify that coverage of gender dysphoria treatment is applicable regardless of past history of transition. |
| <u>Glaucoma Surgical</u> <u>Procedures – (CP</u> <u>0035)</u> | Update | Important changes in coverage criteria/policy: Removed policy statements and associated codes for the following because they are not managed: Removing CPT code 66180, C1783, and L8612 from aqueous shunts/aqueous drainage devices coverage statement Removing statement of coverage for Glaukos iStent[®] Trabecular Micro Bypass Stent, Glaukos iStent Inject and Ivantis Hydrus[™] Microstent along with corresponding CPT codes 66989, 66991, C1783, and L8612. Remove CPT code C1783 and L8612 from XEN[®]45 Gel Stent coverage statement. |

| | | Removing statement of non- coverage for ab interno suprachoroidal microstent (i.e., ab interno suprachoroidal microstent (i.e., CyPass Micro-Stent) Micro-Stent) (CPT Codes[®] 0253T; 0474T) Removing statement of non- coverage for drug-eluting ocular devices and the following CPT Codes[®] 68841, 0444T, 0445T, 0660T, 0661T. Removing statement of coverage for Goniotomy (i.e. trabeculotomy, trabeculotomy ab interno) and CPT Code[®] 65820. Removing statement of non- coverage for excimer laser trabeculostomy (i.e., ExTra ELT) (CPT Code[®] 0621T, 0622T, 0730T) |
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| <u>Kidney</u> <u>Transplantation,</u> <u>Pancreas-Kidney</u> <u>Transplantation, and</u> <u>Pancreas</u> <u>Transplantation Alone</u> <u>- (CP 0146)</u> | Update | Minor changes in coverage criteria/policy: Removed content re Mechanical Preservation Machines because a statement was added to R24 Omnibus Reimbursement Policy as of 6/15/2024 'Organ transport (e.g., transport systems, perfusion and/or preservation machines, modes of transportation) and procurement are considered integral to the primary transplant procedure and will not be separately reimbursed.' |
| Minimally Invasive Spine Surgery Procedures and Trigger Point Injections - (CP 0139) | Update | Posted 7/15/2024; Effective 10/15/2024. Important changes in coverage criteria: Limited coverage for trigger point injections to no more than ten (10) in a rolling 12-month period. Added not covered statement for the use of ultrasound guidance (CPT code 76942) for trigger point injections. |
| <u>Omnibus Codes -</u> (0504) | Update | Effective 10/15/2024: Removed content and placed in another policy with no policy statement changes: Radiofrequency Ablation for Thyroid Nodules (CP 0575) Radiofrequency Therapy for Fecal Incontinence (Secca[®] System Secca[®] procedure) (CP 0576) Mucosal Integrity Testing (MiVu[™] Mucosal Integrity Testing System) (CP 0577) Removed content and placed in Cardiac Omnibus Codes CP 0574 with no policy statement changes: Endovascular Repair of Iliac Artery by Deployment of an Iliac Branched Endograft (GORE[®] EXCLUDER[®] Iliac Branch Endoprosthesis [IBE] device) (CP 0574) |

| | | Pulmonary Artery Pressure Sensor (CardioMEMS[™] HF system, Cordella[™] Pulmonary Artery Sensor System) (CP 0574) Cardiac Contractility Modulation (CCM[®]) Therapy (Optimizer[®] Smart CCM device/ OPTIMIZER Smart System) (CP 0574) Coronary Intravascular Lithotripsy (IVL) (CP 0574) Removed content and no longer review: Transanal Endoscopic Microsurgery (TEMS) Approach for Excision of Rectal Tumor Vibrant[®] System IBSchek[®] 13C-Spirulina Gastric Emptying Breath Test (GEBT) Physiologic Recording of Tremor Using Accelerometer/Gyroscope Current perception threshold/sensory nerve conduction threshold (sNCT) test Thoracic Electrical Bioimpedance for the Measurement of Cardiac Output Near-Infrared Guidance for Vascular Access Requiring Real-Time Digital Visualization for Evaluation of Potential Access Sites and Vessel Patency |
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| Sacral Nerve and Tibial Nerve Stimulation for Urinary Voiding Dysfunction, Fecal Incontinence and Constipation – (CP 0404) | Update | Important changes in coverage criteria: Removed the policy statement bullets for replacement/revision of a sacral nerve stimulator and percutaneous tibial nerve stimulation because the corresponding codes for these procedures are not managed. Changed language for sacral nerve stimulation for any other indication from EIU to NMN because this technology doesn't meet Cigna's definition of EIU. |
| <u>Tissue-Engineered</u> <u>Skin Substitutes -</u> (CP0068) | Update | Posted and Effective 10/18/2024. Minor changes in coverage criteria/policy: Added new CPT code for Matrix HD. This product is currently listed in the policy as EIU with a generic CPT code. |
| <u>Tissue-Engineered</u> <u>Skin Substitutes – (CP</u> <u>0068)</u> | Update | Posting date 10/15/2024, Effective date 1/15/2025. Important changes in coverage criteria: Added not covered: code Q4205 for Membrane graft or membrane wrap. This code was previously in the policy as experimental, investigational, or unproven (EIU) and has been added back to the EIU section of the coverage statement. Clarified the wording for the conditions of coverage that apply for the diabetic foot ulcers (DFUs). |

| | | Expanded coverage: Added increased initial applications for venous stasis ulcers (VSUs) as was approved for diabetic foot ulcers (DFUs) at May HMAC this year |
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| <u>Transcranial Magnetic</u> <u>Stimulation – (CP</u> <u>EN0383)</u> | Update | Posting date: 7/15/2024; Effective date: 10/15/2024 Important changes in coverage criteria: 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. |
| Airway Clearance Devices in the Ambulatory Setting - (CP 0069)Autism Spectrum Disorders/ Pervasive Developmental Disorders: Assessment and Treatment - (CP 0047)Diabetes Equipment and Supplies - (CP | Update | Statements related to HCPCS E1399 (Durable medical equipment, miscellaneous) were added into the listed CP. All the equipment that was added had previously been in the respective CPs. Current evidence for the equipment was reviewed. The equipment was determined to be either not medically necessary or experimental, investigational, or unproven. The updated CPs were posted 10/15/2024 and effective 1/15/2025 . |

| <u>Total Artificial Heart –</u> (<u>CP 0054)</u> | | |
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| Autologous Platelet- Derived Growth Factors (Platelet-Rich Plasma [PRP]) – (CP 0507) | Update | No change in coverage. |
| Manipulation Under Anesthesia – (CP 0276) | Update | No change in coverage. |
| Cardiac Electrophysiological (EP) Studies - (CP 0532) | Update | No change in coverage. |
| Orthognathic Surgery - (CP 0209) | Update | No change in coverage. |
| Radiofrequency Ablation (RFA) Thyroid Nodules – (CP 0575) | New | No change in coverage. Topic removed from Omnibus 0504 and is now an independent policy 0575. |
| Radiofrequency Therapy for Fecal Incontinence – (CP 0576) | New | No change in coverage. Topic removed from Omnibus 0504 and is now an independent policy 0576. |
| Mucosal Integrity Testing – (CP 0577) | New | No change in coverage. Topic removed from Omnibus 0504 and is now an independent policy 0577. |
| Subtalar Joint Implantation (Subtalar Arthroereisis) - (CP 0486) | Update | No change in coverage. |
| Comparative Genomic Hybridization (CGH)/Chromosomal Microarray Analysis (CMA) for Selected | Retired | Retiring 11/1/2024. Replaced with new cobranded Cigna-EviCore Lab Management Program guidelines (effective 11/1/2024). |

| Hereditary Conditions - (CP 0493) | | |
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| Discography - (CP 0393) | Retired | Retiring 11/1/2024 . Replaced with new cobranded Cigna-EviCore guideline CMM-401 Discography (effective 11/1/2024). |
| Genetic Testing for Hereditary Cancer Susceptibility Syndromes - (CP 0518) | Retired | Retiring 11/1/2024. Replaced with new cobranded Cigna-EviCore Lab Management Program guidelines (effective 11/1/2024). |
| Genetic Testing for Hereditary Cardiomyopathies and Arrhythmias - (CP 0517) | Retired | Retiring 11/1/2024. Replaced with new cobranded Cigna-EviCore Lab Management Program guidelines (effective 11/1/2024). |
| Lumbar Fusion for Spinal Instability and Degenerative Disc Conditions, Including Sacroiliac Fusion - (CP 0303) | Retired | Retiring 11/1/2024. Replaced with new cobranded Cigna-EviCore guidelines CMM-609 Lumbar Fusion (Arthrodesis), CMM-611 Sacroiliac Joint Fusion or Stabilization, and CMM-614 Thoracic and Thoracolumbar Fusion (Arthrodesis) (effective 11/1/2024). |
| Percutaneous Revascularization of the Lower Extremities in Adults - (CP 0537) | Retired | Retiring 11/1/2024. Replaced by the EviCore cobranded Peripheral Vascular Intervention Guideline, effective 11/1/2024. |
| Venous Angioplasty and/or Stent Placement in Adults - (CP 0541) | Retired | Retiring 11/1/2024. Replaced by a cobranded vendor policy, effective 11/1/2024. |

| Whole Exome and Whole Genome Sequencing for Non- Cancer Indications – (CP 0519) | Retired | Retiring 11/1/2024. Replaced with new cobranded Cigna-EviCore Lab Management Program guidelines (effective 11/1/2024). |
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| ASH Guidelines | New, Updated, or Retired? | Comments |
| | | No updates in October 2024 |
| eviCore Guidelines | New, Updated, or Retired? | Comments |
| Cobranded Cigna- EviCore High-Tech Imaging Guidelines | Update | Posted 7/1/2024; Effective 10/15/2024 Important changes in coverage criteria. • Cardiac Imaging Guidelines • Guidelines underwent numerous revisions which both expand and limit coverage. |
| <u>Cobranded Cigna- EviCore Lab</u> <u>Management Program</u> <u>Guidelines</u> | Update | Posted 10/1/2024; Effective 1/1/2025 Important changes in coverage criteria. Expanded coverage for testing addressed in the following guidelines/sections: Expanded Carrier Screening Panels Somatic Mutation Testing BRCA Analysis Epilepsy Genetic Testing Human Platelet and Red Blood Cell Antigen Genotyping Special Circumstances Influencing Coverage Determinations New guidelines/sections: Laboratory Billing and Reimbursement |

| Administrative Policy | New, Updated, or Retired? | Inflammatory Bowel Disease Biomarker Testing Non-Invasive Prenatal Screening Retired sections/guidelines: Bloom Syndrome Genetic Testing Canavan Disease Genetic Testing Gaucher Disease Genetic Testing Niemann-Pick Disease Types A and B Genetic Testing Niemann-Pick Disease Type C Genetic Testing AlloMap Gene Expression Profiling for Heart Transplant Rejection AlloSure for Kidney Transplant Rejection Genetic Presymptomatic and Predictive Testing for Adult-Onset Conditions in Minors Laboratory Procedure Code Requirements Remaining guidelines/sections had no clinically impactful changes. |
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| <u>Preventive Care</u> <u>Services – (A004)</u> | Update | Important changes to the policy: Policy criteria section: Removed 0455, which was previously added in error Removed CPT 92652, 92653 from Hearing Screening guideline section. These codes were determined to not reflect hearing screening Coding table changes: 92652 and 92653 removed |
| Cigna Healthcare Drug Coverage Policy | New, Updated, or Retired? | Comments All policy changes effective October 1, 2024, unless otherwise stated |

| <u>Allergen</u> <u>Immunotherapy –</u> <u>Palforzia - (IP0141)</u> | Update | Effective: 10/15/2024 Peanut allergy: The age requirement was updated to approve if the patient is 1 to 17 years of age. Previously, this criterion approved if the patient is 4 to 17 years of age. |
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| <u>Amyloidosis –</u> <u>Amvuttra - (IP0478)</u> | Update | Effective: 10/1/2024 Polyneuropathy of Hereditary Transthyretin-Mediated Amyloidosis (hATTR). Removed 'Documentation that other causes of neuropathy have been excluded (for example, diabetes)' Updated 'Documented diagnosis of hereditary transthyretin-mediated (hATTR) amyloidosis confirmed by a transthyretin (<i>TTR</i>) genetic variant (pathogenic or likely pathogenic variant)' to 'Patient has a transthyretin pathogenic variant as confirmed by genetic testing' Updated 'Documentation of symptomatic polyneuropathy confirmed by history and clinical exam, electromyography, or nerve conduction velocity' to 'Patient has symptomatic polyneuropathy; <u>Note</u>: Examples of symptomatic polyneuropathy include reduced motor strength/coordination, and impaired sensation (e.g., pain, temperature, vibration, touch). Examples of assessments for symptomatic disease include history and clinical exam, electromyography, or nerve conduction velocity testing.' Added to dosing 'The dose is administered not more frequently than once every 3 months.' Conditions Not Covered. Removed (1) Treatment of Cardiomyopathy hATTR in the Absence of Polyneuropathy Symptoms, (2) Treatment of Polyneuropathy Not Related to hATTR Amyloidosis. Updated title from "Vutrisiran' to 'Amyloidosis – Amvuttra' |
| <u>Amyloidosis –</u> <u>Onpattro - (IP0418)</u> | Update | Effective: 10/1/2024 Polyneuropathy of Hereditary Transthyretin–Mediated Amyloidosis (hATTR). Removed 'Documentation that other causes of neuropathy have been excluded (for example, diabetes)' |

| | | Updated 'Documented diagnosis of hereditary transthyretin-mediated (hATTR) amyloidosis confirmed by a transthyretin (<i>TTR</i>) genetic variant (pathogenic or likely pathogenic variant)' to 'Patient has a transthyretin pathogenic variant as confirmed by genetic testing' Updated 'Documentation of symptomatic polyneuropathy confirmed by history and clinical exam, electromyography, or nerve conduction velocity' to 'Patient has symptomatic polyneuropathy; <u>Note</u>: Examples of symptomatic polyneuropathy include reduced motor strength/coordination, and impaired sensation (e.g., pain, temperature, vibration, touch). Examples of assessments for symptomatic disease include history and clinical exam, electromyography, or nerve conduction velocity testing.' Conditions Not Covered. Removed (1) Treatment of Cardiomyopathy hATTR in the Absence of Polyneuropathy Symptoms, (2) Treatment of Polyneuropathy Not Related to hATTR Amyloidosis. Updated title from 'Patisiran' to 'Amyloidosis – Onpattro' |
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| <u>Amyloidosis – Tegsedi</u> <u>- (IP0417)</u> | Update | Effective: 10/1/2024 Polyneuropathy of Hereditary Transthyretin-Mediated Amyloidosis (hATTR). Removed 'Documentation that other causes of neuropathy have been excluded (for example, diabetes)' Updated 'Documented diagnosis of hereditary transthyretin-mediated (hATTR) amyloidosis confirmed by a transthyretin (<i>TTR</i>) genetic variant (pathogenic or likely pathogenic variant)' to 'Patient has a transthyretin pathogenic variant as confirmed by genetic testing' Updated 'Documentation of symptomatic polyneuropathy confirmed by history and clinical exam, electromyography, or nerve conduction velocity' to 'Patient has symptomatic polyneuropathy; <u>Note</u>: Examples of symptomatic polyneuropathy include reduced motor strength/coordination, and impaired sensation (e.g., pain, temperature, vibration, touch). Examples of assessments for symptomatic disease include history and clinical exam, electromyography, or nerve conduction velocity testing.' Conditions Not Covered. Removed (1) Treatment of Cardiomyopathy hATTR in the Absence of Polyneuropathy Symptoms, (2) Treatment of Polyneuropathy Not Related to hATTR Amyloidosis. |

| | | Updated title from 'Inotersen' to 'Amyloidosis – Tegsedi' |
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| <u>Antihyperglycemic</u> <u>Therapy (Non-Insulin)</u> <u>- (IP0098)</u> | | Effective 10/15/2024 Removed Adlyxin, Byetta, Bydureon, Ozempic, Rybelsus, Trulicity, Victoza and Mounjaro. The products have been moved to CP IP0701 (Diabetes – Glucagon-Like Peptide-1 Agonists for Employer Plans: Standard/Performance, Value/Advantage, Legacy, Total Savings Prescription Drug Lists). |
| <u>Brands with</u> <u>Bioequivalent Generics</u> <u>– (IP0011)</u> | Update | Effective: 10/15/2024 Added to the policy for Employer Plans: Accupril, Accuretic, Altace, Anafranil, Ativan, Cardizem CD, Clobex 0.05% shampoo, Clobex 0.05% Spray, Cymbalta, Detrol, Detrol LA, Elixophyllin, EryPed 400, Halog 0.1% cream, Lexapro, Lotensin, Lotensin HCT, Lotrel, Pamelor, Parnate, Toviaz, Vanos 0.1% cream, Vaseretic, Vasotec, Vesicare, Zestoretic, Zestril |
| <u>Cardiology –</u> <u>Ivabradine - (IP0286)</u> | Update | Effective: 10/15/2024 Updated Policy title: title from "Ivabradine" to "Cardiology – Ivabradine". Added ivabradine generic tablets to the policy. Heart Failure: For the criterion that the patient has a left ventricular ejection fraction ≤ 35% prior to initiation of Corlanor therapy, "Corlanor" was changed to "ivabradine". Added "Note: Examples of beta blockers are metoprolol succinate sustained-release, carvedilol, bisoprolol, and Coreg CR (carvedilol extended-release capsules)." Added "Note: Examples that are contraindications to use of beta blockers are bronchospastic disease such as chronic obstructive pulmonary disease and asthma, severe hypotension or bradycardia." Added criterion, "Medication is prescribed by, or in consultation with, a cardiologist." |

| | | Removed criterion, "Individual has a left ventricular ejection fraction (LVEF) less than or equal to 45% prior to initiation of ivabradine (Corlanor) therapy" Removed criterion, "Individual is on stable treatment for heart failure" Removed criterion, Individual is in sinus rhythm with specific resting heart rate for different age groups (≥ 105 bpm for ages 6-12 months, ≥ 95 bpm for 1-3 years, ≥ 75 bpm for ages 3-5 years; and ≥ 70 bpm for ages 5-18 years)". Added criterion, "Medication be prescribed by, or in consultation with, a cardiologist". |
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| <u>Complement Inhibitors</u> <u>– PiaSky - (IP0594)</u> | New | Effective 10/15/2024 New coverage policy. |
| <u>Complement Inhibitors</u> <u>– Voydeya - (IP0647)</u> | New | Effective 10/15/2024 New coverage policy. |
| <u>Cystic Fibrosis –</u> <u>Orkambi - (IP0432)</u> | Update | Effective: 10/15/2024 Preferred Product Table. Updated "inadequate response" to "failure" Updated "Individual is less than 6 years of age" to "Individual is less than 2 years of age" |
| <u>Dermatology – Gene</u> <u>Therapy – Vyjuvek -</u> <u>(IP0572)</u> | Update | Effective 10/1/2024 Updated title from 'Beremagene' to 'Dermatology – Gene Therapy – Vyjuvek' Dystrophic Epidermolysis Bullosa. Updated 'Documented diagnosis of dystrophic epidermolysis bullosa confirmed by genetic testing showing pathogenic, or likely pathogenic, variant in the collagen type VII alpha 1 chain (<i>COL7A1</i>) gene' to 'The diagnosis is confirmed by genetic testing showing a pathogenic variant in the collagen type VII alpha 1 chain (<i>COL7A1</i>) gene' Removed 'Prescriber attestation that individual is receiving concomitant standard of care wound prevention and/or treatment' Added 'documentation required' for (1) The diagnosis is confirmed by genetic testing showing a pathogenic variant in the collagen type VII alpha 1 chain (COL7A1) gene, and (2) Patient has at least one clinical feature of dystrophic epidermolysis bullosa |

| | | Added 'The medication is prescribed by or in consultation with a dermatologist or wound care specialist' to the section 'Patient is Currently Receiving Vyjuvek on Previously Treated Wound(s)' |
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| Diabetes - Glucagon- Like Peptide-1 Agonists for Employer Plans: Standard/Performance, Value/Advantage, Legacy, Total Savings Prescription Drug Lists - (IP0701) | New | Effective 10/15/2024 New coverage policy. |
| Drugs Requiring <u>Medical Necessity</u> <u>Review for Employer</u> <u>Plans - (1602)</u> | Update | Effective: 10/15/2024 Updated Policy Name: title from "Drugs/Biologics Not Covered Unless Approved Under Medical Necessity Review: Employer Group Plans: Value, Advantage, or Cigna Total Savings Prescription Drug List" to "Drugs Requiring Medical Necessity Review for Employer Plans" Added preferred product step requirement for the following products: Aplenzin, bupropion hydrochloride 450 mg extended release tablets, Forfivo XL, Iopidine 1%, baclofen 15 mg tablets, doxycycline monohydrate IR 40 mg, ondansetron ODT, sitagliptin/metformin tablets,, Furoscix, Lidocan IV, Lidocan V, Tridacaine, and Sovuna. Updated preferred product step requirement for the following products: Cabtreo, Qbrelis, Firvanq, Likmez, Solosec, vancomycin 25 mg/mL oral solution, Primidone 125mg tablets, Sitavig, Auvelity, Karbinal RR, Versacloz, Edecrin, ethacrynic acid, Tekturna HCT, Alkindi Sprinkle, dexamethasone 1.5 mg tablets dose pack, Dxevo 11- Day, TaperDex 6-Day, 7-Day, and 12-Day, Cortifoam, Halog Ointment, Halog Solution, Kenalog Spray, Sernivo, triamcinolone acetonide 0.147 mg/gm topical aerosol, triamcinolone acetonide 0.05% ointment, Verdeso, Novolin 70/30, Novolin N, Novolin R, Novolog Mix 70/30, Rayos, Absorica LD, Kristalose, lactulose packets , Zyflo, Soaanz, GoNitro, Oxytrol, Vesicare LS, Gelnique 10% gel, Tudorza Pressair, desvenlafaxine ER, Lexette, and Ultravate. |

| | | Removed the following medications: Accupril, Altace, Lotensin, Prinivil, Vasotec, Zestril, Lotrel, Tarka, EryPed 400, DDAVP, Elixophyllin, Dutoprol, Aldactazide 25mg/25mg, Aldactazide 50mg/50mg, Accuretic, Lotensin HCT, Vaseretic, Zestoretic, Cardizem CD, Clobex 0.05% Lotion, Clobex 0.05% Shampoo, Clobex 0.05% Spray, Cutivate, Halog 0.1% cream, hydrocortisone butyrate 0.1% cream, Trianex, Impeklo, Vanos, Iopidine 0.05%, Detrol, Detrol LA, Toviaz, Vesicare, Ativan, Parnate, Anafranil, Pamelor, Ditropan XL, Seebri Neohaler, Cymbalta, Lexapro, halobetasol 0.05% foam, and Pexeva. |
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| <u>Erythropoiesis –</u> | Update | Effective: 10/15/2024 |
| <u>Stimulating Agents –</u> <u>Aranesp - (IP0293)</u> | | Updated policy name from "Darbepoetin Alfa" to "Erythropoiesis-Stimulating Agents – Aranesp" Anemia in an Individual with Chronic Kidney Disease who is not on Dialysis; Anemia in an Individual with Cancer due to Cancer Chemotherapy; Anemia Associated with Myelodysplastic Syndrome; Anemia Associated with Myelofibrosis. Added dosing. Added "Patient is Currently Receiving an Erythropoiesis-Stimulating Agent" Anemia in an Individual with Cancer due to Cancer Chemotherapy. Added "According to the prescriber, myelosuppressive chemotherapy is considered non-curative;" Conditions Not Covered. Removed "Use in Individuals Receiving Myelosuppressive Chemotherapy with a Curative Intent." |
| <u>Erythropoiesis –</u> | Update | Effective: 10/15/2024 |
| <u>Stimulating Agents –</u> <u>Epoetin Alfa Products -</u> <u>(IP0296)</u> | | Updated policy name from "Epoetin Alfa Products" to "Erythropoiesis-Stimulating Agents - Epoetin Alfa Products" Anemia in a Patient with Chronic Kidney Disease who is not on Dialysis. Added "Patient is Currently Receiving an Erythropoiesis-Stimulating Agent" criteria Anemia in an Individual with Cancer due to Cancer Chemotherapy. |

| | | Added "Patient is Currently Receiving an Erythropoiesis-Stimulating Agent" criteria Anemia in an Individual with Human Immunodeficiency Virus who is Receiving Zidovudine. Added "Patient is Currently Receiving an Erythropoiesis-Stimulating Agent" criteria Added "Patient is currently receiving zidovudine therapy"Anemia Associated with Myelodysplastic Syndrome. Added "Patient is Currently Receiving an Erythropoiesis-Stimulating Agent" criteria Anemia Associated with Myelofibrosis. Added "Patient is Currently Receiving an Erythropoiesis-Stimulating Agent" criteria Anemia associated with Myelofibrosis. Added "Patient is Currently Receiving an Erythropoiesis-Stimulating Agent" criteria Anemia associated with Hepatitis C Treatment. Added "Patient is Currently Receiving an Erythropoiesis-Stimulating Agent" criteriaPrefered Product Criteria Table. Updated "There is documentation the individual is intolerant to Procrit [may require prior authorization]" to "Patients meets BOTH of the following: (1) Patient has tried Procrit [may require prior authorization], (2) Patient cannot continue to use Procrit due to a formulation difference in the inactive ingredient(s) [e.g., differences in stabilizing agent, buffering agent, and/or surfactant] which, according to the prescriber, would result in a significant allergy or serious adverse reaction Conditions Not Covered. Removed "Anemia of Prematurity, Use in Individuals Receiving Myelosuppressive Chemotherapy with a Curative Intent" Removed "not medically necessary" language |
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| <u>Erythropoiesis-</u> <u>Stimulating Agents –</u> <u>Mircera - (IP0297)</u> | Update | Effective: 10/1/2024 Updated coverage policy title from <i>Methoxy polyethylene glycol-epoetin beta</i> to <i>Erythropoiesis-Stimulating Agents – Mircera</i> Patient Currently Receiving an Erytrhopoiesis-Stimulating Agent: Removed_age requirement; previously age requirement was >/= age 18 years Added new requirement that the hemoglobin level has been stabilized by treatment with erythropoiesis-stimulating agents for patients less than age 18 years Dosing: |

| | | Added a requirement that the patient be age 18 years or more for every 2 weeks dosing regimen |
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| <u>Gastroenterology –</u> <u>Gattex – (IP0288)</u> | Update | Effective: 10/1/2024 Updated coverage policy title from "Teduglutide" to "Gastroenterology – Gattex". Short Bowel Syndrome. |
| | | Initial Therapy: Added criteria to establish, "According to the prescriber, the patient is unable to receive adequate total parenteral nutrition (TPN) required for caloric needs". |
| | | Currently Receiving Gattex: Added criteria to establish, "Patient has already received at least 6 months of therapy with Gattex; Note: A patient who has received < 6 months of continuous therapy should be considered under criterion 1A (Initial Therapy)". |
| <u>Gaucher Disease –</u> Enzyme Replacement | Update | Effective: 10/15/2024 |
| <u>Therapy – Cerezyme –</u> (IP0162) | | Updated Policy Name from "Imiglucerase" to "Gaucher Disease - Enzyme Replacement Therapy - Cerezyme." Gaucher Disease - Type 1: Added qualifier "Type 1" to the condition name and Note to indicate Type 1 disease is also referred to as non-neuronopathic disease. Added age > 2 years as a condition of approval. |
| | | Removed statement " or type 3 Gaucher disease that results in at least one of the following: anemia, thrombocytopenia, bone disease, hepatomegaly, or splenomegaly." Added dosing information. Gaucher Disease – Type 3: |
| | | Added the new condition of approval under other uses with supportive evidence. |
| <u>Gaucher Disease –</u> Enzyme Replacement | Update | Effective: 10/15/2024 |

| <u>Therapy – Elelyso -</u> (<u>IP0163)</u> | | Updated Policy Name from "Taliglucerase" to "Gaucher Disease – Enzyme Replacement Therapy – Elelyso." Gaucher Disease – Type 1: Added qualifier "Type 1" to the condition name and Note to indicate Type 1 disease is also referred to as non-neuronopathic disease. Removed statement " or type 3 Gaucher disease that results in at least one of the following: anemia, thrombocytopenia, bone disease, hepatomegaly, or splenomegaly." Added age requirement of 4 years or older. Added dosing information. Gaucher Disease – Type 3: Added the new condition of approval under other uses with supportive evidence. |
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| <u>Gaucher Disease –</u> <u>Enzyme Replacement</u> <u>Therapy – Vpriv –</u> <u>(IP0164)</u> | Update | Effective: 10/15/2024 Updated Policy Name from "Velaglucerase" to "Gaucher Disease – Enzyme Replacement Therapy – Vpriv." Gaucher Disease – Type 1: Added qualifier "Type 1" to the condition name and Note to indicate Type 1 disease is also referred to as non-neuronopathic disease. Added age ≥ 4 years as a condition of approval. Removed statement " or type 3 Gaucher disease that results in at least one of the following: anemia, thrombocytopenia, bone disease, hepatomegaly, or splenomegaly." Added dosing information. Gaucher Disease – Type 3: Added the new condition of approval under other uses with supportive evidence. |
| <u>Hematology – Gene</u> <u>Therapy – Casgevy -</u> <u>(IP0615)</u> | Update | Effective: 10/10/2024 Transfusion-Dependent Beta-Thalassemia: The upper age threshold (< 51 years of age) was removed; the lower age threshold remains: Patient is ≥ 12 years of age. In the Note for the criterion regarding evidence of severe iron overload, the threshold |

| | | for high liver iron concentration, \geq 15.5 mg/g, was changed to \geq 15 mg/g to align with labeling. |
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| <u>Hematology – Gene</u> <u>Therapy – Zynteglo -</u> <u>(IP0486)</u> | Update | Effective date: 10/17/2024 Transfusion-Dependent Beta-Thalassemia: The upper age threshold (< 51 years of age) was removed; the lower age threshold remains: Patient is ≥ 4 years of age. In the Note for the criterion regarding evidence of severe iron overload, the threshold for high liver iron concentration, ≥ 15.5 mg/g, was changed to ≥ 15 mg/g to align with labeling. |
| <u>Hematology – Rytelo -</u> (IP0693) | New | Effective: 10/1/2024 New policy |
| <u>Hemophilia – Gene</u> <u>Therapy – Roctavian –</u> <u>(IP0580)</u> | Update | Effective: 10/10/2024 Updated policy title: from "Valoctocogene roxaparvovec-rvox" to "Hemophilia – Gene Therapy – Roctavian." Added "Policy Statement" to the policy. Added "Documentation: Documentation is required for use of Roctavian as noted in the criteria as [documentation required]. Documentation may include, but is not limited to chart notes, laboratory results, medical test results, claims records, prescription receipts, and/or other information." Hemophilia A: Added "verification in claims history required" for criteria which addresses that the patient meets ALL of the following:." Added "verification in claims history required" for criteria which addresses that the patient has not received Roctavian in the past and added "Note: If no claim for Roctavian is present (or if claims history is not available), the prescribing physician confirms that the patient has not previously received Roctavian." Updated criterion from "Documentation showing negative for human immunodeficiency virus" to "Patient is not human immunodeficiency virus positive [documentation required]." |

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| | The phrase "according to the prescribing physician" was added to the requirement that the patient has a history of use of Factor VIII therapy for at least 150 exposure days. |
| | The phrase "within 30 days before the intended receipt of Roctavian" was replaced with "within the past 30 days" regarding the requirement that Factor VIII inhibitor |
| | titer testing has been performed. |
| | The requirement was removed that the patient does not have an active acute or uncontrolled chronic infection. |
| | The phrase "liver health assessment" was replaced with "liver function testing." Also, the phrase "within 30 days before the intended receipt of Roctavian" was replaced |
| | with "within the past 30 days" regarding the liver function testing. |
| | The phrase, "within 30 days before the intended receipt of Roctavian" was replaced with "within the past 30 days" regarding the requirement that the platelet count was ≥ 100 x 10⁹/L. |
| | The phrase "within 30 days before the intended receipt of Roctavian" was replaced with "within the past 30 days" regarding the requirement that the creatinine level was < 1.4 mg/dL. |
| | • The requirement (along with the related Note) was removed that the patient has not used a systemic immunosuppressive agent within 30 days before intended receipt of Roctavian. |
| | The requirement was removed that the patient does not have any disease or condition that would interfere with the compliance requirements that involve use of systemic corticosteroid therapy or systemic alternative immunosuppressive medications. |
| | The requirement was removed that the patient does not have an immunosuppressive disorder. |
| | The requirement was removed that the patient does not have any additional bleeding disorder, besides hemophilia A. |
| | • The requirement was removed that the patient does not have a history of thrombosis or thrombophilia. |
| | The requirement (along with the related Note) was removed that the patient does not have a current active malignancy. |
| | The requirement was removed that the patient does not have a history of hepatic malignancy. |
| | The requirement was removed that the patient has not received a live vaccine within 30 days before intended receipt of Roctavian. |
| | • The requirement was removed that the hemophilia specialist physician has discussed with the patient that for a period of up to 6 months after administration of Roctavian that precautions should be taken that a male of reproductive potential (and his |

| | | female partner) prevent or postpone pregnancy by utilizing an effective form of contraception and that a male should not donate semen. The phrase "within 30 days before the intended receipt of Roctavian" was replaced with "within the past 30 days" regarding the requirement that current patient body weight has been obtained. Conditions Not Recommended for Approval: The condition of "Prior Receipt of Gene Therapy" was added. |
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| <u>Hemophilia – Hemlibra</u> <u>– (IP0121)</u> | Update | Effective: 10/1/2024 Updated coverage policy title from <i>Emicizumab-kxwh</i> to <i>Hemophilia – Hemlibra</i> |
| <u>Hyperhidrosis –</u> <u>Qbrexza - (IP0074)</u> | Update | Effective 10/1/52024 Removed the requirement for a patient to have tried, or experienced significant intolerance, to one prescription aluminum chloride-containing topical antiperspirant. Added a preferred product requirement, with a step through Drysol, for the Standard and Value Drug Plans. |
| Idiopathic Pulmonary Fibrosis and Related Lung Disease – Ofev - (IP0312) | Update | Effective: 10/15/2024 Updated policy name from "Nintedanib" to "Idiopathic Pulmonary Fibrosis and Related Lung Disease - Ofev." Idiopathic Pulmonary Fibrosis - Initial Therapy. Removed examples of findings on high-resolution computed tomography that indicate usual interstitial pneumonia. Removed requirement for both high-resolution computed tomography and biopsy pattern to indicate "probable" usual interstitial pneumonia. Removed criterion to exclude other potential causes of interstitial lung disease (for example, medication use, environmental exposures). Interstitial Lung Diseases, Chronic Fibrosing with a Progressive Phenotype - Initial Therapy. Added a note listing examples of conditions associated with this phenotype. Updated criterion from "documentation the individual has fibrosing lung disease on high-resolution computed tomography" to "According to the prescriber, the patient has fibrosing lung disease impacting more than 10% of lung volume on high-resolution computed tomography." |

| | | Updated criterion from "Individual has clinical signs of progression" to "According to the prescriber, the patient has clinical signs of progression." Patient is Currently Receiving Ofev. Added a note to all approved uses stating, "for a patient who has received less than 1 year of therapy, response is from baseline prior to initiating Ofev". |
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| <u>Idiopathic Pulmonary</u> <u>Fibrosis and Related</u> <u>Lung Disease –</u> <u>Pirfenidone - (IP0311)</u> | Update | Effective: 10/15/2024 Updated policy name from "Pirfenidone" to "Idiopathic Pulmonary Fibrosis and Related Lung Disease – Pirfenidone." Idiopathic Pulmonary Fibrosis – Initial Therapy. Removed the requirement for both high-resolution computed tomography and biopsy pattern to indicate "probable" usual interstitial pneumonia. Removed the criterion to exclude other potential causes of interstitial lung disease. Idiopathic Pulmonary Fibrosis – Patient is Currently Receiving Pirfenidone. Added a note stating that for patients who have received less than 1 year of therapy, the beneficial response is from baseline prior to initiating pirfenidone. |
| <u>Immune Globulin -</u> (5026) | Update | Effective: 10/1/2024 Chronic Inflammatory Demyelinating Polyneuropathy (CIDP): Updated initial authorization duration from "6 months" to "3 months" Updated reauthorization duration from "6 months" to "12 months" Preferred Product Table: Removed preferred product criteria for Cuvitru Added Cuvitru to Gammagard Liquid step requirement For Subcutaneous (SC) route Added Cuvitru to HyQvia step requirement |
| <u>Interferon –</u> <u>Actimmune - (IP0201)</u> | Update | Effective: 10/1/2024 Updated coverage policy title from <i>Interferon Gamma-1b for Non-Oncology Uses</i> to <i>Interferon – Actimmune</i> Removed <i>Reauthorization Criteria</i> |

| <u>Lipodystrophy – Egrifta</u> <u>- (IP0209)</u> | Update | Effective: 10/1/2024 Updated coverage policy title from "Tesamorelin" to "Lipodystrophy – Egrifta". Lipodystrophy Associated with Human Immunodeficiency Virus (HIV) Infection. Removed upper age limit of 65 years for use with Egrifta SV. Added an (*) next to specified gender where in this context, the specified gender is defined. Updated reauthorization approval duration from 6 months to 1 year. |
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| <u>Lipodystrophy –</u> <u>Myalept - (IP0340)</u> | Update | Effective: 10/1/2024 Updated policy title from "Metreleptin" to "Lidodystrophy – Myalept" No clinical content changes. |
| <u>Metabolic Disorders –</u> <u>Phenylbutyrate</u> <u>Products - (IP0169)</u> | Update | Effective: 10/1/2024 Urea Cycle Disorders: Added note listing examples of urea cycle disorders. Removed the requirement for initiating treatment in individuals with suspected urea cycle disorder based on abnormal biochemical testing. Updated approval criteria for 3 months to require a diagnosis of hyperammonemia, with ammonia levels exceeding the upper limit of the normal reference range for the reporting laboratory and added a note indicating that reference ranges vary depending on the patient's age. Removed Pheburane preferred product step requirement for Employer Plans. Updated preferred product step requirement for Buphenyl powder and tablets for Individual and Family Plans. Conditions Not Covered: Removed N-acetylglutamate synthase (NAGS) deficiency. |
| <u>Muscular Dystrophy –</u> Agamree - (IP0624) | Update | Effective: 10/15/2024 Duchenne Muscular Dystrophy: |

| | | Removed criteria asking for "muscle biopsy showing the absence of, or marked decrease in, dystrophin protein" for diagnosis confirmation of Duchenne muscular dystrophy. Added the requirement that the patient has tried prednisone or prednisolone for ≥ 6 months and according to the prescriber, experienced at least one significant intolerable adverse effect: Cushingoid appearance, central (truncal) obesity, undesirable weight gain (≥ 10% body weight increase over 6 months), or difficult-to-manage diabetes and/or hypertension. Updated the requirement that the patient has experienced significant adverse effects while on prednisone or prednisolone therapy to now state that "according to the prescriber, the patient has experienced significant a severe behavioral adverse effects event while on prednisone or prednisolone therapy that has or would require a prednisone or prednisolone dose reduction." Added "documentation required" for use of Agamree as noted in the criteria. |
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| <u>Muscular Dystrophy –</u> <u>Deflazacort - (IP0131)</u> | Update | Effective: 10/15/2024 Removed "generic for tablets only" from policy heading since the oral suspension is now available as a generic. Duchenne Muscular Dystrophy: Updated the diagnosis to require confirmation by genetic testing with a confirmed pathogenic variant in the dystrophin gene. Removed the criteria requiring a muscle biopsy showing the absence of, or marked decrease in, dystrophin protein for diagnosis confirmation. Added the requirement that the patient has tried prednisone or prednisolone for ≥ 6 months and according to the prescriber, experienced at least one significant intolerable adverse effect: Cushingoid appearance, central (truncal) obesity, undesirable weight gain (≥ 10% body weight increase over 6 months), or difficult-to-manage diabetes and/or hypertension. Updated the requirement that the patient has experienced significant adverse effects while on prednisone or prednisolone therapy to now state that "according to the prescriber, the patient has experienced significant a severe behavioral adverse effects event while on prednisone or prednisolone therapy that has or would require a prednisone or prednisolone dose reduction." |

| | Added "documentation required" for use of deflazacort as noted in the criteria. |
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| Neurology – Oxybate Products - (IP0103) | Effective: 10/15/2024 Updated policy name from 'Oxybate' to 'Neurology – Oxybate Products' Cataplexy Treatment in a Patient with Narcolepsy. Updated description from 'Narcolepsy Type 1 (Narcolepsy with Cataplexy)' to 'Cataplexy Treatment in a Patient with Narcolepsy' Updated 'ONE of the following: (i) Mean Sleep Latency Test (MSLT) performed according to standard techniques, showing a mean sleep latency of less than or equal to 8 minutes and two or more sleep-onset rapid eye movement periods (SOREMPs) following a nocturnal polysomnogram (PSG) that rules out other causes of excessive daytime sleepiness, (ii) A SOREMP (within 15 minutes of sleep onset) on a nocturnal PSG' TO 'Patient has been evaluated using polysomnography and a multiple sleep latency test' Removed 'Cataplexy' Removed 'The hypersomnolence and/or MSLT findings are not better explained by other causes such as insufficient sleep, delayed sleep phase disorder, or the effect of medication or substances or their withdrawal' Removed 'No concurrent use with other sedative hypnotic drugs or alcohol' Added 'Diagnosis of narcolepsy has been confirmed, according to the prescriber' Updated 'Documentation of failure, contraindication or intolerance to ONE of the following: (i) Treatment of Cataplexy and ONE of the following: (ii) Treatment of Excessive Daytime Sleepiness and ONE of the following: (ii) Treatment of Excessive Daytime Sleepiness and ONE of the following: (ii) Treatment of Excessive Daytime Sleepiness and ONE of the following: (ii) modafinil OR armodafinil, (2) dextroamphetamine, dexmethylphenidate OR methylphenidate' TO 'Patient meets ONE of the following (i or ii); (i) Patient has tried dextroamphetamine; OR (ii) Patient has a contraindication or intolerance to dextroamphetamine, indivaning, is a contraindication or intolerance to dextroamphetamine, according to the prescriber.Note: Contraindications to dextroamphetamine, include |

| | hyperthyroidism; known hypersensitivity to sympathomimetic amines; glaucoma; agitated states; and concomitant administration with monoamine oxidase inhibitors (MAOIs), or within 14 days of stopping MAOIs.' Removed pulmonologist as specialist option from 'prescribed by' criteria Excessive Daytime Sleepiness in a Patient with Narcolepsy. Updated description from 'Narcolepsy Type 2 (Narcolepsy without Cataplexy)' to 'Excessive Daytime Sleepiness in a Patient with Narcolepsy' Removed 'Daily periods of irrepressible need to sleep or lapses into sleep during waking hours, occurring for at least three months' Updated 'Mean Sleep Latency Test (MSLT) performed according to standard techniques, showing a mean sleep latency of less than or equal to 8 minutes and two or more sleep-onset rapid eye movement periods (SOREMPs) following a nocturnal polysomnogram (PSG) that rules out other causes of excessive daytime sleepiness. A SOREMP (within 15 minutes of sleep nest) on a nocturnal PSG may replace one of the SOREMPs on the MSLT' TO 'Patient has been evaluated using polysomnography and a multiple sleep latency test' Removed 'The hypersomnolence and/or MSLT findings are not better explained by other causes such as insufficient sleep, delayed sleep phase disorder, or the effect of medication or substances or their withdrawal' Removed 'No concurrent use with other sedative hypnotic drugs or alcohol' Updated 'Documentation of failure, contraindication or intolerance to ONE of the following treatments: a central nervous system (CNS) stimulant, modafinil, or armodafinil. Note: Examples of CNS stimulants include methylphenidate, dexmethylphenidate, and dextroamphetamine.' Removed 'Daily periods of irrepressible need to sleep or lapses into sleep during waking hours, occurring for at least three months' Updated 'Documentation of railere, contraindication or intolerance to ONE of the following: (i) modafinil OR armodafinil, (2) dextroamphetamine |
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| Removed 'Absence of cataplexy' Updated 'The hypersomnolence and/or MSLT findings are not better explained by other sleep disorders (for example, insufficient sleep syndrome [if deemed necessary, by lack of improvement of sleepiness after an adequate trial of increased nocturnal time in bed], delayed sleep phase disorder, other medical or psychiatric disorders, the effect of medication or substances or their withdrawal)' TO 'Results of the polysomnography and a multiple sleep latency test are congruent with a diagnosis of idiopathic hypersomnia, according to the prescriber' Removed 'No concurrent use with other sedative hypnotic drugs or alcohol' Updated 'Documentation of failure, contraindication or intolerance to ONE of the following: (i) armodafinil or modafinil, (2) methylphenidate.' Removed pulmonologist as specialist option from 'prescribed by' criteria |
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| Preferred Product Criteria Table. Lumryz. Updated Lumryz from 'There is documentation of failure, contraindication, or intolerance to Wakix (pitolisant) [may require prior authorization]' TO 'Patients ≥ 18 years of age: approve if the patient has tried and, according to the prescriber, has experienced inadequate efficacy OR a significant intolerance with Wakix [may require prior authorization]' Xyrem (Individual and Family Plan). Updated 'Failure, contraindication, or intolerance to Wakix (pitolisant) [may require prior authorization]' TO 'Patient has tried and, according to the prescriber, has experienced inadequate efficacy OR a significant intolerance with Wakix [may require prior authorization] Xywav. Updated 'Failure, contraindication, or intolerance to Wakix (pitolisant) [may require prior authorization] Xywav. Updated 'Failure, contraindication, or intolerance to Wakix (pitolisant) [may require prior authorization]' TO '1. patient has tried and, according to the prescriber, has experienced inadequate efficacy OR a significant intolerance with Wakix [may require prior authorization]' TO '1. patient has tried and, according to the prescriber, has experienced inadequate efficacy OR a significant intolerance with Wakix [may require prior authorization]' TO '1. patient has tried and, according to the prescriber, has experienced inadequate efficacy OR a significant intolerance with Wakix [may require prior authorization]' |
| Conditions Not Covered. |

| | | Updated 'Concomitant use of Lumryz, sodium oxybate oral solution, Xyrem and/or Xywav' TO 'Concomitant use of Lumryz, sodium oxybate oral solution, and/or Xywav with each other or an oxybate product used in combination with Wakix (pitolisant tablets) and/or Sunosi (solriamfetol tablets)' |
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| <u>Neurology – Qalsody -</u> (<u>IP0567)</u> | Update | Effective: 10/15/2024 Updated Policy Name from "Tofersen" to "Neurology – Qalsody." Amyotrophic Lateral Sclerosis (ALS) - Patient is Currently Receiving Qalsody. Updated the criteria "Individual continues to benefit from therapy" to more specifically say "According to the prescriber, the patient continues to benefit from therapy." Updated duration of therapy from 12 months to 6 months. |
| <u>Neurology – Vyvgart</u> <u>Hytrulo - (IP0574)</u> | Update | Effective: 10/15/2024 Updated policy name from "Efgartigimod Subcutaneous Injection" to "Neurology – Vyvgart Hytrulo" Generalized Myasthenia Gravis. Updated "Treatment cycles are no more frequent than every 50 days from the start of the previous treatment cycle" from Dosing section to criteria under Generalized Myasthenia Gravis. Added "Patient is Currently Receiving Vyvgart Hytrulo (or Vyvgart Intravenous [efgartigimod alfa-fcab intravenous infusion])" criteria Chronic Inflammatory Demyelinating Polyneuropathy (CIDP). Added this condition and criteria for approval. |
| <u>Oncology Medications -</u> (IP 1403) | Update | Effective: 10/15/2024 Anktiva Added Anktiva preferred product criteria requirement for Employer Plans and Individual and Family Plans Besremi Updated from "Employer Plans and" to "Employer Plans and Individual and Family Plans" Docivyx |

| Added Docivyx preferred product criteria requirement for Employer Plans and Individual and Family Plans |
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| Yonsa |
| Updated from "Yonsa (abiraterone) is considered medically necessary when BOTH of the following are met:1. When the Oncology Medications criteria above the table are met; 2. Documented trial of, contraindication, or intolerance to generic abiraterone" to "Yonsa (abiraterone) is considered medically necessary when BOTH of the following are met:1. When the Oncology Medications criteria above the table are met; 2. For Prostate Cancer – Metastatic, Castration-Resistant, documentation of ONE of the following: A. Documented trial of, contraindication, or intolerance to generic abiraterone, B. |
| Patient has been started on therapy with Yonsa |
| Sandostatin LAR Depot. |
| Removed criteria for Employer Plans and Individual and Family Plan and relocated to Somatostatin Analogs – Sandostatin LAR Depot (IP0489). |
| Effective 1/1/2025 : |
| Keytruda. |
| Added Keytruda preferred product criteria requirement for Cigna Pathwell Specialty Drug List Plans. |
| Lupron Depot. |
| Added Lupron Depot preferred product criteria for Employer Plans and Individual and Family Plans. |
| Onivyde. |
| Added Onivyde preferred product criteria for Employer Plans and Individual and Family Plans. |
| Opdivo. |
| Added Opdivo preferred product criteria requirement for Cigna Pathwell Specialty Drug List Plans. |
| Orgovyx. |
| Updated from "Trial of, contraindication, or intolerance to ONE of the following: Eligard [may require prior authorization], Firmagon [may require prior authorization], Lupron Depot [may require prior authorization], Trelstar [may require prior authorization]" to "Patient has tried ONE of the following: Eligard [may require prior authorization], Firmagon [may require prior |

| | | authorization], Trelstar [may require prior authorization" for Individual and Family Plan Vectibix. Added Vectibix preferred product criteria requirement for Cigna Pathwell Specialty Drug List Plans. Votrient Added Votrient preferred product criteria for Individual and Family Plans. |
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| <u>Pharmacy Prior</u> <u>Authorization – (1407)</u> | Update | Effective: 10/15/2024 Added Individual and Family Plan product-specific medical necessity criteria for: Carac, Klisyri, imiquimod 3.75%, Zyclara 3.75%, Zyclara 2.5%, ondansetron ODT 16mg, carbinoxamine maleate 4 mg/ 5 mL suspension, Karbinal ER suspension, Innopran XL, Inderal LA, Inderal XL, Kapspargo, Katerzia, Norliqva, hydrocortisone 2% lotion, sitagliptin-metformin, Estratest FS, Furoscix, Clinpro 5000, Fraiche 5000 Previ, Fraiche 5000 Sensitive, Just Right 5000, Prevident 1.1%, Prevident Kids 5000 PPM, Prevident 5000 Booster Plus, Prevident Dry Mouth, Prevident Orthodefens, Prevident 5000 Plus, Prevident Rinse 0.2%, Prevident 5000 Sensitive, Prevident 5000 Enamel. Updated Individual and Family Plan product-specific medical necessity criteria for: Rextovy, loteprednol etabonate 0.2% |
| <u>Psychiatry – Zulresso -</u> (IP0270) | Update | Effective: 10/1/2024 Updated coverage policy title from <i>Brexanolone</i> to <i>Psychiatry – Zulresso</i>. Postpartum Depression. Added criterion requirement screening patient is <u>not</u> currently pregnant. Added dosing to medical necessity criteria stem. |
| Quantity Limitations - (1201) | Update | Effective 10/15/2024 Add quantity limitations requirements for Rinvoq and Rinvoq LQ. |
| <u>Sickle Cell Disease –</u> Oxbryta - (IP0119) | Update | Effective 10/15/204 |

| | | Pfizer is voluntarily withdrawing Oxbryta from the market.Coverage of Oxbryta will not be approved. |
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| Somatostatin Analogs <u>– Octreotide</u> <u>Immediate-Release</u> <u>Products – (IP0490)</u> | Update | Effective: 10/15/2024 Updated Policy Name from "Somatostatin Analogs – Octreotide Immediate-Release Products (for Non-Oncology Uses)" to "Somatostatin Analogs – Octreotide Immediate-Release Products" Neuroendocrine Tumor(s) [NETs] of the Gastrointestinal Tract, Lung, Thymus (Carcinoid Tumors), and Pancreas (including glucagonomas, gastrinomas, vasoactive intestinal peptides-secreting tumors [VIPomas], insulinomas). Added criteria for NETs Meningioma. Added criteria for Meningioma Pheochromocytoma and Paraganglioma. Added criteria for Pheochromocytoma and Paraganglioma. Added criteria for Thymoma and Thymic Carcinoma Preferred Product Requirement Table. Sandostatin (octreotide acetate immediate release). Added criteria for Sandostatin[®] (octreotide acetate immediate-release), for Individual and Family Plans Enterocutaneous Fistulas: The condition enterocutaneous fistulas was added under "Other Uses with Supportive Evidence." Pancreatic Fistulas: The condition pancreatic fistulas was added under "Other Uses with Supportive Evidence." |
| <u>Somatostatin Analogs</u> <u>– Sandostatin LAR</u> <u>Depot - (IP0489)</u> | Update | Effective: 10/15/2024 Policy Name. Updated from "Somatostatin Analogs – Sandostatin LAR Depot (for Non-Oncology Uses) to "Somatostatin Analogs – Sandostatin LAR Depot" Neuroendocrine Tumor(s) [NETs] of the Gastrointestinal Tract, Lung, Thymus (Carcinoid Tumors), and Pancreas (including glucagonomas, gastrinomas, vasoactive intestinal peptides-secreting tumors [VIPomas], insulinomas). Added criteria and dosing for NETs |

| Tolvaptan Products – | Update | Meningioma. Added criteria and dosing for Meningioma Pheochromocytoma and Paraganglioma. Added criteria and dosing for Pheochromocytoma and Paraganglioma Thymoma and Thymic Carcinoma. Added criteria and dosing for Thymoma and Thymic Carcinoma Preferred Product Requirement Table. Sandostatin LAR Depot. [This preferred product criteria is being removed from CP1403 Oncology Medications and added to IP0489 Somatostatin Analogs - Sandostatin LAR Depot] Updated from "Documented failure, contraindication, or intolerance to Somatuline Depot (lanreotide acetate) injection" to "ONE of the following: 1. <u>Acromegaly</u>: Documentation the patient has tried Somatuline Depot.; <u>2.Patient with neuroendocrine tumors</u>: The patient meets the following (A or B):<u>Note</u>: This includes (but is not limited to) carcinoid tumors, vasoactive intestinal peptide tumors (VIPomas), glucagonomas, gastrinomas, insulinomas. A.Documentation the patient has tried one of Somatuline Depot subcutaneous injection; OR B.Patient has already been started on therapy with Sandostatin LAR; 3.Patient with <u>pheochromocytoma/ paraganglioma</u>: The patient meets the following (A or B): Note: The condition enterocutaneous fistula; meningioma; pancreatic fistula; thymoma/thymic carcinoma." Enterocutaneous Fistulas: The condition enterocutaneous fistulas was added under "Other Uses with Supportive Evidence." Pancreatic Fistulas: The condition pancreatic fistulas was added under "Other Uses with Supportive Evidence." Effective: 10/15/2024 |
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| <u>Jynarque - (IP0287)</u> | | Updated policy title from "Tolvaptan (Jynarque)" to "Tolvaptan Products – Jynarque." Autosomal Dominant Polycystic Kidney Disease: Added note listing examples of rapidly declining renal function, such as eGFR decline of ≥ 3.0 mL/min/1.73 m², and Mayo Classification of 1D or 1E. |

| | | Added note defining Stage 5 chronic kidney disease as having an eGFR < 15 mL/min/1.73 m² or receiving dialysis. |
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| <u>Tolvaptan Products -</u> <u>Tolvaptan (Samsca)</u> <u>for Individual and</u> <u>Family Plans -</u> <u>(IP0471)</u> | Update | Effective: 10/15/2024 Updated policy title from "Tolvaptan (Samsca) for Individual and Family Plans" to "Tolvaptan Products - Tolvaptan (Samsca) for Individual and Family Plans." Hyponatremia: Updated the statement "individual has initiated a course of tolvaptan and requires further medication to complete the current course of therapy up to 30 days' to say "patient has already been started on tolvaptan and has received < 30 days of therapy" Added a note saying that for a patient who has been started on tolvaptan and has received < 30 days of therapy, approve for a sufficient duration to complete 30 total days of therapy. |
| <u>Wakefulness-</u> <u>Promoting Agents –</u> <u>Armodafinil, Modafinil -</u> <u>(IP0075)</u> | Update | Effective: 10/15/2024 Excessive Daytime Sleepiness Associated with Narcolepsy. Updated 'Treatment of Excessive Daytime Sleepiness Associated with Narcolepsy (Type 1 or 2)' TO 'Excessive Daytime Sleepiness Associated with Narcolepsy.' Removed 'Daily periods of irrepressible need to sleep or lapses into sleep during waking hours, occurring for at least three months' Updated 'Documentation of ONE of the following: (i) Diagnosis of narcolepsy type 1 and ONE of the following: (a) Mean Sleep Latency Test (MSLT) performed according to standard techniques, showing a mean sleep latency of less than or equal to 8 minutes and two or more sleep-onset rapid eye movement periods (SOREMPs) following a nocturnal polysomnogram (PSG) that rules out other causes of excessive daytime sleepiness, (b) A SOREMP (within 15 minutes of sleep onset) on a nocturnal PSG; (ii) Diagnosis of narcolepsy type 2 and Mean Sleep Latency Test (MSLT) performed according to standard techniques, showing a mean sleep latency of less than or equal to 8 showing a mean sleep latency of less than or equal to 8 leep onset) on a nocturnal PSG; (ii) Diagnosis of narcolepsy type 2 and Mean Sleep Latency Test (MSLT) performed according to standard techniques, showing a mean sleep latency of less than or equal to 8 minutes and two or more sleep-onset rapid eye movement periods (SOREMPs) following a nocturnal polysomnogram (PSG) that rules out other more sleep-onset rapid eye movement periods (SOREMPs) following a nocturnal polysomnogram (PSG) that rules out other |

| | causes of excessive daytime sleepiness. A SOREMP (within 15 minutes of sleep onset) on a nocturnal PSG may replace one of the SOREMPs on the MSLT' TO 'Patient has been evaluated using polysomnography and a multiple sleep latency test' Removed 'The hypersomnolence and/or MSLT findings are not better explained by other causes such as insufficient sleep, delayed sleep phase disorder, or the effect of medication or substances or their withdrawal' Removed pulmonologist from 'Medication is prescribed by, or in consultation with' bullet Added 'Diagnosis of narcolepsy has been confirmed, according to the prescriber' Excessive Daytime Sleepiness Associated with Obstructive Sleep Apnea/Hypoapnea Syndrome. Removed 'Dally periods of irrepressible need to sleep or lapses into sleep during waking hours, occurring for at least three months' Removed 'Documentation of diagnosis of Obstructive Sleep Apnea (OSA)/Hypoapnea Syndrome (OSAHS) is confirmed by sleep study' Removed 'Dhe hypersomnolence and/or sleep study findings are not better explained by other causes such as insufficient sleep, delayed sleep phase disorder, or the effect of medication or substances or their withdrawal' Removed pulmonologist from 'Medication is prescribed by, or in consultation with' bullet Removed 'Documentation of inadequate response to at least 1 month of non-pharmacologic treatment for OSA (for example, continuous positive airway pressure [CPAP])' Removed 'Patient meets one of the following (i or ii): (i)Armodafinil/modafinil will be used in combination with continuous positive airway pressure therapy;" Excessive Sleepiness Associated with Shift Work Sleep Disorder. Removed 'Documentation of insomnia and/or excessive sleepiness, accompanied by a reduction of total sleep time, which is associated with a |
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| | recurring work schedule that overlaps the usual time for sleep' Removed 'Documentation of sleep log, completed on work and free days, demonstrating a disturbed sleep and wake pattern' Removed 'Documentation that the sleep and/or wake disturbance cannot be better explained by another cause (for example, concurrent sleep disorder, medical or neurological disorder, mental disorder, medication use, poor sleep hygiene, substance use disorder)' Removed pulmonologist from 'Medication is prescribed by, or in consultation with' bullet Adjunctive/Augmentation Treatment for Depression in Adults. Removed 'Medication is prescribed by, or in consultation with, a neurologist or psychiatrist" Excessive Daytime Sleepiness Associated with Myotonic Dystrophy. Removed 'Daily periods of irrepressible need to sleep or daytime lapses into sleep occurring for at least three months' Removed 'Medication is prescribed by, or in consultation with, a neurologist, pulmonologist, or sleep specialist' Excessive Daytime Sleepiness Associated with Parkinson's Disease. Removed pulmonologist from 'Medication is prescribed by, or in consultation with' bullet Fatigue Associated with Multiple Sclerosis. Removed pulmonologist from 'Medication is prescribed by, or in consultation with' bullet Idiopathic Hypersonnia. Removed pulmonologist from 'Medication is prescribed by, or in consultation with' bullet Idiopathic Hypersonnia. Removed 'Documentation of 'Medication is prescribed by, or in consultation with' bullet Removed 'Documentation of Multiple Sleep Latency Test (MSLT) performed according to standard techniques demonstrating an average sleep latency of less than or equal to 8 minutes with a total of less than 2 sleep onset rapid eye movement periods (SOREMPs)' Removed 'Documented absence of cataplexy' |
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| | | Removed 'The hypersomnolence and/or MSLT findings are not better explained by other causes such as insufficient sleep, delayed sleep phase disorder, or the effect of medication or substances or their withdrawal' |
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| Wakefulness- Promoting Agents – Sunosi - (IP0102) | Update | Effective: 10/15/2024 Updated policy name from 'Solriamfetol' to 'Wakefulness-Promoting Agents – Sunosi' Excessive Daytime Sleepiness Associated with Narcolepsy. Updated 'Treatment of Excessive Daytime Sleepiness Associated with Narcolepsy (Type 1 or 2)' TO 'Excessive Daytime Sleepiness Associated with Narcolepsy.' Added 'Diagnosis of narcolepsy has been confirmed, according to the prescriber' Removed 'Daily periods of irrepressible need to sleep or lapses into sleep during waking hours, occurring for at least three months' Updated 'Documentation of ONE of the following: (i) Diagnosis of narcolepsy type 1 and ONE of the following: (a) Mean Sleep Latency Test (MSLT) performed according to standard techniques, showing a mean sleep latency of less than or equal to 8 minutes and two or more sleep-onset rapid eye movement periods (SOREMPs) following a nocturnal polysomnogram (PSG) that rules out other causes of excessive daytime sleepiness, (b) A SOREMP (within 15 minutes of sleep onset) on a nocturnal PSG, (2) Diagnosis of narcolepsy type 2 and Mean Sleep Latency Test (MSLT) performed according to standard techniques, showing a mean sleep latency of less than or equal to 8 minutes and two or more sleep-onset rapid eye movement periods (SOREMPs) following a nocturnal PSG, (2) Diagnosis of narcolepsy type 2 and Mean Sleep Latency Test (MSLT) performed according to standard techniques, showing a mean sleep latency of less than or equal to 8 minutes and two or more sleep-onset rapid eye movement periods (SOREMPs) following a nocturnal polysomnogram (PSG) that rules out other causes of excessive daytime sleepiness. A SOREMP (within 15 minutes of sleep onset) on a nocturnal PSG may replace one of the SOREMPs on the MSLT' 'TO 'Patient has been evaluated using polysomnography and a multiple sleep latency test' Removed 'The hypersomnolence and/or MSLT findings are not better explained by other causes such as insufficient sleep, delayed sleep phase disor |

| | | dexmethylphenidate OR methylphenidate' TO 'Patient has tried generic modafinil or generic armodafinil. Note: An exception to this requirement is allowed if the patient has previously tried brand Provigil or brand Nuvigil.' Removed pulmonologist from 'Medication is prescribed by, or in consultation with' bullet Excessive Daytime Sleepiness Associated with Obstructive Sleep Apnea. Removed 'Daily periods of irrepressible need to sleep or lapses into sleep during waking hours, occurring for at least three months' Removed 'Documentation of diagnosis of Obstructive Sleep Apnea (OSA) is confirmed by sleep study' Removed 'Documentation or substances or their withdrawal' Removed 'The hypersomnolence and/or sleep study findings are not better explained by other causes such as insufficient sleep, delayed sleep phase disorder, or the effect of medication or substances or their withdrawal' Removed 'Sunosi will be used in combination with non-pharmacologic treatment for obstructive sleep apnea (OSA), unless contraindicated or intolerant' Updated 'Documentation of inadequate response to at least 1 month of non-pharmacologic treatment for OSA (for example, continuous positive airway pressure [CPAP])' TO 'Patient meets one of the following (i or ii): (i) Sunosi will be used in conjunction with continuous positive airway pressure (CPAP) therapy; OR (ii) Patient is unable to initiate or tolerate CPAP therapy' Updated 'Documentation of failure, contraindication, or intolerance to ONE of the following: (i) armodafinil, (ii) modafinil' TO 'Patient has tried generic modafinil or generic armodafinil, Note: An exception to this requirement is allowed if the patient has previously tried brand Provigil or brand Nuvigil.' |
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| <u>Wakefulness-</u> <u>Promoting Agents –</u> <u>Wakix - (IP0292)</u> | Update | Effective: 10/15/2024 Cataplexy Treatment in a Patient with Narcolepsy. Updated diagnosis from 'Narcolepsy Type 1 (Narcolepsy with Cataplexy)' to 'Cataplexy Treatment in a Patient with Narcolepsy' Removed 'Daily periods of irrepressible need to sleep or lapses into sleep during waking hours, occurring for at least three months' Removed 'Cataplexy' |

| | | Updated 'Documentation of a Mean Sleep Latency Test (MSLT) performed according to standard techniques, showing a mean sleep latency of less than or equal to 8 minutes and two or more sleep-onset rapid eye movement periods (SOREMPs) following a nocturnal polysomnogram (PSG) that rules out other causes of excessive daytime sleepiness. A SOREMP (within 15 minutes of sleep onset) on a nocturnal PSG may replace one of the SOREMPs on the MSLT.' TO 'Patient has been evaluated using polysomnography and a multiple sleep latency test' Removed 'Daily periods of irrepressible need to sleep or lapses into sleep during waking hours, occurring for at least three months' Added 'Diagnosis of narcolepsy has been confirmed, according to the prescriber' Removed pulmonologist from specialist bullet Updated 'Documentation of ONE of the following: (i) Failure, contraindication, or intolerance to dextroamphetamine, dexmethylphenidate OR methylphenidate, (3) History of substance abuse and, according to the prescriber, a wakefulness-promoting agent that is not a controlled substance is necessary Conditions Not Covered. Added 'Concomitant Use of Wakix with an Oxybate Product and/or Sunosi (solriamfetol tablets)' |
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| Selumetinib (Non- Oncology Uses) - (IP0038) | Retired | Retired effective 10/15/2024 Koselgo used for the treatment of Neurofibromatosis Type 1 will follow Oncology Medications CP1403 |
| Bupropion Extended- Release Products - (IP0058) | Retired | Effective 10/15/2024 Products moved into CP #1602 for Employer Plans and CP #1407 for Individual and Family Plans |

| Isotretinoin Low Dose - (IP0193) | Retired | Effective 10/15/2024 Products moved into CP #1602 for Employer Plans and CP #1407 for Individual and Family Plans |
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| Drugs/Biologics Not Covered Unless Approved Under Medical Necessity Review: Employer Group Plans: Standard, Performance, or Legacy Prescription Drug List – (1601) | Retired | Effective 10/15/2024 Products moved into CP #1602 and IP0011 for Employer Plans |
| Selumetinib (Non- Oncology Uses) - (IP0038) | Retired | Retired effective 10/15/2024 Koselgo used for the treatment of Neurofibromatosis Type 1 will follow Oncology Medications CP1403 |
| CareAllies Medical Necessity Guideline | New, Updated, or Retired? | Comments |
| | | All above updates apply |
| Precertification Policy* | New, Updated, or Retired? | Comments |
| | | No updates for October 2024 |
| Reimbursement Policy* | New, Updated, | Comments |

| | or Retired? | |
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| Unlisted Codes - (R08) | Update | Updated full policy language to align with industry standard and to support internal stakeholders. Policy received a full annual review. |
| Diagnosis Coding Guidelines - (R47) | Update | Removed notification banner, effective 08/14/2024 , Cigna will deny claims when one or more not covered "Z" diagnosis codes are the only diagnosis on the claim. |
| Retail Pharmacy Reimbursement Policy - (R48) | New | Effective 09/01/2024 Cigna has developed a new policy for retail pharmacy. |
| Other Coding and Reimbursement Documents | New, Updated, or Retired? | Comments |
| | | No updates for October 2024 |
| ClaimsXten Documents* | New, Updated, or Retired? | Comments |
| Code Editing Policy and Guidelines | Update | On November 10, 2024, ClaimsXten will be updated to Fourth Quarter Knowledge Base content and NCCI Version 30.3 for all medical and behavioral claims we process. |

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