

Coverage Policy Unit (CPU) - Monthly Policy Updates

Effective December 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 Care Professionals</u> > Resources > Reimbursement and Payment Policies.

Medical Coverage Policy	New, Updated, or Retired?	Comments
<u>Cardiac Omnibus Codes -</u> (<u>CP0574</u>)	Updated	 Important changes in coverage criteria: Added CPT codes to carotid sinus baroreflex activation device policy statement and cardiac contractility modulation therapy policy statement
		(Effective 12/15/2024). • Removing policy statement for coronary intravascular lithotripsy (Effective 12/30/2024).
Cardioverter-Defibrillator Devices – (CP0431)	Updated	Posted 9/15/2024, now effective 12/15/2024 Important changes in coverage criteria: • Clarified coverage by moving pediatric wearable cardioverter-defibrillator
		(WCD) criteria out of the AED section of the policy and into the WCD section of the policy.

Category III Current Procedural Terminology (CPT®) codes- (CP0558)	Updated	 Minor changes in coverage criteria/policy: Replaced the verbiage "these codes" with "Category III codes" to clarify intent of language.
Colorectal Cancer Screening and Surveillance - (CP0148) Note Title change: Chromoendoscopy - (CP0148)	Updated	Important changes in coverage criteria: • Title change: Chromoendoscopy Colorectal Cancer Screening and Surveillance • Scope of CP tightened to address surveillance chromoendoscopy • Scope of CP broadened to address Barrett's esophagus surveillance
Corneal Remodeling for Refractive Errors - (CP0141)	Updated	 Removed policy statements for corneal collagen crosslinking and corneal wedge resection. Revised noncoverage statement for INTACS from experimental, investigational or unproven to not medically necessary. Added not covered refractive procedures: corneal allogenic intrastromal ring segments (CAIRS); corneal tissue addition keratoplasty (CTAK).
Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal Conditions and Soft Tissue Wounds - (CP0004)	Updated	 Policy title updated to reflect content changes: "Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal Conditions and Soft Tissue Wounds" Removed policy statement verbiage regarding ESWT for soft tissue wounds (including EPAT and PACE therapies. Extracorporeal shock wave therapy (ESWT), including extracorporeal pulse activation therapy (EPAT®) and Pulsed Acoustic Cellular Expression (PACE™) therapy, is considered experimental, investigational or unproven for ANY indication, including but not limited to the treatment of musculoskeletal conditions and soft tissue wounds. Revised overview statement to reflect updated scope of policy: "This Coverage Policy addresses extracorporeal shock wave therapy (ESWT) for a variety of applications including musculoskeletal conditions and wound healing.

Heart, Lung and Heart-Lung Transplantation - (CP0129)	Updated	Minor changes in coverage criteria/policy: • Removed 'from a deceased donor' from lung transplant policy statement.
High Intensity Focused Ultrasound (HIFU) - (CP0274)	Updated	Removed the policy statement for MRgFUS unilateral thalamotomy for the treatment of essential tremor because the associated CPT code is not managed.
<u>Laboratory Testing Services - (CP0604)</u>	New	New CP, effective 3/15/2025; advance posted Dec 15, 2024 • Medical necessity criteria for laboratory testing services
Serum Folate and Red Blood Cell Folate Testing - (CP0567)	Updated	 Minor changes in coverage criteria/policy: Adding coverage for acute myeloblastic leukemia (AML) (ICD10 code C92 range) for CPT code 82746 Adding coverage for cytopenia, myelodysplastic syndrome (MDS) (ICD10 code D46 range) for CPT code 82747
Skin Cancer Surveillance Technologies – (CP0240)	Updated	 Important changes in coverage criteria: Title change from Skin Cancer Surveillance Technologies to Reflectance Confocal Microscopy Removed all unmanaged codes and related content: removed all content except for reflectance confocal microscopy (CPT 96932)
Stem Cell Therapy for Orthopaedic Applications – (CP0552)	Updated	 Important changes in coverage criteria: Changed EIU language to NMN because stem cell therapy does not fit Cigna's definition of EIU. Removed "all indications" from the statement because stem cell therapy is not NMN for all indications.
Surgical Treatments for Obstructive Sleep Apnea – (CP0158)	Updated	 Added coverage statements to address drug-induced sleep endoscopy (DISE) for a child and for an adolescent Removed trachesotomy and tonsillectomy/adenoidectomy for the policy because the associated CPT codes are not managed Added verbiage to uvulectomy coverage statement to clarify signs/symptoms not intended to be addressed

		 Revised coverage criteria for implantable upper airway hypoglossal nerve stimulation device in individauls age 18 or older, based on current FDA approval Added coverage statement for am implantable upper airway hypoglossal nerve stimulation device in individaulage 13-18 with Down syndrome.
Tilt Table Testing and Computerized Dynamic Posturography – (CP0270)	Updated	 Important changes in coverage criteria: Title changed from "Tilt Table Testing and Computerized Dynamic Posturography" to "Tilt Table Testing". Removed policy statement for computerized dynamic posturography, as aligned codes are no longer managed by this policy.
<u>Tissue-Engineered Skin</u> <u>Substitutes - (CP0068)</u>	Updated	 Minor changes in coverage criteria/policy: added code Q4204, representing the product XWRAP, PER SQUARE CENTIMETER. This product and code was previously in the policy as EIU and will be put back in the policy as such. It is being added to precert, will need 90-day notice. Effective date will be 3/15/2025.
Plantar Fasciitis Treatments - (CP0097)	Updated	No change in coverage.
Temporomandibular Joint (TMJ) Disorder Surgery - (CP0156)	Updated	No change in coverage.
Transcatheter Heart Valve Procedures - (CP0501)	Updated	No change in coverage.
Transvaginal Ultrasound, Non- Obstetrical - (CP0398)	Updated	No change in coverage.
Intestinal and Multivisceral Transplantation - (CP0288)	Updated	No change in coverage.
Pediatric Intensive Feeding Programs – (CP0422)	Updated	No change in coverage.
Gastric Pacing/Gastric Electrical Stimulation (GES) – (CP0103)	Updated	No change in coverage.
Deep Brain, Motor Cortex and Responsive Cortical Stimulation – (CP0184)	Updated	No change in coverage.

Transplantation Donor Charges - (CP0132)	Retired	There is no longer a business need
ASH Guidelines	New, Updated, or Retired?	Comments
Physical Therapy – (CPG 135)	Updated	No change in coverage.
Occupational Therapy – (CPG 155)	Updated	Important changes in coverage criteria: • Added a policy statement for feeding therapy for food aversions and a policy statement for when a home feeding program can be utilized to the Not Medically Necessary statement. • state to perform occupational therapy services).
Chiropractic Care – (CPG 278)	Updated	Important changes in coverage criteria: • Added the 'Atlas Orthogonal Technique' to the EIU list.
eviCore Guidelines	New, Updated, or Retired?	Comments
Cobranded Cigna-EviCore Spine Surgery Guidelines	New	Posted 11/8/2024; Effective 2/6/2025 New spine surgery guideline: • CMM-308: Intradiscal Procedures
Cobranded Cigna-EviCore High- Tech Imaging Guidelines	Updated	Posted 12/1/2024; Effective 3/1/2025 Important changes in coverage criteria. Two guidelines were updated with clinical changes that both expand and limit coverage: • Cardiac Imaging • Peripheral Vascular Disease Imaging Two guidelines were updated with no change in coverage: • Pediatric Cardiac Imaging

		Pediatric Peripheral Vascular Disease Imaging
		Posting 1/10/2025; Effective 2/14/2025 Important changes in coverage criteria. Two guidelines were updated with clinical changes that expand coverage: • Musculoskeletal Imaging • Spine Imaging One guideline was updated with no change in coverage: • Chest Imaging
Administrative Policy	New, Updated, or Retired?	Comments
		No updates for December 2024
Cigna Healthcare Drug Coverage Policy	New, Updated, or Retired?	Comments
Aflibercept - (IP0540)	Updated	Updated review date, disclaimer, refreshed background, and references, and added change history. Eylea, Eylea HD: For the exclusion criterion "Patient has diabetic macular edema and a baseline visual acuity worse than 20/40", the threshold was rephrased as "20/50 or worse (< 69 Early Treatment Diabetic Retinopathy Study [ETDRS] letters)" to align with the language used in the study. In addition, baseline visual acuity was clarified as "ETDRS best-corrected visual acuity (BCVA)." Updated Coding:

		Removed J3590 Added J0177 (effective 4/1/2024)
Betaine for Individual and Family Plans - (IP0465)	Updated	Homocystinuria Updated criterion from "Documented diagnosis of ONE of the following (i, ii, or iii) is confirmed by enzymatic, biochemical, or genetic analysis" to "Documented diagnosis based on genetic testing demonstrating ONE of the following (i, ii, or iii)." Added criterion "Patient has tried or is concurrently receiving vitamin B6 (pyridoxine), vitamin B12 (cobalamin), or folate supplementation." Updated criterion from "The medication is prescribed by or in consultation with a clinical geneticist or metabolic disease specialist" to "The medication is prescribed by or in consultation with a clinical geneticist, metabolic disease specialist, or a physician who specializes in the management of homocystinuria."
Brexucabtagene autoleucel - (IP0199)	Updated	Acute Lymphoblastic Leukemia. Updated from "Received lymphodepleting chemotherapy prior to Tecartus infusion to "Received or plans to receive lymphodepleting chemotherapy prior to Tecartus infusion" Updated from "Medication is prescribed by, or in consultation with, an oncologist or hematologist" to "Tecartus is prescribed by, or in consultation with, an oncologist." Mantle Cell Lymphoma. Removed "Documentation that individual previously received BOTH of the following: A. Chemoimmunotherapy, B. A bruton tyrosine kinase inhibitor" Added "has relapsed or refractory disease" Updated from "Received lymphodepleting chemotherapy prior to Tecartus infusion to "Received or plans to receive lymphodepleting chemotherapy prior to Tecartus infusion" Updated from "Medication is prescribed by, or in consultation with, an oncologist or hematologist" to "Tecartus is prescribed by, or in consultation, with an oncologist."
Burosumab - (IP0285)	Updated	Updated review date, disclaimer, refreshed background and references, addition of change history.

Cardiology – Zontivity for Individual and Family Plans –	New	Conditions Not Recommended for Approval: Epidermal Nevus Syndrome was clarified to include Cutaneous Skeletal Hypophosphatemia Syndrome. Effective: 12/15/2024 New policy
(IP0707) Chenodiol - (IP0203)	Updated	Effective: 12/15/2024
<u> </u>		Updated review date, disclaimer, refreshed background and references, addition of change history.
Clotting Factors and Antithrombin – (8007)	Updated	Removed from the policy: Adynovate, Eloctate, Esperoct, Jivi, Advate, Afstyla, Kogenate, Kovaltry, Novoeight, Nuwiq, Recombinate, Xyntha, Hemofil M, Alphanate, Humate-P, Koate, and Wilate. All were relocated to new policy, Hemophilia - Factor VIII Products (IP0618). Mononine was discontinued by the manufacturer and also removed from the policy. Coding Information: Removed HCPCS codes: J7178, J7182, J7183, J7185, J7186, J7187, J7189, J7190, J7192, J7198, J7199, J7204, J7205, J7207, J7208, J7209, J7210, J7211
Complement Inhibitors – Empaveli – (IP0194)	Updated	Paroxysmal Nocturnal Hemoglobinuria: For patients who are currently receiving Empaveli, Added to the Note regarding examples of benefit of Empaveli to also now include "improvement in Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue score". Conditions Not Covered: Added Voydeya to the criterion addressing concomitant use of Empaveli with Fabhalta (iptacopan capsule) or Ultomiris (ravulizmab-cwvz intravenous infusion).
<u>Complement Inhibitors – Fabhalta</u> <u>- (IP0614)</u>	Updated	Effective 12/15/2024

		Paroxysmal Nocturnal Hemoglobinuria: Patient is currently receiving Fabhalta: Added "Improvement in Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue score" to the Note of examples of benefit.
		Primary Immunoglobulin A Nephropathy: Updated the criterion requiring that the patient is at high risk of disease progression, defined by ONE of the following: urine-to-protein-creatinine ratio ≥ 1.5 g/g OR proteinuria ≥ 1 g/day was revised to now require that the patient is at high risk of disease progression, defined by urine-to-protein-creatinine ratio ≥ 1.5 g/g OR proteinuria ≥ 0.5 g/day.
COVID-19 Emerging Drug and	Updated	Effective 11/14/2024
Biologic Therapeutics – (2016)		Added Pemgarda (pemivibart) coverage criteria consistent with Emergency Use Authorization issued on 8/26/2024 for use as pre-exposure prophylaxis of COVID-19 in certain adults and adolescents
		Coding Information Added: M0224 (effective 3/22/2024), Q0224 (effective 3/22/2024)
<u>Diabetes – Glucagon-Like Peptide-</u>	New	Effective 12/1/2024
1 Agonists for Individual and Family Plans - (IP0702)		New policy
<u>Diabetes – Symlin for IFP -</u>	New	Effective: 12/1/2024
(<u>IP0698)</u>		New coverage policy.
<u>Difelikefalin - (IP0436)</u>	Updated	Effective: 12/15/2024
		Chronic Kidney Disease Associated Pruritus: Updated from "Chronic Kidney Disease Associated Pruritus" to "Chronic Kidney Disease Associated Pruritus in Hemodialysis." Updated criterion from "Documented inadequate response, contraindication or intolerance to ONE of the following:" to "Documented failure, contraindication or intolerance to ONE of the following therapies for chronic kidney disease-associated pruritus:" and added Topical Emollient to the list." Updated criterion from "The medication is prescribed by or in consultation with a dermatologist or nephrologist" to "The medication is prescribed by or in consultation with a nephrologist."
		Reauthorization Criteria:

		Updated criterion from "Difelikefalin (Korsuva) is considered medically necessary for continued use when initial criteria are met AND there is documentation of beneficial response" to "Continuation of Difelikefalin (Korsuva) is considered medically necessary for Chronic Kidney Disease Associated with Pruritus when the above medical necessity criteria are met AND there is documentation of beneficial response."
Drug and Medical Necessity (Injectables) – medical benefit - (IP2027)	Updated	Updated adult from 'Analgesia, postsurgical (as a single dose only)' to "Regional analgesia via an interscalene brachial plexus nerve block in adults; Regional analgesia via a sciatic nerve block in the popliteal fossa in adults; Regional analgesia via an adductor canal block in adults. Updated adult dosing from "Infiltration: 266 mg (20 mL) as a single-dose infiltration according to the prescribing information.; Interscalene brachial plexus nerve block: 133 mg (10 mL) according to the prescribing information" to "Regional anesthesia: Single dosage; 133 mg"
Eculizumab - (IP0549)	Updated	Conditions Not Covered: Updated from "Concomitant Use with a Rituximab Product, a Neonatal Fc Receptor Blocker, Enspryng (satralizumab-mwge subcutaneous injection), Fabhalta (iptacopan capsule), Ultomiris (ravulizumab-cwvz intravenous infusion or subcutaneous injection), Uplizna (inebilizumab-cdon intravenous infusion), or Zilbrysq (zilucoplan subcutaneous injection). There is no evidence to support concomitant use of Soliris with a rituximab product, a neonatal Fc receptor blocker, Enspryng, Fabhalta, Ultomiris, Uplizna, or Zilbrysq. Examples of Neonatal Fc receptor blockers are: Vyvgart (efgartigimod alfa-fcab IV infusion), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc SC injection), and Rystiggo (rozanolixizumab-noli SC infusion)." to "Concomitant Use with Empaveli > 4 Weeks. Concomitant use of Soliris with Empaveli is not recommended. However, to reduce the risk of hemolysis from abrupt treatment discontinuation in a patient switching from Soliris to Empaveli, patient should use both therapies for 4 weeks; after which, Soliris is discontinued and patient is continued on Empaveli monotherapy; Concomitant Use with Another Complement Inhibitor Except Voydeya (danicopan tablets). There is no evidence to support concomitant use of Soliris with another complement inhibitor, except Voydeya. Note: Examples of complement inhibitors are Fabhalta (iptacopan capsules), PiaSky (crovalimab-akkz intravenous

		infusion or subcutaneous injection), and Ultomiris (ravulizumab-cwzy intravenous infusion); Concomitant Use with a Rituximab Product, a Neonatal Fc Receptor Blocker, or Zilbrysq (zilucoplan subcutaneous injection). There is no evidence to support concomitant use of Soliris with a rituximab product, a neonatal Fc receptor blocker, or Zilbrysq. Note: Examples of Neonatal Fc receptor blockers are Rystiggo (rozanolixizumab-noli subcutaneous infusion), Vyvgart (efgartigimod alfa-fcab intravenous infusion), and Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc subcutaneous injection); Concomitant Use with Enspryng (satralizumab-mwge subcutaneous injection) or Uplizna (inebilizumab-cdon intravenous infusion). There is no evidence to support concomitant use of Soliris with Enspryng or Uplizna"
Eliglustat - (IP0441)	Updated	Gaucher Disease Type 1: Removed criterion "Individual is age 18 years or older" Updated criterion from "deficiency of glucosylceramidase [also known as acid β-glucosidase or glucocerebrosidase] in peripheral blood leukocytes or other nucleated cells" to "demonstration of deficient beta-glucocerebrosidase activity in leukocytes or fibroblasts." Updated criterion from "Confirmation of biallelic pathogenic variants in the GBA gene" to "Confirmation of molecular genetic test documenting biallelic pathogenic glucocerebrosidase (GBA) gene variants." Updated criterion from "Individual is ONE of the following: CYP2D6 extensive metabolizer (EM), CYP2D6 intermediate metabolizer (IM) or CYP2D6 poor metabolizer (PM)" to "Individual is ONE of the following as detected by an approved test: CYP2D6 extensive metabolizer (EM), CYP2D6 intermediate metabolizer (IM) or CYP2D6 poor metabolizer (IM) or CYP2D6 poor metabolizer (PM)" Reauthorization Criteria: Updated criterion from "Eliglustat (Cerdelga) is considered medically necessary for continued use when initial criteria are met AND there is documentation of beneficial response" to "Continuation of Eliglustat (Cerdelga) is considered medically necessary for Gaucher Disease Type 1 when the above medical necessity criteria are met AND there is documentation of beneficial response." Conditions Not Covered: Concomitant use with other approved therapies for Gaucher disease was added.
Faricimab - (IP0542)	Updated	Effective: 12/1/2024

		Dosing: Updated dosing from "6 mg administered by intravitreal injection not more frequent than once every 4 weeks for each eye being treated" to "The requested dose of faricimab (Vabysmo) meets the following: 1. 6 mg administered by intravitreal injection for each eye being treated; 2. The dosing interval is not more frequent than once every 4 weeks for each eye being treated" for all indications.
		Preferred Product Table: Added criteria "Documentation of ONE of the following: 1. Currently receiving Vabysmo; 2. ONE of the following: a. Documentation of failure, contraindication, or intolerance to repackaged bevacizumab; b. If, in the professional opinion of the prescriber, the safety of using the repackaged bevacizumab or the supplier of the repackaged bevacizumab is of significant concern" for all indications for both employer plans and individual and family plans. Added new exclusion criterion: According to the prescriber, patient has diabetic macular edema and a baseline ETDRS BCVA of 20/50 or worse (< 69 ETDRS letters).
Finerenone - (IP0314)	Updated	Effective: 12/1/2024
		Diabetic Kidney Disease. Added "Meets ONE of the following (a or b): a. Patient is currently receiving a maximally tolerated labeled dosage of an angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB); b. According to the prescriber, patient has a contraindication to ACE inhibitor and ARB therapy" Added "At baseline (prior to the initiation of Kerendia), individual meets ALL of the following (a, b, and c): a. Estimated glomerular filtration rate ≥ 25 mL/min/1.73 m²; b. Urine albumin-to-creatinine ratio ≥ 30 mg/g; c. Serum potassium level ≤ 5.0 mEq/L" Added preferred product requirement criteria for Individual and Family Plans
Gaucher Disease – Substrate Reduction Therapy – Miglustat - (IP0446)	Updated	Gaucher Disease Type 1: Updated criterion from "The diagnosis is established by ONE of the following: Demonstration of deficient beta-glucocerebrosidase activity in leukocytes or fibroblasts OR Molecular genetic test documenting biallelic pathogenic

		glucocerebrosidase (GBA) gene variants" to "There is documentation of ONE of the following (i or ii): Demonstration of deficient beta-glucocerebrosidase activity in leukocytes or fibroblasts OR Molecular genetic testing documenting glucocerebrosidase gene mutation." Added preferred product requirement criteria table for Individual and Family Plans. Conditions Not Covered: Concomitant use with other approved therapies for Gaucher disease was added.
<u>Hematology – Fibrinogen Products</u> <u>- (IP0357)</u>	Updated	Effective: 12/15/2024 Updated review date, disclaimer, refreshed background and references.
		Congenital Fibrinogen Deficiency (Factor I Deficiency), Including Afibrinogenemia and Hypofibrinogenemia: For both Fibryga and RiaSTAP, criteria were removed regarding the diagnosis be confirmed by laboratory testing. This includes the requirement that the patient has a prolonged activated partial thromboplastin time and prothrombin time at baseline (as defined by the laboratory reference values) AND the patient has lower than normal plasma functional and antigenic fibrinogen levels at baseline (as defined by the laboratory reference values). Acquired Fibrinogen Deficiency: This was added as a new approval indication for Fibryga only. Dosing was also added.
Immunologicals - Dupixent - (IP0453)	Updated	Effective: 12/15/2024 Chronic Rhinosinusitis with Nasal Polyps: Updated the age of approval from ≥ 18 years of age to ≥ 12 years of age. Asthma: Updated to clarify Eosinophil level requirements to require a level ≥ 150 cells/microliter either within the previous 6 weeks OR prior to treatment with a monoclonal antibody that may alter eosinophil levels. Previously, criteria required a level ≥ 150 cells/microliter either within the previous 6 weeks OR within 6 weeks prior to treatment with a monoclonal antibody that may lower eosinophil levels. Added Ebglyss (lebrikizumab-lbkz subcutaneous injection) and Nemluvio (nemolizumab-ilto subcutaneous injection) throughout the policy to notes as examples of monoclonal antibody therapies.

		Chronic Obstructive Pulmonary Disease: Added this condition and criteria for approval were to the policy. New approval criteria for this indication were added that include an age requirement, an eosinophil requirement, a trial of inhaled therapies, a history of chronic bronchitis signs or symptoms, a history of COPD exacerbations, and specialist involvement.
Immunologicals – Fasenra - (IP0421)	Updated	Asthma: Eosinophil level requirements were clarified to require a level ≥ 150 cells/microliter either within the previous 6 weeks OR prior to treatment with a monoclonal antibody that may alter eosinophil levels. Previously, criteria required a level ≥ 150 cells/microliter either within the previous 6 weeks OR within 6 weeks prior to treatment with a monoclonal antibody that may lower eosinophil levels. Eosinophilic Granulomatosis with Polyangiitis: New approval criteria for this indication were added. Initial approval criteria include an age requirement, a requirement that the patient's disease be active and non-severe, a trial of a systemic corticosteroid, an eosinophil level requirement, and specialist involvement.
		Throughout the policy, Ebglyss (lebrikizumab-lbkz subcutaneous injection) and Nemluvio (nemolizumab-ilto subcutaneous injection) were added to notes as examples of monoclonal antibody therapies.
Immunologicals – Nucala - (IP0422)	Updated	Asthma: Eosinophil level requirements were clarified to require a level ≥ 150 cells/microliter either within the previous 6 weeks OR prior to treatment with a monoclonal antibody that may alter eosinophil levels. Previously, criteria required a level ≥ 150 cells/microliter either within the previous 6 weeks OR within 6 weeks prior to treatment with a monoclonal antibody that may lower eosinophil levels. Eosinophilic granulomatosis with polyangiitis: Updated from "A.iii. Patient has tried therapy with a corticosteroid (e.g., prednisone) for a minimum of 4 weeks" to "A.iii.a) Patient is currently receiving has tried therapy with a systemic corticosteroid (e.g., prednisone) for a minimum of 4 weeks"

		Initial approval duration was changed from 6 months to 9 months. Eosinophil level requirements were clarified to require a level ≥ 150 cells/microliter either within the previous 4 weeks OR prior to treatment with a monoclonal antibody that may alter eosinophil levels. Previously, criteria required a level ≥ 150 cells/microliter either within the previous 6 weeks OR within 6 weeks prior to treatment with a monoclonal antibody that may lower eosinophil levels. Hypereosinophilic Syndrome: Eosinophil level requirements were clarified that the level be taken prior to treatment with any monoclonal antibody therapy that may alter blood eosinophil levels. Previously, criteria required the level to be taken prior to any monoclonal antibody therapy that may lower blood eosinophil levels. Throughout the policy, Ebglyss (lebrikizumab-lbkz subcutaneous injection) and Nemluvio (nemolizumab-ilto subcutaneous injection) were added to notes as examples of monoclonal antibody therapies.
<u>Lasmiditan - (IP0114)</u>	Updated	No criteria changes. Updated review date, disclaimer, refreshed background, and references added change history.
Multiple Sclerosis and Crohn's Disease - Tysabri Prior Authorization Policy - (IP0690)	New	Effective 12/1/2024 This policy replaces CP IP0215 (Natalizumab) New policy
Multiple Sclerosis and Ulcerative Colitis – Zeposia Preferred Specialty Management Policy for Employer Plans: Standard/ Performance, Value/Advantage, Legacy, Total Savings Prescription Drug Lists - (PSM004)	New	Effective 12/1/2024
Multiple Sclerosis and Ulcerative Colitis – Zeposia Preferred Specialty Management Policy for Individual and Family Plans - (PSM008)	New	Effective 12/1/2024 New policy

Multiple Sclerosis and Ulcerative Colitis – Zeposia Prior Authorization Policy - (IP0655)	New	Effective 12/1/2024 This policy replaces CP IP0214 (Ozanimod) New policy
Multiple Sclerosis – Avonex - (IP0254)	Updated	Added a definition for documentation. Added a specialist prescribing requirement. Added criteria for patient Currently Receiving Avonex for ≥ 1 Year. Removed Employer Plans preferred product requirements. Ocrevus Zunovo was added to the Appendix.
Multiple Sclerosis – Bafiertam – (IP0255)	Updated	Added a definition for documentation. Added a specialist prescribing requirement. Added criteria for patient Currently Receiving Bafiertam for ≥ 1 Year. Removed Employer Plans preferred product requirements. Ocrevus Zunovo was added to the Appendix.
Multiple Sclerosis – Betaseron - (IP0256)	Updated	Removed Extavia from the policy. Added a specialist prescribing requirement. Added criteria for patient Currently Receiving Betaseron or Extavia for ≥ 1 Year. Removed Employer Plans preferred product requirements for Betaseron. Updated Individual and Family Plans preferred product requirements for Betaseron. Ocrevus Zunovo was added to the Appendix.
Multiple Sclerosis – Briumvi – (IP0545)	Updated	Added a definition for documentation. Added a specialist prescribing requirement. Added criteria for patient Currently Receiving Briumvi for ≥ 1 Year. Removed Employer Plans preferred product requirements. Ocrevus Zunovo was added to the Appendix.

Multiple Sclerosis – Dimethyl fumarate - (IP0266)	Updated	Added a definition for documentation. Added a specialist prescribing requirement. Added criteria for patient Currently Receiving Dimethyl Fumarate for ≥ 1 Year. Updated the preferred product multi-source brand language to current standards. Ocrevus Zunovo was added to the Appendix.
Multiple Sclerosis – Glatiramer Products - (IP0257)	Updated	Added a definition for documentation. Added a specialist prescribing requirement. Added criteria for patient Currently Receiving Glatiramer for ≥ 1 Year. Updated the preferred product multi-source brand language to current standards. Ocrevus Zunovo was added to the Appendix.
Multiple Sclerosis – Fingolimod - (IP0259)	Updated	Added a definition for documentation. Added a requirement for a patient to be ≥ 10 years of age. Added a specialist prescribing requirement. Added criteria for patient Currently Receiving Fingolimod for ≥ 1 Year. Updated the preferred product multi-source brand language to current standards. Ocrevus Zunovo was added to the Appendix.
Multiple Sclerosis – Kesimpta - (IP0260)	Updated	Added a definition for documentation. Removed Employer Plans preferred product requirements. Added a specialist prescribing requirement. Added criteria for a Patient Currently Receiving Kesimpta for ≥ 1 Year. Ocrevus Zunovo was added to the Appendix.
Multiple Sclerosis – Lemtrada - (IP0213)	Updated	Added a definition of documentation. Updated Multiple Sclerosis prerequisite therapy requirement from "failure, contraindication, or intolerance to BOTH of dimethyl fumarate OR fingolimod and ONE other disease modifying agent used for Multiple Sclerosis" to "According to

		the prescriber, the patient has experienced inadequate efficacy or significant intolerance to two disease-modifying agents used for multiple sclerosis". Updated the criteria that requires the patient to try one alternative it was added that the patient has experienced inadequate efficacy or significant intolerance (according to the prescriber) to this agent. Also, Ocrevus Zunovo was added to the list of disease-modifying multiple sclerosis drugs that count toward meeting this requirement. The individual listing of Tysabri and Tyruko among these alternatives was changed to state "a natalizumab intravenous product (Tysabri, biosimilar)". Lemtrada was separated from this listing of agents into an individual criterion in which receipt of Lemtrada in the past counts (without requiring inadequate efficacy or significant intolerance [according to the prescriber]). Updated the specialist prescribing requirement from a "neurologist" to "neurologist or a physician that specializes in the treatment of multiple sclerosis". Added criteria for a Patient Currently Receiving Lemtrada for ≥ 1 Year.
Multiple Sclerosis – Mavenclad - (IP0261)	Updated	Added a definition for documentation. Multiple Sclerosis: For initial therapy, for the criteria that requires the patient to try one alternative (and has experienced inadequate efficacy or significant intolerance [according to the prescriber]), Ocrevus Zunovo was added to the list of disease-modifying multiple sclerosis drugs that count toward meeting this requirement. Ocrevus Zunovo added to the appendix.
Multiple Sclerosis – Mayzent - (IP0262)	Updated	Added a definition for documentation. Added a specialist prescribing requirement. Added criteria for patient Currently Receiving Mayzent for ≥ 1 Year. Removed Employer Plans preferred product requirements. Ocrevus Zunovo was added to the Appendix.
Multiple Sclerosis – Ocrevus - (IP0212)	Updated	Added a definition of documentation. Removed Employer Plans preferred product requirements. Added a specialist prescribing requirement. Added criteria for a Patient Currently Receiving Ocrevus for ≥ 1 Year. Ocrevus Zunovo added to the Appendix.

<u>Multiple Sclerosis – Ocrevus</u> <u>Zunovo - (IP0705)</u>	New	Effective 12/15/2024 New coverage policy.
Multiple Sclerosis – Plegridy - (IP0263)	Updated	Effective 12/1/2024 Added a definition for documentation. Added a specialist prescribing requirement. Added criteria for patient Currently Receiving Plegridy for ≥ 1 Year. Removed Employer Plans preferred product requirements. Updated Individual and Family Plans preferred product requirements. Ocrevus Zunovo was added to the Appendix.
Multiple Sclerosis – Ponvory - (IP0264)	Updated	Effective 12/1/2024 Added a definition for documentation. Added a specialist prescribing requirement. Added criteria for patient Currently Receiving Ponvory for ≥ 1 Year. Removed Employer Plans preferred product requirements. Ocrevus Zunovo was added to the Appendix.
Multiple Sclerosis – Rebif - (IP0265)	Updated	Added a definition for documentation. Added a specialist prescribing requirement. Added criteria for patient Currently Receiving Rebif for ≥ 1 Year. Removed Employer Plans preferred product requirements. Updated Individual and Family Plans preferred product requirements. ○ Ocrevus Zunovo was added to the Appendix.
Multiple Sclerosis – Tascenso ODT – (IP0514)	Updated	Added a definition for documentation. Added a specialist prescribing requirement. Added criteria for patient Currently Receiving Tascenso ODT for ≥ 1 Year. Added preferred product criteria for Individual and Family Plans. Ocrevus Zunovo was added to the Appendix.
Multiple Sclerosis – Teriflunomide for Employer Plans: Standard/ Performance, Value/Advantage,	Updated	Added a definition for documentation. Added a specialist prescribing requirement.

Legacy, Total Savings Prescription Drug Lists - (IP0252)		Added criteria for patient Currently Receiving Teriflunomide for ≥ 1 Year. Updated the preferred product multi-source brand language to current standards. Ocrevus Zunovo was added to the Appendix.
Multiple Sclerosis - Teriflunomide for Individual and Family Plans - (IP0560)	Updated	Added a definition for documentation. Added a specialist prescribing requirement. Added criteria for patient Currently Receiving Teriflunomide for ≥ 1 Year. Updated the preferred product multi-source brand language to current standards. Ocrevus Zunovo was added to the Appendix.
Multiple Sclerosis – Vumerity - (IP0253)	Updated	Added a definition for documentation. Added a specialist prescribing requirement. Added criteria for patient Currently Receiving Vumerity for ≥ 1 Year. Removed Employer Plans preferred product requirements. Ocrevus Zunovo was added to the Appendix.
Nephrology – Filspari - (IP0565)	Updated	Primary Immunoglobulin A Nephropathy: The criterion requiring that the patient is at high risk of disease progression, defined by ONE of the following: urine-to-protein-creatinine ratio ≥ 1.5 g/g OR proteinuria ≥ 1 g/day was revised to require that the patient is at high risk of disease progression, defined by urine-to-protein-creatinine ratio ≥ 0.8 g/g OR proteinuria ≥ 0.5 g/day. The approval duration was changed to 1 year for initial and continuation therapy (previously the approval duration was 9 months for initial and 1 year for continuation therapy).
Nephrology – Tarpeyo - (IP0413)	Updated	Primary Immunoglobulin A Nephropathy: The criterion requiring that the patient is at high risk of disease progression, defined by ONE of the following: urine-to-protein-creatinine ratio ≥ 0.8 g/g OR proteinuria ≥ 0.75 g/day was revised to require that the patient is at high risk of disease progression, defined by urine-to-protein-creatinine ratio ≥ 0.8 g/g OR proteinuria ≥ 0.5 g/day.

Nephrology - Vafseo - (IP0706)	New	Effective 12/1/2024
		New policy.
Oncology Medications - (CP1403)	Updated	Effective: 12/5/2024
Oncology Fiedredcions (CF 1103)	Opaatea	
		Ibrance. Added "Patient will be using Ibrance in combination with Itovebi"
		Scemblix. Added "Patient has newly diagnosed disease" option under generic imatinib criteria
Oteseconazole - (IP0513)	Updated	Effective: 12/15/2024
		Recurrent Vulvovaginal Candidiasis. Added "Is ≥ 18 years of age" Added "Has had at least three episodes of vulvovaginal candidiasis in a 12-month period; Note: A patient who has had two or more previous episodes of vulvovaginal candidiasis in the previous 12 months (prior to the current infection) would meet this requirement." Added "Not pregnant"
Palivizumab - (IP0321)	Updated	Effective: 12/15/2024
		Updated review date, disclaimer, refreshed background and references, addition of change history.
Pegvisomant - (IP0291)	Updated	Effective: 12/15/2024
		Acromegaly. Updated from "Documentation of ONE of the following: A. Pre-treatment insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender for the reporting laboratory. B. Growth Hormone (GH) suppression testing demonstrating a lack of growth hormone suppression" to "Documentation the individual has (or had) a pre-treatment (baseline) insulin-like growth factor-1 (IGF-1) level above the upper limit of normal based on age and gender for the reporting laboratory"
Pharmacy Prior Authorization -	Updated	Effective: 12/1/2024
(1407)		Added Individual and Family Plan product-specific medical necessity criteria, EFFECTIVE on 1/1/2025 for: sulconazole nitrate 1% cream, sulconazole

		nitrate 1% solution, Ergomar, alogliptin tablet, Nesina, Onglyza, alogliptin and metformin tablet, alogliptin and pioglitazone tablet, Kazano, Kombiglyze XR, Oseni, sitagliptin and metformin oral tablet, Zituvimet, Zituvimet XR, Glyxambi, Qtern, Steglujan, Trijardy XR, insulin glargine, insulin glargine Solostar 100 units/ mL, insulin glargine-YFGN 100 units/ mL, insulin glargine Max Solostar U300 300 units/ mL, Lantus, Lantus SoloStar, Levemir, Rezvoglar Kwikpen, Semglee (non-YFGN), Semglee-YFGN, Toujeo Solostar, Toujeo Max SoloStar, Femring, Imvexxy, Premarin, Serevent Diskus, naproxen sodium controlled-release/ extended-release 375 mg, Creon, Pertzye, Zenpep, ArmonAir Digihaler, Flovent Diskus, Flovent HFA, fluticasone propionate HFA, fluticasone inhalation powder, Pulmicort Flexhaler, Advair Diskus, Advair HFA, AirDuo Digihaler, AirDuo Respiclick, fluticasone furoate and vilanterol inhalation powder, fluticasone propionate and salmeterol HFA oral inhalation, Symbicort, Breztri Aerosphere, Osphena
Pharmacy Prior Authorization - (1407)	Updated	Effective: 12/15/2024 Add: Added Individual and Family Plan product-specific medical necessity criteria: Fanapt, Clindesse, Glimepiride 3 mg, fluticasone propionate/ salmeterol, Ohtuvayre, Zoryve 0.15% cream, Zoryve 0.3% cream, Zoryve foam
Ravulizumab-swvz Intravenous - (IP0550)	Updated	Conditions Not Covered: Updated from "Concomitant Use with Another Complement Inhibitor, a Rituximab Product, or a Neonatal Fc Receptor Blocker, Enspryng (satralizumab- mwge subcutaneous injection), or Uplizna (inebilizumab-cdon intravenous infusion). There is no evidence to support concomitant use of Ultomiris intravenous with another complement inhibitor, a rituximab product, or a neonatal Fc receptor blocker, Enspryng, or Uplizna.Examples of complement inhibitors are Empaveli (pegcetacoplan subcutaneous injection), Fabhalta (iptacopan capsule), Soliris (eculizumab intravenous infusion), and Zilbrysq (zilucoplan subcutaneous injection). Examples of neonatal Fc receptor blockers are Vyvgart (efgartigimod alfa-fcab intravenous infusion), Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc subcutaneous injection), and Rystiggo (rozanolixizumab-noli subcutaneous infusion)." to "Concomitant Use with Another Complement Inhibitor, Except Voydeya (danicopan tablets). There is no evidence to support concomitant use of Ultomiris with another complement inhibitor, except Voydeya. Note: Examples of complement inhibitors are Empaveli (pegcetacoplan subcutaneous injection),

		Fabhalta (iptacopan capsule), PiaSky (crovalimab-akkz intravenous infusion or subcutaneous injection), and Soliris (eculizumab intravenous infusion); Concomitant Use with a Rituximab Product, a Neonatal Fc Receptor Blocker, or Zilbrysq (zilucoplan subcutaneous injection). There is no evidence to support concomitant use of Ultomiris with a rituximab product, a neonatal Fc receptor blocker, or Zilbrysq. Note: Examples of neonatal Fc receptor blockers are Rystiggo (rozanolixizumab-noli subcutaneous infusion), Vyvgart (efgartigimod alfa-fcab intravenous infusion), and Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc subcutaneous injection); Concomitant Use with Enspryng (satralizumab-mwge subcutaneous injection) or Uplizna (inebilizumab-cdon intravenous infusion). There is no evidence to support concomitant use of Ultomiris with Enspryng or Uplizna."
Sapropterin - (IP0295)	Updated	Effective: 12/15/2024
		Phenylketonuria: Removed criterion "No concomitant use with Palynziq once stabilized on Kuvan."
		Reauthorization Criteria: Added criterion "Patient has had a clinical response (e.g., cognitive and/or behavioral improvements) as determined by the prescriber." Updated criterion from "Treatment with sapropterin has resulted in an increase in dietary phenylalanine tolerance or an improvement in neuropsychiatric symptoms (e.g., cognitive and/or behavioral improvements)" to "Treatment with sapropterin has resulted in an increase in dietary phenylalanine tolerance, according to the prescriber." Updated criterion from "NOT receiving concomitant therapy with Palynziq (pegvaliase-pqpz)" to "Patient is not receiving concomitant Palynziq (pegvaliase-pqpz subcutaneous injection) at a stable maintenance dose."
		Preferred Product Table: Added preferred product step requirement for Kuvan Tablets and Powder for Oral Solution and Javygtor Tablets and Powder for Oral Solution for Individual and Family Plans.
Topical Diclofenac Sodium 3% Gel	Updated	Effective: 12/15/2024
<u>- (IP0282)</u>		Actinic Keratoses. Updated from Documentation of failure, contraindication, or intolerance to ONE of the following: 5-fluorouracil cream, 5-fluorouracil solution (2% or 5%),

		imiquimod 5% cream to "Documentation of failure, contraindication, or intolerance to BOTH of the following: 5-fluorouracil cream or solution (2% or 5%), imiquimod 5% cream" Actinic Cheilitis. Updated from Documentation of failure, contraindication, or intolerance to ONE of the following: 5-fluorouracil cream, 5-fluorouracil solution (2% or 5%), imiquimod 5% cream to "Documentation of failure, contraindication, or intolerance to BOTH of the following: 5-fluorouracil cream or solution (2% or 5%), imiquimod 5% cream" Disseminated Superficial Actinic Porokeratosis. Updated from Documentation of failure, contraindication, or intolerance to ONE of the following: 5-fluorouracil cream, 5-fluorouracil solution (2% or 5%), imiquimod 5% cream to "Documentation of failure, contraindication, or intolerance to BOTH of the following: 5-fluorouracil cream or solution (2% or 5%), imiquimod 5% cream"
<u>Uridine Triacetate - (IP0307)</u>	Updated	Hereditary Orotic Aciduria (Orotic Aciduria Type 1). Updated from "Hereditary Orotic Aciduria" to "Hereditary Orotic Aciduria (Orotic Aciduria Type 1)" Added "First-degree family relative (i.e., parent or sibling) with hereditary orotic aciduria"
Viltolarsen - (IP0066)	Updated	Updated review date, disclaimer, refreshed background and references, addition of change history.
Hemophilia – Factor VIII Products – (IP0618)	New	Effective 12/15/2024 New policy: Medical necessity criteria were previously housed in Clotting Factors and Antithrombin class policy. Added dosing to the policy for all products. For Alphanate, Humate-P, and Wilate: Updated preferred product criteria requirements and exceptions. Removed Stimate nasal spray (desmopressin acetate 1.5mg/ml nasal spray) from the preferred product requirements.

		Previously, both the desmopressin injection (DDAVP injection) and nasal spray (Stimate) were required for mild to moderate von Willebrand disease.
Belumodusil - (IP0313)	Updated	Effective: 12/1/2024
Collagenase Clostridium Histolyticum – (IP0143)	Updated	Effective: 12/1/2024
Dextromethorphan/quinidine (Nuedexta) for Individual and Family Plans – (IP0324)	Updated	Effective: 12/1/2024
Filgrastim - (IP0258)	Updated	Effective: 12/15/2024
Givosiran - (IP0118)	Updated	Effective: 12/15/2024
Gonadotropin-Releasing Hormone (GnRH) Antagonists for Infertility Use - (IP0333)	Updated	Effective: 12/15/2024
Hemophilia – Gene Therapy – Beqvez - (IP0648)	Updated	Effective: 12/15/2024
Intraarticular Hyaluronic Acid Derivatives - (IP0322)	Updated	Effective: 12/15/2024
Intravenous Iron Replacement Therapy - (IP0222)	Updated	Effective: 12/15/2024
Lodoco (colchicine capsules) - (IP0595)	Updated	Effective: 12/15/2024
Metyrosine- (IP0450)	Updated	Effective: 12/15/2024
Midazolam Nasal Spray - (IP0338)	Updated	Effective: 12/15/2024
Motixafortide - (IP0597)	Updated	Effective: 12/15/2024
Nusinersen - (IP0182)	Updated	Effective: 12/15/2024
Olipudase alfa-rpcp - (IP0500)	Updated	Effective: 12/15/2024
Pegfilgrastim - (IP0070)	Updated	Effective: 12/15/2024

Pulmonary Arterial Hypertension – Endothelin Receptor Antagonists - (IP0631)	Updated	Effective: 12/15/2024
Risdiplam - (IP0063)	Updated	Effective: 12/15/2024
Romosozumab - (IP0179)	Updated	Effective: 12/15/2024
Sedative Hypnotic Medications - (IP0023)	Updated	Effective: 12/15/2024
Sodium thiosulfate – (IP0512)	Updated	Effective: 12/15/2024
Sofosbuvir/Velpatasvir/Voxilaprevir - (IP0188)	Updated	Effective: 12/15/2024
Testosterone (Injectables and Implantable Pellets) - (IP0351)	Updated	Effective: 12/1/2024
Ozanimod - (IP0214)	Retired	Policy retirement effective 12/1/2024
		Policy replaced by CP IP0655 (Multiple Sclerosis and Ulcerative Colitis – Zeposia Prior Authorization Policy)
Natalizumab - (IP0215)	Retired	Policy retirement effective 12/1/2024
		Policy replaced by CP IP0690 (Multiple Sclerosis and Crohn's Disease – Tysabri Prior Authorization Policy)
CareAllies Medical Necessity Guideline	New, Updated, or Retired?	Comments
		All above updates apply
Precertification Policy*	New, Updated, or Retired?	Comments
		No updates for December 2024

Reimbursement Policy*	New, Updated, or Retired?	Comments
		No updates for December 2024
Other Coding and Reimbursement Documents	New, Updated, or Retired?	Comments
		No updates for December 2024
ClaimsXten Documents*	New, Updated, or Retired?	Comments
		No updates for December 2024

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