



Coverage Policy Unit (CPU) - Monthly Policy Updates

Effective August 15, 2024 (unless otherwise noted)

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

Medical Coverage Policy	New, Updated, or Retired?	Comments
Cardiac Resynchronization Therapy (CRT) and Advanced Cardiac Pacing Technologies - (0174)	Update	Posting/effective September 1, 2024: Minor changes in coverage criteria/policy: • Removed leadless pacemakers from the policy statement; coverage criteria to be addressed in cobranded Cigna-EviCore Pacemaker Guidelines effective 9/1/2024. • Revised Note to update the name of related policy 0431 from "Implantable Cardioverter Defibrillator (ICD)" to "Cardioverter-Defibrillator Devices" due to policy 0431 title change.
Genetic Testing for Hereditary Cancer Susceptibility Syndromes - (0518)	Update	Important changes in coverage criteria: • Added kidney cancer as a covered hereditary cancer susceptibility syndrome to align with National Comprehensive Cancer Network (NCCN) guideline. • Minor changes:

		1. Removed von Hippel-Lindau Syndrome section and criteria, as this criteria is included in the NCCN Kidney Cancer guideline. 2. Updated genetics nurse credentialing information to reflect current accreditation options. 3. Other minor editorial changes for clarification.
Male Sexual Dysfunction Treatment: Non-pharmacologic – (0403)	Update	Minor changes in coverage criteria/policy: • Changed language from EIU to NMN for the not covered list of procedures because these don't meet Cigna's definition of EIU. • Removed "venous occlusive surgery (e.g., venous ligation) from the not medically necessary (previously EIU) statement because this procedure/code is not managed.
Serum Folate and Red Blood Cell Folate Testing – (0567)	NEW	Posting 5/15/2024; Effective 8/17/2024:
Thymus Tissue Transplantation – (0561)	Update	Minor clarification in coverage criteria: 1. No change in intent of coverage
Wearable Cardioverter Defibrillator and Automatic External Defibrillator – (0431)	Update	Important changes in coverage criteria: • Title change from "Wearable Cardioverter Defibrillator and Automatic External Defibrillator" to "Cardioverter-Defibrillator Devices" to reflect the expanded scope of the policy. • Combined content from CP 0181 Implantable Cardioverter Defibrillator (ICD) into CP 0431 Wearable Cardioverter Defibrillator and Automatic External Defibrillator because there is overlap of content between the two policies. • Minor change to add headers for "Wearable Cardioverter-Defibrillator" and "Automatic External Defibrillator" improved organization and readability of the content. • Minor change to update EIU language for wearable cardioverter-defibrillators for any other indication to NMN instead because these devices do not meet the definition of EIU. • Expanded coverage by removing the age range that's part of the non-wearable AED criteria because the age range isn't supported by the evidence.
Anesthesia and Facility Services for Dental Treatment - (0415)	Update	• No change in coverage.

Breast Reduction - (0152)	Update	No change in coverage.
Category III Current Procedural Terminology (CPT®) codes – (0558)	Update	No change in coverage.
Continuous Passive Motion (CPM) Devices - (0198)	Update	No change in coverage.
Extracorporeal Photophoresis – (0320)	Update	No change in coverage.
Gynecomastia Surgery - (0195)	Update	No change in coverage.
Head and Neck Ultrasound – (0549)	Update	No change in coverage.
Laser Interstitial Thermal Therapy – (0528)	Update	No change in coverage.
Minimally Invasive Anti-Reflux Procedures and Peroral Endoscopic Myotomy (POEM) - (0019)	Update	No change in coverage.
Scrotal Ultrasound - (0548)	Update	No change in coverage.
Stem Cell Transplantation: Blood Cancers – (0533)	Update	No change in coverage.
Vitamin D Testing – (0526)	Update	No change in coverage.

Implantable Cardioverter Defibrillator (ICD) – (0181)	Retired	Retired effective 8/15/2024 because content was moved to and combined with CP 0431 Wearable Cardioverter Defibrillator and Automatic External Defibrillator.
ASH Guidelines	New, Updated, or Retired?	Comments
Electric Stimulation for Pain, Swelling and Function in a Clinic Setting – (CPG 272)	Update	No change in coverage.
eviCore Guidelines	New, Updated, or Retired?	Comments
Cobranded Cigna-EviCore Lab Management Program Guidelines	New	Posting August 1, 2024 . Effective November 1, 2024 : New guidelines. New guidelines with coverage criteria for select laboratory tests.
Cobranded Cigna-EviCore Comprehensive Musculoskeletal Management Guidelines	Update	Posted May 1, 2024 . Effective August 1, 2024 : Important changes in coverage criteria. Three guidelines had an expansion of coverage: CMM-314: Hip Surgery-Arthroscopic and Open Procedures CMM-315: Shoulder Surgery – Arthroscopic and Open Procedures CMM-318: Shoulder Arthroplasty/Replacement/Resurfacing/Revision/Arthrodesis Three guidelines had positive and adverse changes in coverage: CMM-311: Knee Replacement/Arthroplasty CMM-312: Knee Surgery: Arthroscopic and Open Procedures CMM-313: Hip Replacement/Arthroplasty

		Posted June 27, 2024. Effective August 1, 2024: Informational document updated, no change to coverage: Preface to the Comprehensive Musculoskeletal Management (CMM) Guidelines
Cobranded Cigna-EviCore High-Tech Imaging Guidelines	Update	Posted May 1, 2024. Effective August 1, 2024: Important changes in coverage criteria. One guideline had an expansion of coverage: Oncology Imaging One guideline was updated with no change in coverage: Spine Imaging
Cobranded Cigna-EviCore Interventional Pain Management Guidelines	Update	Posted April 1, 2024. Effective August 1, 2024: The following guidelines underwent annual review with editorial updates and minor updates for clarification; no changes to coverage: CMM-200 Epidural Steroid Injections CMM-201 Facet Joint Injections/Medial Branch Blocks CMM-203 Sacroiliac Joint Procedures CMM-204 Prolotherapy CMM-207 Epidural Adhesiolysis CMM-208 Radiofrequency Joint Ablations/Denervations CMM-209 Regional Sympathetic Blocks CMM-210 Implantable Intrathecal Drug Delivery System
Cobranded Cigna-EviCore Pacemaker Guidelines	Update	Posted August 1, 2024. Effective September 1, 2024: Important changes in coverage criteria. Added coverage criteria for leadless pacemakers.
Cobranded Cigna-EviCore Radiation Oncology Guidelines	Update	Posted August 1, 2024. Effective November 1, 2024: New guideline: Biology-Guided Radiation Therapy (BgRT)

		Important changes in coverage criteria. Two guidelines were updated to reflect an expansion of coverage: Cervical Cancer Removed exceptions required for coverage of intensity-modulated radiation therapy (IMRT). Prostate Cancer Added option of 36 Gy in six fractions for treatment of low-volume metastatic disease and removed statement requiring contraindication to National Comprehensive Cancer Network (NCCN) category 1 systemic regimens. The remaining guidelines had no clinical changes.
Administrative Policy	New, Updated, or Retired?	Comments
		No updates for August 2024
Drug & Biologic Coverage Policy	New, Updated, or Retired?	Comments
		All policy changes effective October 1, 2023, unless otherwise stated
Allergen Immunotherapy – Palforzia - (IP0141)	Update	Effective 8/15/2024 Policy Name Change: Updated Policy Name from “Peanut (Arachis hypogaea) Allergen Powder-dnfp” to “Allergen Immunotherapy – Palforzia.” Peanut Allergy: Removed the note stating that a positive food challenge result, at or before the 100 mg challenge dose of peanut protein, would be an acceptable alternative for SPT or psIgE testing requirements. Removed the requirement that the individual must not have either eosinophilic esophagitis or other eosinophilic gastrointestinal condition. Conditions Not Covered: Removed the criterion regarding emergency treatment of allergic reactions, including anaphylaxis.

Anticoagulants – Eliquis – (IP0030)	Update	Effective 8/1/2024 Updated policy title, it previously was Apixaban. All Covered Conditions: Added Patient is ≥ 18 years of age Conditions Not Covered: Removed "Prophylaxis of Venous Thromboembolism in Individuals with Factor V Leiden thrombophilia and Antiphospholipid syndrome." from the listed conditions. This does not imply a change in coverage status; only list maintenance.
Anticoagulants – Xarelto – (IP0032)	Update	Effective 8/1/2024 Updated policy title, it previously was Rivaroxaban. Atrial Fibrillation (or Atrial Flutter): Added Patient is ≥ 18 years of age; AND If Xarelto oral suspension is being requested, approve if the patient is unable to have Xarelto tablets appropriately administered. Coronary Artery Disease: Added Patient is ≥ 18 years of age; AND If Xarelto oral suspension is being requested, approve if the patient is unable to have Xarelto tablets appropriately administered. Deep Vein Thrombosis in a Patient Undergoing Knee or Hip Replacement Surgery, Prophylaxis: Added Patient is ≥ 18 years of age; AND If Xarelto oral suspension is being requested, approve if the patient is unable to have Xarelto tablets appropriately administered. Deep Vein Thrombosis or Pulmonary Embolism, to Reduce the Risk of Recurrence: Added differentiation between tablets and suspension and for Xarelto oral suspension: Approve if the patient meets one of the following: Patient is unable to have Xarelto tablets appropriately administered; OR The prescribed Xarelto dose cannot be achieved by Xarelto 10 mg, 15 mg, or 20 mg tablets. Peripheral Artery Disease: Added Patient is ≥ 18 years of age; AND If Xarelto oral suspension is being requested, patient is unable to have Xarelto tablets appropriately administered. Thromboprophylaxis in a Patient with Congenital Heart Disease: Added Patient is ≥ 2 years of age and < 18 years of age

		Venous Thromboembolism in an Acutely Ill Medical Patient, Prophylaxis: Added Patient is $\geq$ 18 years of age; AND If Xarelto oral suspension is being requested, patient is unable to have Xarelto tablets appropriately administered. Conditions Not Covered: Removed Prophylaxis of Venous Thromboembolism in Individuals with Factor V Leiden thrombophilia and Antiphospholipid syndrome. This does not imply a change in coverage status; only list maintenance.
Antiseizure Medications – Fintepla - (IP0042)	Update	Effective: 8/1/2024 Dravet Syndrome, Lennox-Gastaut Syndrome. Updated terminology used for alternative therapy requirement Added 'Patient is Currently Receiving Fintepla' criteria
Antiseizure Medications – Vigabatrin - (IP0049)	Update	Effective: 8/1/2024 Updated coverage policy title from <i>Vigabatrin</i> to <i>Antiseizure Medications - Vigabatrin</i>. Infantile Spasms: Updated authorization durations to 6 months (whether initial or reauthorization). Treatment-Refractory Complex Partial Seizures: Updated initial authorization duration from 6 months to 3 months. Updated language to "tried and/ or concomitantly receiving" from "failure" for criterion requiring other antiseizure medications.
Apremilast - (IP0226)	Update	Effective: 8/2/2024 Plaque Psoriasis. Updated from "Failure after at least 6 weeks to ONE of the following, unless contraindicated or intolerant to ALL of the following:" TO "Failure to ONE of the following, unless contraindicated or intolerant to ALL of the following:"
Brands with Bioequivalent Generics - (IP0011)	Update	Effective 8/15/2024 Removed Taytulla Added Moviprep, Mepron (effective 9/1/2024) for medical necessity review for both Employer and Individual and Family Plans.
Contraceptives - (IP0036)	Update	Effective: 8/15/2024

		Removed Estrostep FE, LoSeasonique, and Ortho Micronor from coverage policy; no longer marketed. Added clarification that policy supports preferred product requirements for Employer and Individual and Family plans. Added Taytulla for Individual and Family Plans.
Corticosteroids (Intraarticular) – Zilretta - (IP0140)	Update	Effective: 8/15/2024 Osteoarthritis Pain of the Knee. Updated requirement of intraarticular corticosteroid injection from failure, contraindication, or intolerance to tried. Updated 'Patient is not receiving re-treatment of knee(s) previously treated with Zilretta from conditions not covered section to authorization criteria. Conditions Not Covered. Removed 'Treatment in joints other than the knee'
Cushing's – Isturisa - (IP0044)	Update	Effective: 8/1/2024 Endogenous Cushing's Syndrome: A patient who is awaiting surgery and a patient who is awaiting therapeutic response after radiotherapy were added as options of approval; for these conditions (patient who is awaiting surgery and a patient who is awaiting therapeutic response after radiotherapy) a requirement was added that the patient has tried one other medication, or the patient is currently receiving Isturisa were added. Endogenous Cushing's Syndrome – Patient Awaiting Surgery: This condition was removed from the policy and is now addressed under Endogenous Cushing's Syndrome. Endogenous Cushing's Syndrome – Patient Awaiting Therapeutic Response After Radiotherapy: This condition was removed from the policy and is now addressed under Endogenous Cushing's Syndrome. Endogenous Cushing's Syndrome – Individuals Awaiting Surgery, :Endogenous Cushing's Syndrome – Individuals Awaiting Therapeutic Response After Radiotherapy: Authorization changed from up to 6 months to 1 year
Cushing's – Mifepristone - (IP0092)	Update	Effective: 8/1/2024 Endogenous Cushing's Syndrome: A patient who is awaiting surgery and a patient who is awaiting therapeutic response after radiotherapy were added as options of approval; for these conditions patient who is awaiting surgery and a patient who is awaiting therapeutic response

		after radiotherapy, a requirement was added that the patient has tried one other medication, or the patient is currently receiving mifepristone were added. Endogenous Cushing's Syndrome – Patient Awaiting Surgery: This condition was removed from the policy and is now addressed under Endogenous Cushing's Syndrome. Endogenous Cushing's Syndrome – Patient Awaiting Therapeutic Response After Radiotherapy: This condition was removed from the policy and is now addressed under Endogenous Cushing's Syndrome.
Cushing's – Signifor - (IP0482)	Update	Effective 8/1/2024 Endogenous Cushing's Syndrome: This condition and criteria for approval were added under Other Uses with Supportive Evidence. Endogenous Cushing's Syndrome – Patient Awaiting Surgery: This condition was removed from the policy and is now addressed under Endogenous Cushing's Syndrome. Endogenous Cushing's Syndrome – Patient Awaiting Therapeutic Response After Radiotherapy: This condition was removed from the policy and is now addressed under Endogenous Cushing's Syndrome. Endogenous Cushing's Syndrome. Updated initial authorization duration from 4 months to 1 year Endogenous Cushing's Syndrome – Individual Awaiting Surgery: removed from authorization duration: 'if individual is still awaiting surgery, then reauthorize for 4 months' Cushing Disease: Added 'Patient is Currently Receiving Signifor/Signifor LAR' criteria
Cushing's – Recorlev - (IP0389)	Update	Effective 8/1/2024 Endogenous Cushing's Syndrome: Criteria that patient who is awaiting surgery for endogenous Cushing's Syndrome or awaiting therapeutic response after radiotherapy for endogenous Cushing's Syndrome were added. Endogenous Cushing's Syndrome – Patient Awaiting Surgery: This condition was removed from the policy and is now addressed under Endogenous Cushing's Syndrome.

		Endogenous Cushing's Syndrome – Patient Awaiting Therapeutic Response After Radiotherapy: This condition was removed from the policy and is now addressed under Endogenous Cushing's Syndrome.
Cystic Fibrosis – Symdeko – (IP0433)	Update	Effective: 8/1/2024 Updated coverage policy title from Tezacaftor/ Ivacaftor to Cystic Fibrosis – Symdeko. Added preferred product criterion to allow coverage Symdeko if there is at least one of the following mutations in the CFTR gene: 711+3A > G, E831X, 2789+5G > A, 3272-26A > G, OR 3849 + 10kbC > T Specified Preferred Product Table applies to Total Savings Drug List Plans. Infertility: Added this indication to conditions not recommended for approval. CFTR-related disorder: Removed indication from Conditions Not Covered. CFTR-related metabolic syndrome, CF Screen Positive, Inconclusive Diagnosis (CRMS/CF SPID): Removed indications from Conditions Not Covered.
Enspryng – (IP0078)	Update	Effective: 8/1/2024 Neuromyelitis Optica Spectrum Disorder. Added criteria for 'Patient is Currently Receiving Enspryng' Conditions Not Covered. Added Ultomoris to no concomitant use statement as 'Concomitant Use with a Rituximab Product, Soliris (eculizumab intravenous infusion), Ultomiris (ravulizumab-cwyz intravenous infusion), or Uplizna (inebilizumab-cdon intravenous infusion)'
Enzyme Replacement Therapy – Aldurazyme – (IP0445)	Update	Effective: 8/1/2024 Mucopolysaccharidosis Type I (Hurler Syndrome, Hurler-Scheie Syndrome, and Scheie Syndrome). Removed: ONE of the following forms: Severe Mucopolysaccharidosis I (MPS I) or Attenuated Mucopolysaccharidosis I (MPS I) with moderate to severe symptoms

Enzyme Replacement Therapy – Elaprase - (IP0444)	Update	Effective: 8/1/2024 Mucopolysaccharidosis Type II (Hunter Syndrome). Added dosing
Enzyme Replacement Therapy – Kanuma - (IP0448)	Update	Effective: 8/1/2024 Lysosomal Acid Lipase Deficiency. Added dosing
Enzyme Replacement Therapy – Mepsevii - (IP0449)	Update	Effective: 8/1/2024 Updated coverage policy title from <i>Vestronidase Alfa-vjbk</i> to <i>Enzyme Replacement Therapy - Mepsevii</i> . <u>Mucopolysaccharidosis Type VII (Sly Syndrome):</u> Added dosing.
Enzyme Replacement Therapy – Naglazyme - (IP0443)	Update	Effective: 8/1/2024 Updated coverage policy title from <i>Galsulfase</i> to <i>Enzyme Replacement Therapy – Naglazyme</i> . <u>Mucopolysaccharidosis Type VI (Maroteaux – Lamy Syndrome):</u> Added dosing.
Enzyme Replacement Therapy – Sucraid - (IP0447)	Update	Effective 8/1/2024 • Policy Name Change: Updated Policy Name from “Sacrosidase” to “Enzyme Replacement Therapy – Sucraid.” • Congenital Sucrase-Isomaltase Deficiency: ➢ Disaccharidase levels consistent with congenital sucrase-isomaltase deficiency was changed from “decreased to normal” to “decreased or normal” isomaltase and lactase levels. ➢ Updated duration approval from 6 months to 12 months.
Enzyme Replacement Therapy – Vimizim - (IP0442)	Update	Effective: 8/1/2024 Updated coverage policy title from <i>Elosulfase Alfa</i> to <i>Enzyme Replacement Therapy – Vimizim</i> . <u>Mucopolysaccharidosis Type IVA (Morquio A Syndrome):</u> Added dosing.

Gonadotropin – Releasing Hormone Antagonists – Myfembree - (IP0205)	Update	Effective: 8/1/2024 Uterine Fibroids (Leiomyomas). Updated 'Uterine fibroids have been confirmed by imaging' TO 'Uterine fibroids have been confirmed by a pelvic ultrasound, including transvaginal ultrasonography or sonohysterography; hysteroscopy; or magnetic resonance imaging' Uterine Fibroids (Leiomyomas), Endometriosis. Updated authorization duration from 12 months to 24 months
Gonadotropin- Releasing Hormone Antagonists – Oriahnn – (IP0087)	Update	Effective: 8/1/2024 Updated coverage policy title from <i>Oriahnn</i> to <i>GnRH Receptor Antagonist - Oriahnn</i>. Updated initial approval authorization from 12 months to 24 months. Removed reauthorization criteria.
Gonadotropin- Releasing Hormone Antagonists – Orilissa - (IP0196)	Update	Effective 8/1/2024 Policy Name Change: Updated Policy Name from "Elagolix" to "Gonadotropin-Releasing Hormone Antagonists – Orilissa." Authorization Duration: Updated initial therapy duration from 12 months to 6 months for the treatment of Endometriosis.
Growth Disorders – Increlex - (IP0310)	Update	Effective 8/1/2024 Insulin-Like Growth Factor-1 (IGF-1) Deficiency – Severe, Primary Disease, Growth Hormone Gene Deletion. Added criteria for 'Patient Has Been Receiving Increlex for ≥ 1 Year' Updated specialist from 'endocrinologist' to 'pediatric endocrinologist' Conditions Not Covered. Removed (1) Amyotrophic Lateral Sclerosis (ALS), (2) Autism Spectrum Disorder, (3) Bone Loss Associated with Anorexia, (4) Phelan- McDermid Syndrome, (5) Prevention of Retinopathy of Prematurity, (6) Rett Syndrome Updated 'Idiopathic (i.e. of unknown origin) Short Stature' from not medical necessary to only conditions not covered

Hematology – Gene Therapy – Casgevy - (IP0615)	Update	Effective 8/15/2024 Transfusion-Dependent Beta-Thalassemia: This condition and criteria for approval were added to the policy. Conditions Not Recommended for Approval: For the criterion “Prior Receipt of Gene Therapy”, Zynteglo (betibeglogene autotemcel intravenous infusion” was added as an example; a new criterion “Concurrent Use with Reblozyl (luspatercept-aamt subcutaneous injection” was added to the policy.
Hemophilia – Altuviiio - (IP0564)	Update	Effective 8/15/2024 Pre-exposure Prophylaxis (PrEP) of Human Immunodeficiency Virus (HIV)-1 Infection: • Updated the scenarios for Altuviiio use • Added Factor VIII testing requirements • Updated the specialist prescribing requirement • Added criteria for a patient currently receiving Altuviiio or has received Altuviiio in the past
Hepatitis C – Epclusa - (IP0184)	Update	Effective: 8/1/2024 Aligned with ESI Standard PA Policy; Custom in the Preferred Product Table (use inability to obtain rather than patient is directed to use) Chronic Hepatitis C Virus (HCV) Genotype 1, 2, 3, 4, 5, or 6, No Cirrhosis or Compensated Cirrhosis (Child-Pugh A). Removed ‘Has NOT been previously treated with NS5A inhibitor-based therapy (see Appendix for examples)’ Added velpatasvir to: ‘Patient has not been previously treated with sofosbuvir/velpatasvir’ Chronic Hepatitis C Virus (HCV) Genotype 1, 2, 3, 4, 5, or 6, Decompensated Cirrhosis (Child-Pugh B or C), Adult. Updated ‘ONE of the following: Is ribavirin-eligible AND sofosbuvir/velpatasvir (Epclusa) will be prescribed in combination with ribavirin or Is ribavirin-ineligible, according to the prescriber’ TO ‘Patient meets ONE of the following (i or ii): (i) Patient is ribavirin-eligible, according to the prescriber: Approve for 12 weeks, if the medication is prescribed in combination with ribavirin; OR, (ii) Patient is ribavirin-ineligible, according to the prescriber: Approve for 24 weeks’ Chronic Hepatitis C Virus (HCV) Genotype 1, 2, 3, 4, 5, or 6, Decompensated Cirrhosis (Child-Pugh B or C), Pediatric Patient.

		Removed 'Has NOT been previously treated with sofosbuvir-containing or NS5A inhibitor-based therapy (see Appendix for examples)' Chronic Hepatitis C Virus (HCV), Genotype Unknown/Undetermined. Updated as stand-alone new condition of approval [prior combined with: Chronic Hepatitis C Virus (HCV) Genotype 1, 2, 3, 4, 5, or 6, No Cirrhosis or Compensated Cirrhosis (Child-Pugh A)] Chronic Hepatitis C Virus (HCV), Genotype 1, 2, 3, 4, 5, or 6, Decompensated Cirrhosis (Child-Pugh B or C), Prior Null Responder, Prior Partial Responder, and Prior Relapser to sofosbuvir/velpatasvir or Vosevi. Updated 'BOTH of the following: (A) Has been previously treated with sofosbuvir-containing or NS5A inhibitor-based treatment (see Appendix for examples), (B) Sofosbuvir/velpatasvir (Epclusa) will be prescribed in combination with ribavirin' TO 'Patient meets ONE of the following (i or ii): (i) Patient has been previously treated with sofosbuvir/velpatasvir; OR (ii) Patient has previously been treated with Vosevi'
HIV Products - (P0050)	Update	Effective 8/15/2024 Descovy removed from the policy.
Homozygous Familial Hypercholesterolemia – Evkeeza – (IP0128)	Update	Effective 8/15/2024 Updated the title of the policy from Evinacumab to Homozygous Familial Hypercholesterolemia – Evkeeza. Homozygous Familial Hypercholesterolemia: Clarified "Initial Therapy" versus "Currently Receiving Evkeeza" criteria and added additional examples of what is considered a response to therapy; Removed "Use is adjunctive to diet and maximally tolerated statin therapy [unless contraindicated or intolerant]"; Updated the statin intolerance criteria, to clearly define what is considered statin intolerant, with notes and examples also included. For <u>Initial Therapy</u>, the specialist physician requirement was removed. The requirement that the patient has had genetic confirmation by two mutant alleles at the low-density lipoprotein receptor, apolipoprotein B, proprotein convertase subtilisin kexin type 9, or low-density lipoprotein receptor adaptor protein 1 gene locus was changed to state that the patient has phenotypic confirmation of homozygous familial hypercholesterolemia and the above examples moved to a Note. The diagnostic criterion which stated that the patient has an untreated low-density lipoprotein cholesterol level > 500 mg/dL was changed to > 400 mg/dL. The criterion (which is in two places [those with an untreated low-density lipoprotein cholesterol level > 400 mg/dL and a treated low-density lipoprotein cholesterol level ≥ 300 mg/dL]) that both parents of the patient had untreated low-density lipoprotein cholesterol levels or total cholesterol levels consistent with heterozygous familial hypercholesterolemia was changed to state that at

		least one parent of the patient had untreated low-density lipoprotein cholesterol levels or total cholesterol levels consistent with familial hypercholesterolemia. The related Note that “An example of heterozygous familial hypercholesterolemia in both parents would be if both had an untreated low-density lipoprotein cholesterol level $\geq$ 190 mg/dL and/or an untreated total cholesterol level > 250 mg/dL” was changed to state “An example of familial hypercholesterolemia is an untreated low-density lipoprotein cholesterol level $\geq$ 190 mg/dL and/or an untreated total cholesterol level > 250 mg/dL.”
Homozygous Familial Hypercholesterolemia – Juxtapid – (IP0221)	Update	Effective 8/15/2024 Updated policy title from Lomitapide to Homozygous Familial Hypercholesterolemia – Juxtapid Homozygous Familial Hypercholesterolemia: Clarified “Initial Therapy” versus “Currently Receiving Lomitapide” criteria and added additional examples of what is considered a response to therapy. Removed “Use is adjunctive to diet and maximally tolerated statin therapy [unless contraindicated or intolerant]”. Updated the statin intolerance criteria, to clearly define what is considered statin intolerant, with notes and examples also included. The specialist physician requirement was removed. The requirement that the patient has had genetic confirmation by two mutant alleles at the low-density lipoprotein receptor, apolipoprotein B, proprotein convertase subtilisin kexin type 9, or low-density lipoprotein receptor adaptor protein 1 gene locus was changed to state that the patient has phenotypic confirmation of homozygous familial hypercholesterolemia and the examples moved to a Note. The diagnostic criterion which stated that the patient has an untreated low-density lipoprotein cholesterol level > 500 mg/dL was changed to > 400 mg/dL. The criterion (which is in two places [those with an untreated low-density lipoprotein cholesterol level > 400 mg/dL and a treated low-density lipoprotein cholesterol level $\geq$ 300 mg/dL]) that both parents of the patient had untreated low-density lipoprotein cholesterol levels or total cholesterol levels consistent with heterozygous familial hypercholesterolemia was changed to state that at least one parent of the patient had untreated low-density lipoprotein cholesterol levels or total cholesterol levels consistent with familial hypercholesterolemia. The related Note that “An example of heterozygous familial hypercholesterolemia in both parents would be if both had an untreated low-density lipoprotein cholesterol level $\geq$ 190 mg/dL and/or an untreated total cholesterol level > 250 mg/dL” was changed to state “An example of familial hypercholesterolemia is an untreated low-density lipoprotein cholesterol level $\geq$ 190 mg/dL and/or an untreated total cholesterol level > 250 mg/dL.”
Hyperlipidemia – Nexletol – (IP0248)	Update	Effective: 8/15/2024 Updated policy title from “Bempedoic Acid” to “Hyperlipidemia – Nexletol.”

		<u>All Indications:</u> Clarified “Initial Therapy” versus “Currently Receiving Nexletol” criteria and added additional examples of what is considered a response to therapy. Removed “Use is adjunctive to diet and maximally tolerated statin therapy [unless contraindicated or intolerant]”. Updated the statin intolerance criteria, to clearly define what is considered statin intolerant, with notes and examples also included. Updated the preferred criteria. <u>Established Cardiovascular Disease:</u> Changed the name of the indication to as stated (previously “Atherosclerotic Cardiovascular Disease”). Changed the requirement that the low-density lipoprotein cholesterol level after treatment with one high-intensity statin therapy be ≥ 70 mg/dL to ≥ 55 mg/dL [based on guideline update]. <u>Heterozygous Familial Hypercholesterolemia:</u> Removed specialist physician requirement. <u>Primary Hyperlipidemia:</u> Removed specialist physician requirement. Removed “Individual has a coronary artery calcium or calcification score of 100 or greater Agatston units or 75th percentile or greater for the individual’s age, gender and ethnicity [coronary calcium scan may require prior authorization] OR Calculated 10-year ASCVD risk score of 7.5% or higher and replaced with “Patient has a coronary artery calcium or calcification score ≥ 300 Agatston units OR Patient has diabetes”. Added a requirement that “Patient has tried the one high-intensity statin therapy (atorvastatin or rosuvastatin) along with ezetimibe (as a single-entity or as a combination) for ≥ 8 continuous weeks”. Changed the requirement that the low-density lipoprotein cholesterol level after treatment with one high-intensity statin therapy, along with ezetimibe, be ≥ 100 mg/dL to ≥ 70 mg/dL.
Hyperlipidemia – Nexlizet – (IP0249)	Update	Effective: 8/15/2024 Updated coverage policy title from “Bempedoic Acid and Ezetimibe” to “Hyperlipidemia – Nexlizet.” <u>All Indications:</u> Clarified “Initial Therapy” versus “Currently Receiving Nexlizet” criteria and added additional examples of what is considered a response to therapy.

		Removed "Use is adjunctive to diet and maximally tolerated statin therapy [unless contraindicated or intolerant]." Updated the statin intolerance criteria, to clearly define what is considered statin intolerant, with notes and examples also included. <u>Established Cardiovascular Disease:</u> Changed the name of the indication to as stated (previously "Atherosclerotic Cardiovascular Disease"). Changed the requirement that the low-density lipoprotein cholesterol level after treatment with one high-intensity statin therapy be ≥ 70 mg/dL to ≥ 55 mg/dL [based on guideline update]. <u>Primary Hyperlipidemia:</u> Added clinical criteria for coverage of use.
Human Immunodeficiency Virus – Apretude - (IP0435)	Update	Effective 8/1/2024 Pre-exposure Prophylaxis (PrEP) of Human Immunodeficiency Virus (HIV)-1 Infection: • Decreased the approval duration from 12 months to two months. • Added a requirement for the patient to have had a negative HIV-1 test no more than 1 week prior to the dose of Apretude. • Added a requirement for the patient to have no signs or symptoms of acute HIV infection. • Added a specialist prescribing requirement. • Added dosing information.
Human Immunodeficiency Virus – Descovy for Employer Plans - (IP0636)	New	Effective 8/15/2024 • Added criteria for Treatment of Human Immunodeficiency Virus (HIV)-1 Infection. • Updated the current HIV-1 Pre-exposure Prophylaxis (PrEP) medically necessity criteria found in HIV Products coverage policy P0050, to P&T standards. • Added an exception for the treatment of other conditions, for example post exposure prophylaxis.
Human Immunodeficiency Virus – Trogarzo - (IP0171)	Update	Effective: 8/1/2024 Human Immunodeficiency Virus (HIV)-1 Infection.

		Updated 'Documentation of multidrug-resistant HIV-1 infection' TO 'Patient has multiple antiretroviral drug resistance as demonstrated by resistance to at least <u>one</u> antiretroviral from at least THREE of the following antiviral classes' Added age, specialist requirement Added 'patient is currently receiving Trogarzo' criteria Condition Not Covered. Removed 'Human Immunodeficiency Virus (HIV)-2'
Hypoactive Sexual Desire Disorder – Vyleesi - (IP0117)	Update	Effective 8/1/2024 • Added IFP to the policy. • Removed criterion requiring the patient to be female at birth. • Updated the criterion related to depression to the patient has not been diagnosed or treated with depression within the previous 6 months. • Updated the continuation of therapy approach by requiring the patient to be premenopausal
Hyperlipidemia – Omega-3 Fatty Acid Products – (IP0051)	Update	Effective 8/1/2024 Cardiovascular Risk Reduction in a Patient with Elevated Triglycerides: Added examples of cardiovascular disease to a Note for those with established cardiovascular disease; Added examples of risk factors for cardiovascular disease to a Note for those with diabetes. Hypertriglyceridemia with Triglyceride Levels $\geq$ 500 mg/dL and Hypertriglyceridemia with Triglyceride Levels of 150 mg/dL to < 500 mg/dL: Updated the previous indication of Hypertriglyceridemia with Triglyceride (TG) Levels greater than or equal to 150 mg/dL to clearly differentiate between the FDA-Approved Indication versus the Other Uses with Supportive Evidence indications for Vascepa; Added examples of fibrates and statin products.
Immunologics – Adbry - (IP0386)	Update	Effective: 8/1/2024 Atopic Dermatitis. Removed 'Individual has had an inadequate response after at least 3 months of therapy with ONE conventional systemic immunomodulator used for the treatment of atopic dermatitis (for example, cyclosporine, azathioprine, methotrexate, mycophenolate mofetil)' as an alternative

		to corticosteroid Added 'Patient has atopic dermatitis involvement estimated to be $\geq 10\%$ of the body surface area according to the prescriber' Removed 'Individual meets BOTH of the following criteria (1) Individual has atopic dermatitis affecting ONLY the following areas: face, skin folds, and/or genitalia, (2) Individual has had an inadequate response to ONE topical calcineurin inhibitor (pimecrolimus 1% cream [Elidel®], tacrolimus 0.03% or 0.1% ointment [Protopic®]) used for at least 28 days, unless contraindicated or intolerant' Updated initial authorization durations from 12 months to 4 months
Infectious Disease – Impavido - (IP0210)	Update	Effective 8/15/2024 Policy Name Change: Updated Policy Name from "Miltefosine" to "Infectious Disease – Impavido." Leishmaniasis: Removed the criteria specifying treatment for infections caused by specific Leishmania species. Added the requirement for medication to be prescribed by or in consultation with an infectious disease specialist. Ameba Related Infections: Added the requirement for medication to be prescribed by or in consultation with an infectious disease specialist.
Inflammatory Conditions – Entyvio Subcutaneous – (IP0599)	Update	Effective 8/1/2024 Crohn's Disease: Newly approved indication was added to the policy. Ulcerative Colitis: A requirement was added that the patient is ≥ 18 years of age.
Inflammatory Conditions - Entyvio Subcutaneous for Total Savings and Individual and Family Plans – (IP0613)	Update	Effective 8/1/2024 Crohn's Disease: Newly approved indication was added to the policy. Added Zymfentra as a preferred product option for Crohn's Disease for Total Savings Plans. Ulcerative Colitis: A requirement was added that the patient is ≥ 18 years of age. Added Zymfentra as a preferred product option for Ulcerative Colitis for Total Savings Plans.
Inflammatory Conditions – Omvoh Subcutaneous – (IP0602)	Update	Effective 8/1/2024 Added Zymfentra as a preferred product option for Ulcerative Colitis for Employer Plans.

Inflammatory Conditions – Velsipity - (IP0605)	Update	Effective 8/1/2024 Added Zymfentra as a preferred product option, for Ulcerative Colitis, for Employer Plans.
Inflammatory Conditions – Zymfentra – (IP0646)	New	Effective 8/1/2024 New Policy to support medical necessity review for Zymfentra.
Metabolic Disorders – Cysteamine (Oral) Products - (IP0046)	Update	Effective: 8/15/2024 Cystinosis, Nephropathic. Added requirement that patient is $\geq$ 1 year of age. For Procysbi, confirmation of a genetic mutation in the <i>CTNS</i> gene was rephrased to more specifically state, “genetic testing confirmed biallelic pathogenic or likely pathogenic variants in the <i>CTNS</i> gene.”
Metabolic Disorders – Cysteamine (Oral) Products for Individual and Family Plans - (IP0466)	Update	Effective: 8/15/2024 Cystinosis, Nephropathic. Separated criteria of approval for Procysbi and Cystagon. For Procysbi, added requirement that patient is $\geq$ 1 year of age. For both Procysbi and Cystagon, confirmation of a genetic mutation in the <i>CTNS</i> gene was rephrased to more specifically state, “genetic testing confirmed biallelic pathogenic or likely pathogenic variants in the <i>CTNS</i> gene.”
Metabolic Disorders – Imcivree - (IP0104)	Update	Effective: 8/1/2024 Obesity Due to Proopiomelanocortin (POMC), Proprotein Convertase Subtilisin/Kexin Type 1 (PCSK1), or Leptin Receptor (LEPR) Deficiency: Updated the genetic testing requirement by changing <i>biallelic variants</i> to <i>homozygous or compound heterozygous pathogenic variants</i> . Updated the age 6-17 BMI requirement to a body weight requirement. Removed age requirements from the continuation of therapy weight loss requirement. Obesity Due to Bardet-Biedl Syndrome. Updated the less than 18 years of age BMI requirement to a body weight requirement. Removed age requirement from the adult continuation of therapy weight loss requirement. Conditions Not Covered

		Added clinical trial outcome information and examples to Other Genetic Obesity Syndromes.
Metabolic Disorders – Nulibry - (IP0142)	Update	Effective 8/15/2024 Policy Name Change: Updated Policy Name from “Fosdenopterin” to “Metabolic Disorders – Nulibry.” Molybdenum Cofactor Deficiency (MoCD) Type A: Updated criteria for suspected MOCD to rely on laboratory findings rather than clinical presentation and added a note listing examples of such findings. Added dosing information.
Multiple Sclerosis – Mavenclad - (IP0261)	Update	Effective: 8/15/2024 Added new criteria for the patient to have had experienced inadequate efficacy or significant intolerance to two disease-modifying agents used for multiple sclerosis. Or have had experienced inadequate efficacy or significant intolerance to one of Kesimpta, a natalizumab intravenous product, Briumvi, Lemtrada, or Ocrevus. Updated the reauthorization requirements by adding specific examples a beneficial response and an option for the patient to have experienced stabilization, slowed progression, or improvement in at least one symptom such as motor function, fatigue, vision, bowel/bladder function, spasticity, walking/gait, or pain/numbness/tingling sensation. Added a specialist prescribing requirement. Removed the preferred product requirements for both Employer and IFP.
Muscular Dystrophy – Amondys 45 - (IP0137)	Update	Effective 8/15/2024 Updated policy title: previously it was Casimersen. Added dosing to the policy.
Muscular Dystrophy – Exondys 51 - (IP0135)	Update	Effective 8/15/2024 Updated policy title: previously it was Eteplirsen. Added dosing to the policy.
Muscular Dystrophy – Vyondys 53 - (IP0136)	Update	Effective 8/15/2024 Updated policy title: previously it was Golodirsen.

		Added dosing to the policy.
Natpara - (IP0177)	Update	Effective: 8/15/2024 Policy Name Change: Updated Policy Name from "Parathyroid Hormone" to "Natpara." Chronic Hypoparathyroidism - Initial Therapy and Patient is Currently Receiving Natpara: Updated the criterion concerning the patient's 25-hydroxyvitamin D stores, to include the phrase "according to the prescriber."
Neurology – Brineura - (IP0175)	Update	Effective 8/1/2024 No criteria changes
Neurology – Daybue - (IP0578)	Update	Effective: 8/1/2024 Updated coverage policy title from <i>Trofinetide</i> to <i>Neurology – Daybue</i> .
Neurology – Lyrica CR – (IP0183)	Update	Effective: 8/1/2024 Neuropathic Pain Associated with Diabetic Peripheral Neuropathy, Postherpetic Neuralgia. Added 'if brand Lyrica CR is requested, the patient meets BOTH of the following (i) Patient has tried generic pregabalin extended-release tablets; AND (ii) Patient cannot continue to use the generic due to a formulation difference in the inactive ingredient(s) [e.g., differences in dyes, fillers, preservatives] between the brand and the bioequivalent generic product, which, according to the prescriber, would result in a significant allergy or serious adverse reaction. Added 'Patient has tried gabapentin immediate-release (brand [Neurontin] or generic)' as an alternative to generic immediate-release pregabalin
Neurology – Radicava Products - (IP0176)	Update	Effective: 8/15/2024 Amyotrophic Lateral Sclerosis (ALS). Added Patient has received or is currently receiving riluzole tablets, Tiglutik (riluzole oral suspension), or Exservan (riluzole oral film). Added 'Patient is Currently Receiving Radicava IV or Radicava ORS' criteria. Updated policy title from Edaravone.
Neurology – Skyclarys - (IP0566)	Update	Effective: 8/15/2024 Friedreich's Ataxia. Added 'Patient is Currently Receiving Skyclarys' criteria.

Nonsteroidal Anti-inflammatory Drugs - (IP0457)	Update	Effective 8/1/2024 Added preferred product step requirement through five (5) prescription strength NSAIDs for Tolectin (tolmetin) 600 mg tablets for both Employer and Individual and Family Plans
Oncology (Injectable-CAR-T) – Abecma - (IP0168)	Update	Effective: 8/1/2024 Multiple Myeloma: Requirement that the patient has received four or more lines of systemic therapy was revised to patient has received two or more lines of systemic therapy.
Oncology (Other) – Adstiladrin - (IP0579)	Update	Effective: 8/15/2024 Non-Muscle Invasive Bladder Cancer. Updated approval duration from 1 year to approve for the duration noted. Added criterion for Initial therapy approval for 4 months. Removed option for approval that the patient has cytology- and bladder biopsy-positive, imaging and cystoscopy negative, recurrent, or persistent disease. Added option for approval for 3 months for patients currently receiving Adstiladrin if the medication is prescribed by or in consultation with a urologist or an oncologist and the patient is either in remission or has cytology-positive, imaging and cystoscopy-negative, recurrent, or persistent disease.
Oncology (Injectable – CAR-T) – Breyanzi (IP0130)	Update	Effective 8/1/2024 Policy Name Change: Updated Policy Name from “Lisocabtagene maraleucel” to “Oncology (Injectable – CAR-T) – Breyanzi.” B-Cell Lymphoma: Revised acquired immunodeficiency syndrome (AIDS) to human immunodeficiency virus (HIV). Removed criteria requiring both anti-CD20 monoclonal antibody and an anthracycline-containing chemotherapy regimen for systemic therapy. Removed the criteria necessitating an Eastern Cooperative Oncology Group (ECOG) performance status of 0 to 2 and the absence of primary central nervous system lymphoma. Removed the requirement for prescription by or in consultation with a hematologist. Conditions Not Covered: Removed criterion regarding exclusion of repeat administration of Breyanzi.
Oncology (Injectable – CAR-T) – Carvykti - (IP0414)	Update	Effective: 8/1/2024 Multiple Myeloma: Changed patient has received four or more lines of systemic therapy from requirement to option for approval. New option for approval added that the patient has

		received one or more lines of systemic therapy including an immunomodulatory agent and a proteasome inhibitor, and are refractory to lenalidomide.
Oncology – Thalomid (for Non-Oncology Uses) – (IP0493)	Update	Effective: 8/15/2024 All uses with ‘tried’ criteria. Updated formatting to examples of alternatives. Updated title from Thalomid Non-Oncology Uses
Ophthalmology – Dry Eye Disease Cyclosporine Ophthalmic Products - (IP0026)		Effective 8/1/2024 Added diagnosis and age requirements. Updated the Restasis and Restasis Multidose criteria for Employer plans. Updated the Vevye criteria for Employer plans and Individual and Family Plans. Updated and added the Cequa, Restasis and Restasis Multidose criteria for Individual and Family plans. Conditions Not Covered: Miebo was removed from the criterion “Concomitant Use with Another Ophthalmic Cyclosporine Product, Miebo (perfluorohexyloctane ophthalmic solution), Tyrvaya (varenicline nasal spray), or Xiidra (lifitegrast ophthalmic solution)” because Miebo can be used concomitantly with these agents.
Ophthalmology – Dry Eye Disease – Miebo For Individual and Family Plans - (IP0583)	Update	Effective 8/15/2024 Dry Eye Disease: Keratoconjunctivitis sicca was added to the Note of examples of dry eye disease. Updated preferred product criteria by adding an exception for patients with Meibomian gland disease.
Ophthalmology – Dry Eye Disease – Tyrvaya for Individual and Family Plans - (IP0395)	Update	Effective 8/1/2024 IFP added to the policy EMP criteria retired Added diagnosis, age, a previous use of artificial tears and specialist prescribing requirement. Updated preferred product requirements. Conditions Not Recommended for Approval: Miebo was removed from “Concomitant Use With An Ophthalmic Cyclosporine Product, Miebo (perfluorohexyloctane ophthalmic solution), or Xiidra (lifitegrast ophthalmic solution)” because Tyrvaya can be used concomitantly with Miebo.

Ozanimod - (IP0214)	Update	Effective 8/1/2024 Added Zymfentra as a preferred product option, for Ulcerative Colitis, for Employer Plans.
Pharmacy Prior Authorization - (1407)	Update	Effective: 8/1/2024 Added product-specific medical necessity exception criteria for: Aplenzin, Auvelity, Forfivo XL, bupropion hydrochloride 450 mg, Multaq, sitagliptin, Zituvio, baclofen 15 mg, Absorica 10 mg, 20 mg, 25 mg, 30 mg, 35 mg, 40 mg, Absorica LD, isotretinoin 25 mg, 35 mg, doxycycline monohydrate IR 40 mg, Oracea 40 mg
Pompe Disease – Enzyme Replacement Therapy – Lumizyme - (IP0440)	Update	Effective: 8/15/2024 Updated policy title from “Alglucosidase Alfa” to “Pompe Disease – Enzyme Replacement Therapy – Lumizyme.” Acid Alpha-Glucosidase Deficiency (Pompe Disease): Added dosing information. No criteria changes
Pompe Disease – Enzyme Replacement Therapy – Pombiliti - (IP0591)	Update	Effective: 8/15/2024 Updated policy title from “Cipaglucosidase alfa-atga” to “Pompe Disease – Enzyme Replacement Therapy – Pombiliti.” Acid Alpha-Glucosidase Deficiency (Pompe Disease): Confirmation of a genetic mutation in the biallelic acid alpha-glucosidase (GAA) pathogenic variants was rephrased to more specifically state, “genetic test demonstrating biallelic pathogenic or likely pathogenic acid alpha-glucosidase gene variants.” Conditions Not Covered: Removed the criterion regarding concomitant use with other medications used to treat Pompe Disease.
Pompe Disease – Enzyme Stabilization Therapy – Opfolda - (IP0598)	Update	Effective: 8/15/2024 Updated policy title from “Opfolda (miglustat) capsule” to “Pompe Disease – Enzyme Stabilization Therapy – Opfolda.” Acid Alpha-Glucosidase Deficiency (Pompe Disease): Confirmation of a genetic mutation in the biallelic acid alpha-glucosidase (GAA) pathogenic variants was rephrased to more specifically state, “genetic test demonstrating biallelic pathogenic or likely pathogenic acid alpha-glucosidase gene variants.” Conditions Not Covered:

		Removed the criterion regarding concomitant use with other medications used to treat Pompe Disease.
Proleukin for Non-Oncology Uses - (IP0407)	Update	Effective: 8/1/2024 Graft-Versus-Host Disease. Updated initial authorization duration from 4 months to 1 year
Proprotein Convertase Subtilisin Kexin Type 9 Related Products – Leqvio – (IP0380)	Update	Effective 8/15/2024 Updated policy title from Inclisiran to Proprotein Convertase Subtilisin Kexin Type 9 Related Products – Leqvio. All Indications: Clarified “Initial Therapy” versus “Currently Receiving Leqvio” criteria and added additional examples of what is considered a response to therapy; Removed “Use is adjunctive to diet and maximally tolerated statin therapy [unless contraindicated or intolerant”]; Updated the statin intolerance criteria, to clearly define what is considered statin intolerant, with notes and examples also included; Added dosing to the policy; Added a Note: * A patient may have a diagnosis that pertains to more than one FDA-approved indication, therefore, consider review under different approval conditions, if applicable (e.g., a patient with heterozygous familial hypercholesterolemia may have established cardiovascular disease, a patient with primary hyperlipidemia may have heterozygous familial hypercholesterolemia). Heterozygous Familial Hypercholesterolemia: For <u>Initial Therapy</u> , The specialist physician requirement was removed. For the requirement that the patient has had genetic confirmation of heterozygous familial hypercholesterolemia by mutations in the low-density lipoprotein receptor, apolipoprotein B, proprotein convertase subtilisin kexin type 9, or low-density lipoprotein receptor adaptor protein 1 gene was changed to state that the patient has had phenotypic confirmation of heterozygous familial hypercholesterolemia and the above examples moved to a Note. Primary Hyperlipidemia: For <u>Initial Therapy</u> , the specialist physician requirement was removed. Removed “Individual has a coronary artery calcium or calcification score of 100 or greater Agatston units or 75th percentile or greater for the individual’s age, gender and ethnicity [coronary calcium scan may require prior authorization] OR Calculated 10 year ASCVD risk score of 7.5% or higher and replaced with “Patient has a coronary artery calcium or calcification score ≥ 300 Agatston units OR Patient has diabetes”. Added a requirement that “Patient has tried the one high-intensity statin therapy (atorvastatin or rosuvastatin) along with ezetimibe (as a single-entity or as a combination product) for ≥ 8 continuous weeks”. The requirement that the low-density lipoprotein cholesterol level after treatment with one high-intensity statin therapy, along with ezetimibe, be ≥ 100 mg/dL was changed to ≥ 70 mg/dL.

		Established Cardiovascular Disease: The name of the indication was changed to as stated (previously "Atherosclerotic Cardiovascular Disease"). For <u>Initial Therapy</u>, the specialist physician requirement was removed. The requirement that the low-density lipoprotein cholesterol level after treatment with one high-intensity statin therapy be ≥ 70 mg/dL was changed to ≥ 55 mg/dL.
Proprotein Convertase Subtilisin Kexin Type 9 Inhibitors – Praluent – (IP0250)	Update	Effective 8/15/2024 Updated policy title from Alirocumab to Proprotein Convertase Subtilisin Kexin Type 9 Inhibitors – Praluent. All Indications: Clarified "Initial Therapy" versus "Currently Receiving Praluent" criteria and added additional examples of what is considered a response to therapy; Removed "Use is adjunctive to diet and maximally tolerated statin therapy [unless contraindicated or intolerant]"; Updated the statin intolerance criteria, to clearly define what is considered statin intolerant, with notes and examples also included; Updated the preferred product criteria to include an exception for patients between the ages of 8 and 10 years old with heterozygous familial hypercholesterolemia; Added a Note: * A patient may have a diagnosis that pertains to more than one FDA-approved indication, therefore, consider review under different approval conditions, if applicable (e.g., a patient with heterozygous familial hypercholesterolemia or homozygous familial hypercholesterolemia may have established cardiovascular disease, a patient with primary hyperlipidemia may have heterozygous familial hypercholesterolemia). Established Cardiovascular Disease: The name of the indication was changed to as stated (previously "Atherosclerotic Cardiovascular Disease"). For <u>Initial Therapy</u>, the specialist physician requirement was removed. The requirement that the low-density lipoprotein cholesterol level after treatment with one high-intensity statin therapy be ≥ 70 mg/dL was changed to ≥ 55 mg/dL. Heterozygous Familial Hypercholesterolemia: For <u>Initial Therapy</u>, the age of approval was changed from ≥ 18 years of age to ≥ 8 years of age. The specialist physician requirement was removed. For the requirement that the patient has had genetic confirmation of heterozygous familial hypercholesterolemia by mutations in the low-density lipoprotein receptor, apolipoprotein B, proprotein convertase subtilisin kexin type 9, or low-density lipoprotein receptor adaptor protein 1 gene was changed to state that the patient has had phenotypic confirmation of heterozygous familial hypercholesterolemia and the above examples moved to a Note. Homozygous Familial Hypercholesterolemia: For <u>Initial Therapy</u>, the specialist physician requirement was removed. The requirement that the patient has had genetic confirmation by two mutant alleles at the low-density lipoprotein receptor, apolipoprotein B, proprotein

		convertase subtilisin kexin type 9, or low-density lipoprotein receptor adaptor protein 1 gene locus was changed to state that the patient has phenotypic confirmation of homozygous familial hypercholesterolemia and the above examples moved to a Note. The diagnostic criterion which stated that the patient has an untreated low-density lipoprotein cholesterol level > 500 mg/dL was changed to > 400 mg/dL. The criterion (which is in two places [those with an untreated low-density lipoprotein cholesterol level > 400 mg/dL and a treated low-density lipoprotein cholesterol level ≥ 300 mg/dL]) that both parents of the patient had untreated low-density lipoprotein cholesterol levels or total cholesterol levels consistent with heterozygous familial hypercholesterolemia was changed to state that at least one parent of the patient had untreated low-density lipoprotein cholesterol levels or total cholesterol levels consistent with familial hypercholesterolemia. The related Note that “An example of heterozygous familial hypercholesterolemia in both parents would be if both had an untreated low-density lipoprotein cholesterol level ≥ 190 mg/dL and/or an untreated total cholesterol level > 250 mg/dL” was changed to state “An example of familial hypercholesterolemia is an untreated low-density lipoprotein cholesterol level ≥ 190 mg/dL and/or an untreated total cholesterol level > 250 mg/dL.” Primary Hyperlipidemia: For <u>Initial Therapy</u>, the specialist physician requirement was removed. Removed “Individual has a coronary artery calcium or calcification score of 100 or greater Agatston units or 75th percentile or greater for the individual’s age, gender and ethnicity [coronary calcium scan may require prior authorization] OR Calculated 10 year ASCVD risk score of 7.5% or higher and replaced with “Patient has a coronary artery calcium or calcification score ≥ 300 Agatston units OR Patient has diabetes”. Added a requirement that “Patient has tried the one high-intensity statin therapy (atorvastatin or rosuvastatin) along with ezetimibe (as a single-entity or as a combination product) for ≥ 8 continuous weeks”. The requirement that the low-density lipoprotein cholesterol level after treatment with one high-intensity statin therapy, along with ezetimibe, be ≥ 100 mg/dL was changed to ≥ 70 mg/dL.
Proprotein Convertase Subtilisin Kexin Type 9 Inhibitors – Repatha – (IP0195)	Update	Effective 8/15/2024 Updated policy title from Evolocumab to Proprotein Convertase Subtilisin Kexin Type 9 Inhibitors – Repatha. All Indications: Clarified “Initial Therapy” versus “Currently Receiving Repatha” criteria and added additional examples of what is considered a response to therapy; Removed “Use is adjunctive to diet and maximally tolerated statin therapy [unless contraindicated or intolerant”]; Updated the statin intolerance criteria, to clearly define what is considered statin intolerant, with notes and examples also included; Added a Note: * A patient may have a diagnosis that pertains to more than one FDA-approved indication, therefore, consider review under different approval conditions, if applicable (e.g., a patient with heterozygous familial

		hypercholesterolemia or homozygous familial hypercholesterolemia may have established cardiovascular disease, a patient with primary hyperlipidemia may have heterozygous familial hypercholesterolemia). Established Cardiovascular Disease: The name of the indication was changed to as stated (previously "Atherosclerotic Cardiovascular Disease"). For <u>Initial Therapy</u>, the specialist physician requirement was removed. The requirement that the low-density lipoprotein cholesterol level after treatment with one high-intensity statin therapy be ≥ 70 mg/dL was changed to ≥ 55 mg/dL. Heterozygous Familial Hypercholesterolemia: For <u>Initial Therapy</u>, The specialist physician requirement was removed. For the requirement that the patient has had genetic confirmation of heterozygous familial hypercholesterolemia by mutations in the low-density lipoprotein receptor, apolipoprotein B, proprotein convertase subtilisin kexin type 9, or low-density lipoprotein receptor adaptor protein 1 gene was changed to state that the patient has had phenotypic confirmation of heterozygous familial hypercholesterolemia and the above examples moved to a Note. Homozygous Familial Hypercholesterolemia: For <u>Initial Therapy</u>, the specialist physician requirement was removed. The requirement that the patient has had genetic confirmation by two mutant alleles at the low-density lipoprotein receptor, apolipoprotein B, proprotein convertase subtilisin kexin type 9, or low-density lipoprotein receptor adaptor protein 1 gene locus was changed to state that the patient has phenotypic confirmation of homozygous familial hypercholesterolemia and the above examples moved to a Note. The diagnostic criterion which stated that the patient has an untreated low-density lipoprotein cholesterol level > 500 mg/dL was changed to > 400 mg/dL. The criterion (which is in two places [those with an untreated low-density lipoprotein cholesterol level > 400 mg/dL and a treated low-density lipoprotein cholesterol level ≥ 300 mg/dL]) that both parents of the patient had untreated low-density lipoprotein cholesterol levels or total cholesterol levels consistent with heterozygous familial hypercholesterolemia was changed to state that at least one parent of the patient had untreated low-density lipoprotein cholesterol levels or total cholesterol levels consistent with familial hypercholesterolemia. The related Note that "An example of heterozygous familial hypercholesterolemia in both parents would be if both had an untreated low-density lipoprotein cholesterol level ≥ 190 mg/dL and/or an untreated total cholesterol level > 250 mg/dL" was changed to state "An example of familial hypercholesterolemia is an untreated low-density lipoprotein cholesterol level ≥ 190 mg/dL and/or an untreated total cholesterol level > 250 mg/dL." Primary Hyperlipidemia: For <u>Initial Therapy</u>, the specialist physician requirement was removed. Removed "Individual has a coronary artery calcium or calcification score of 100 or
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		greater Agatston units or 75th percentile or greater for the individual's age, gender and ethnicity [coronary calcium scan may require prior authorization] OR Calculated 10 year ASCVD risk score of 7.5% or higher and replaced with "Patient has a coronary artery calcium or calcification score $\geq$ 300 Agatston units OR Patient has diabetes". Added a requirement that "Patient has tried the one high-intensity statin therapy (atorvastatin or rosuvastatin) along with ezetimibe (as a single-entity or as a combination product) for $\geq$ 8 continuous weeks". The requirement that the low-density lipoprotein cholesterol level after treatment with one high-intensity statin therapy, along with ezetimibe, be $\geq$ 100 mg/dL was changed to $\geq$ 70 mg/dL.
Psychiatry – Spravato - (IP0220)	Update	Effective: 8/15/2024 Policy Name Change: Updated Policy Name from "Esketamine" to "Psychiatry – Spravato." Updated initial approval duration to 2 months for Major Depressive Disorder with Acute Suicidal Ideation or Behavior and 6 months for Treatment-Resistant Depression. Added dosing for all FDA Approved Indications. Conditions Not Covered: Removed Anesthetic Use, Bipolar Disorder, Pain Syndromes, and Post-traumatic Stress Disorder.
Pulmonary Arterial Hypertension – Endothelin Receptor Antagonists – (IP0631)	New	Effective 8/15/2024 New stand-alone policy created. The criteria were previously housed in the Pulmonary Hypertension Therapy class policy. Pulmonary Arterial Hypertension (PAH): Updated criteria to include clarification for "Initial Therapy" versus "Patient is Currently Receiving the Requested Endothelin Receptor Antagonist (i.e., ambrisentan [Letairis, generic], Opsumit, or bosentan [Tracleer, generic]) or Opsynvi". Updated confirmation of PAH diagnosis to remove echocardiogram as an option. Added Opsynvi to the Policy, including additional preferred product criteria requirements for Individual and Family Plans. Chronic Thromboembolic Pulmonary Hypertension (CTEPH): Added new criteria for Other Uses with Supportive Evidence for bosentan (Tracleer, generic) including preferred product criteria requirements for the brand name, Tracleer tablets. Digital Ulcers in a Patient with Systemic Sclerosis: Added new criteria for Other Uses with Supportive Evidence for bosentan (Tracleer, generic) including preferred product criteria requirements for the brand name, Tracleer tablets.

		Conditions Not Covered: Added the following statement for Opsynvi, "Concurrent Use with Guanylate Cyclase Stimulators." An example of a guanylate cyclase stimulator was listed in a Note.
Pulmonary Arterial Hypertension – Winrevair - (IP0645)	New	Effective 8/15/2024 New coverage policy
Pulmonary Hypertension (PH) Therapy - (6121)	Update	Effective 8/15/2024 Removed ambrisentan, bosentan, Letairis, Opsumit, Tracleer and relocated to a new stand-alone policy, Pulmonary Arterial Hypertension – Endothelin Receptor Antagonists – IP0631
Repository Corticotropin – Acthar Gel - (IP0178)	Update	Effective: 8/15/2024 Updated policy title from "Repository Corticotropin" to "Repository Corticotropin – Acthar Gel." Infantile Spasms, Treatment: It was added to specify that the formulation of Acthar Gel to be approved for this use is the multidose vial. A Note was added that Acthar Gel single-dose pre-filled SelfJect Injector for subcutaneous use should not be approved. A criterion was added that Acthar is being administered as an intramuscular injection. Added dosing information. Conditions Not Covered: Removed the statement regarding the effectiveness of repository corticotropin (Acthar Gel) not being demonstrated as clinically superior to conventional corticosteroids and/or immunosuppressive therapy for uses other than infantile spasms.
Repository Corticotropin – Cortrophin Gel - (IP0374)	Update	Effective: 8/15/2024 Updated Policy title from "Purified Cortrophin Gel" to "Repository Corticotropin - Cortrophin Gel." Conditions Not Covered: Removed the statement "Purified Cortrophin Gel is FDA approved for the treatment of allergic states, collagen diseases, dermatologic diseases, edematous state, acute exacerbations of multiple sclerosis, respiratory diseases, rheumatoid disorders and ophthalmic diseases; however, there is insufficient clinical efficacy data supporting these uses." Added the following conditions: Ankylosing Spondylitis, Dermatomyositis or Polymyositis, Diabetic Nephropathy, Glomerular Kidney Diseases, Gout, Treatment of Infantile Spasms, Juvenile Idiopathic Arthritis, Lupus Nephritis, Acute Exacerbations of

		Multiple Sclerosis, Ophthalmic Conditions, Psoriatic Arthritis, Rheumatoid Arthritis, and Sarcoidosis.
Scenesse – (IP0159)	Update	Effective: 8/1/2024 Conditions Not Covered. Removed 'Other Photosensitivity Disorders or Photodermatoses (for example, polymorphous light eruption, solar urticaria, drug-induced photosensitivity)'
Sickle Cell Disease – Adakveo – (IP0120)	Update	Effective 8/1/2024 Policy Name Change: Updated Policy Name from "Crizanlizumab-tmca" to "Sickle Cell Disease – Adakveo." Initial Therapy: Replaced the requirement "vaso-occlusive crisis (VOC)" in the previous 12 month period" with "sickle cell-related crisis". Added a note detailing examples of patients ineligible for hydroxyurea therapy. Patient is Currently Receiving Adakveo: Added note with examples of clinical benefit Conditions Not Covered: Removed "Concomitant Oxbryta Therapy."
Sickle Cell Disease – Oxbryta – (IP0119)	Update	Effective: 8/1/2024 Sickle Cell Disease. Added criteria for 'patient is currently receiving Oxbryta' Removed 'Will not be used concurrently with crizanlizumab (Adakveo®)'
Somatostatin Analogs – Lanreotide Products (for Non-Oncology Uses) - (IP0323)	Update	Effective: 8/15/2024 Acromegaly. Removed documentation option of 'Growth hormone suppression testing demonstrating a lack of growth hormone suppression' Removed criteria for Thyroid-stimulating hormone (TSH)-secreting pituitary adenoma from policy Added dosing Preferred Product Preferencing Table.

		Added step through of Somatuline Depot for lanreotide subcutaneous injection (Cipla USA Inc. packager) Updated title from Lanreotide (Non-Oncology Indications)
Somatostatin Analogs – Octreotide Immediate Release Products (for Non-Oncology Uses) - (IP0490)	Update	Effective: 8/15/2024 Removed criteria for: (1) Gastroesophageal variceal hemorrhage, acute, (2) Diarrhea associated with chemotherapy or radiation, (3) Enterocutaneous fistula, (4) Perioperative management of individuals undergoing pancreatic resection (including fistula), (5) Thyroid-stimulating hormone (TSH)-secreting pituitary adenoma, (6) Secretory diarrhea in acquired immune deficiency syndrome (AIDS).
Somatostatin Analogs – Sandostatin LAR Depot (for Non-Oncology Uses) - (IP0489)	Update	Effective: 8/15/2024 Removed criteria for (1) Gastroesophageal variceal hemorrhage, acute, (2) Diarrhea associated with chemotherapy or radiation, (3) Enterocutaneous fistula, (4) Perioperative management of individuals undergoing pancreatic resection (including fistula), (5) Thyroid-stimulating hormone (TSH)-secreting pituitary adenoma, (6) Secretory diarrhea in acquired immune deficiency syndrome (AIDS). Preferred Product Preferencing Table. Removed 'Individual has previously started on or is currently receiving Sandostatin LAR Depot (octreotide acetate) injection' from preferencing table Added step through of somatuline depot for Sandostatin LAR Depot Updated title from Sandostatin LAR Depot (Non-Oncology Indications)
Somatostatin Analogs – Signifor LAR - (IP0165)	Update	Effective: 8/1/2024 Updated coverage policy title from <i>Pasireotide Long-Acting</i> to <i>Somatostatin Analogs – Signifor LAR</i>. Endogenous Cushing's Syndrome: Added this condition and criteria for approval under <i>Other Uses with Supportive Evidence</i>. Endogenous Cushing's Syndrome – Patient Awaiting Surgery: Removed this condition from the policy and is now addressed under Endogenous Cushing's Syndrome. Endogenous Cushing's Syndrome – Patient Awaiting Therapeutic Response After Radiotherapy:

		Removed this condition from the policy and is now addressed under Endogenous Cushing's Syndrome. Endogenous Cushing's Syndrome. Updated initial authorization duration from 4 months to 1 year Endogenous Cushing's Syndrome – Individual Awaiting Surgery: Removed from authorization duration: 'if individual is still awaiting surgery, then reauthorize for 4 months Cushing Disease: Added 'Patient is Currently Receiving Signifor/Signifor LAR' criteria
Thrombocytopenia – Doptelet – (IP0152)	Update	Effective 8/1/2024 Updated policy title to Thrombocytopenia – Doptelet; previously was Avatrombopag Chronic Immune Thrombocytopenia: Updated pre-requisite therapy requirement from "Individual has had an inadequate response to ONE of the following OR Individual has a contraindication or is intolerant to ALL of the following: Systemic corticosteroids, Intravenous immunoglobulin, Anti-D immunoglobulin, Promacta, Nplate, Tavalisse, Rituximab" to now be "Patient has tried at least ONE other therapy" with examples relocated to a Note.
Thrombocytopenia – Mulpleta - (IP0156)	Update	Effective: 8/1/2024 No criteria changes
Thrombocytopenia – Nplate - (IP0155)	Update	Effective 8/1/2024 Thrombocytopenia, Chemotherapy-Induced. Updated '(i) Individual has thrombocytopenia at least 2 weeks after the most recent dose of chemotherapy for 2 week cycle regimens, (ii) Individual has thrombocytopenia at least 3 weeks after the most recent dose of chemotherapy for either 3 or 4 week cycle regimens, TO (a) Patient has thrombocytopenia at least 3 weeks after the most recent dose of chemotherapy; Thrombocytopenia, Chemotherapy-Induced. Updated reauthorization duration from 1 year to 6 months All covered uses; except Hematopoietic Syndrome of Acute Radiation Syndrome. Added 'Patient is Currently Receiving Nplate'

		All covered uses. Added dosing
Topical Retinoids – Aklief - (IP0180)	Update	Effective: 8/1/2024 IFP added to the policy Updated preferred product requirements.
Ublituximab - (IP0545)	Update	Effective: 8/15/2024 Removed exception for patients previously treated with Kesimpta, Lemtrada, Ocrevus or Tysabri from the EMP preferred product approach. Added the "treatment naïve approach" for the IFP preferred product requirements.
Uplizna - (IP0062)	Update	Effective 8/1/2024 • Policy Name Change: ➤ Updated Policy Name from "Inebilizumab" to "Uplizna." • Neuromyelitis Optica Spectrum Disorder: ➤ Added note with examples of clinical benefit from use of Uplizna. Conditions Not Recommended for Approval: Ultomiris (ravulizumab-cwyz intravenous infusion) received FDA approval for treatment of NMOSD and was added to the criterion "Concomitant Use with a Rituximab Product, Enspryng (satralizumab-mwge subcutaneous injection), or Soliris (eculizumab intravenous infusion)."
Weight Loss – Glucagon-Like Peptide-1 Agonists - (IP0206)	Update	Effective: 8/15/2024 Saxenda, Wegovy, and Zepbound Weight Loss, Adult: Initial Therapy and Patient is Continuing on Therapy: Metabolic-dysfunction associated steatotic liver disease (new nomenclature for non-alcoholic fatty liver disease) was added to the list of one of the weight-related comorbidities for a patient with a BMI $\geq$ 27 kg/m2. For the one or more weight-related comorbidity, the criterion was modified to state that the comorbidity is at baseline or current.
Weight Loss – Other Appetite Suppressants and Orlistat - (IP0420)	Update	Effective: 8/15/2024 Updated policy title from "Weight Loss Medications" to "Weight Loss – Other Appetite Suppressants and Orlistat." Medical Necessity Criteria

		Phentermine hydrochloride (Adipex P): Initial therapy: Updated to 3 months from 4 months. Patient is Continuing Therapy: Added note stating that for patients who have not completed 3 months of initial therapy, criterion (1A) must be met. Updated weight loss requirement from $\geq 4\%$ to $\geq 5\%$ of baseline body weight. Contrave: Patient is Continuing Therapy: Added note stating that for patients who have not completed 4 months of initial therapy, criterion (1A) must be met. Updated weight loss requirement from $\geq 4\%$ to $\geq 5\%$ of baseline body weight. Qsymia: Weight Loss, Adult. Initial therapy: Updated to 6 months from 4 months. Patient is Continuing Therapy: Added note stating that for patients who have not completed 6 months of initial therapy, criterion (1A) must be met. Updated weight loss requirement from $\geq 4\%$ to $\geq 5\%$ of baseline body weight. Weight Loss, Pediatric. Initial therapy: Updated to 6 months from 4 months. Patient is Continuing Therapy: Added note stating that for patients who have not completed 6 months of initial therapy, criterion (1A) must be met. Added requirement for a BMI reduction of $\geq 5\%$ from baseline (prior to the initiation of Qsymia). Removed the requirement for BMI in the 85th percentile for age and sex with comorbidities. Removed the requirement for the decrease in BMI percentile for age and weight (taking into account that the individual is increasing in
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		height and will have a different normative BMI from when Qsymia started). Removed the requirement of having a BMI greater than 85th percentile. Orlistat 120 mg (Xenical): Weight Loss, Adult. Initial therapy: Updated to 3 months from 4 months. Patient is Continuing Therapy: Added note stating that for patients who have not completed 3 months of initial therapy, criterion (1A) must be met). Updated weight loss criteria from $\geq 4\%$ to $\geq 5\%$ of baseline body weight Weight Loss, Pediatric. Initial therapy: Updated to 3 months from 4 months. Patient is Continuing Therapy: Added note stating that for patients who have not completed 3 months of initial therapy, criterion (1A) must be met. Removed the requirement for BMI in the 85th percentile for age and sex with comorbidities. Removed the requirement of having a BMI greater than 85th percentile. Conditions Not Covered: Removed treatment of hyperlipidemia in non-obese individuals, binge-eating disorder in non-obese individuals (BMI < 30 kg/m² or < 27 kg/m² with risk factors), and prevention of diabetes in individuals with BMI < 30 kg/m².
Pompe Disease – Enzyme Replacement Therapy – Nexviazyme - (IP0279)	Update	Effective: 8/15/2024 No changes to the criteria

CareAllies Medical Necessity Guideline	New, Updated, or Retired?	Comments
		All above updates apply
Precertification Policy*	New, Updated, or Retired?	Comments
		No updates for August 2024
Reimbursement Policy*	New, Updated, or Retired?	Comments
Bilateral Procedures - (M50)	Update	
Diagnosis Coding Guidelines - (R47)	Update	
Other Coding and Reimbursement Documents	New, Updated, or Retired?	Comments
		No updates for August 2024
ClaimsXten Documents*	New, Updated, or Retired?	Comments
		No updates for August 2024

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