MedStar Family Choice High-Cost Medication PA Criteria

Requires careful review prior to approval and compliance with internal workflow requirements for reporting, tracking and documentation

Disclaimer: Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is on Formulary with PA requirement	**Approval Criteria & Submission Requirements**	**Renewal Criteria**
ADAMTS13 recombinant (**Adzynma**) IV kit **J7171** **NDC: 64764-0130-01** **64764-0135-01** **64764-0140-05** **64764-0145-05** **64764-0515-50**	1. Ordered for an approved indication for use: • Prophylactic or on demand enzyme replacement therapy (ERT) in adult and pediatric patients with congenital (hereditary) thrombotic thrombocytopenic purpura (cTTP). 2. Patient age ≥ 2 years; **AND** 3. Documented diagnosis of (cTTP) confirmed by the following: • Molecular genetic testing showing mutation in the ADAMTS13 gene; **AND** • ADAMTS13 activity testing showing less than 10% of normal activity. 4. Submission of chart notes dated within previous 1 month. 5. Prescribed for Prophylactic OR On Demand ERT, and the following requirements apply (***official labs required***): • **For Prophylactic ERT:** ○ Platelet count > 100,000/µL; **AND** ○ Lactate dehydrogenase (LDH) > 2 times the upper limit of normal (ULN) as defined by laboratory values. • **For On Demand ERT**, the patient must present with the following:	1. Patient meets initial criteria; **AND** 2. Documentation of improved clinical response (e.g., decrease in incidence of acute/subacute TTP events and TTP manifestations, a decreased incidence of supplemental therapy administration, increased platelet count, decrease in LDH level); **AND** 3. Patient has not experienced any treatment-restricting adverse effects; **AND** 4. Dosing is appropriate as per labeling or is supported by compendia. 5. Submission of chart notes updated within previous 3 months. 6. Approval Duration: 3 months

Updated: March 2025

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	○ ≥ 50% drop in platelet count or platelet count < 100,000/µL; **AND** ○ LDH < 2 times the ULN as defined by laboratory values. 6. Ordered by, or in consultation with a Hematologist. 7. Approval Duration: • Prophylactic enzyme replacement therapy (ERT): 3 months • On Demand enzyme replacement therapy (ERT): 2 months	
Alglucosidase alfa (**Lumizyme**) **J0220** **NDC: 58468-0160-01** **58468-0160-02**	1. Ordered for an approved indication for use: • Treatment of late (non-infantile) onset Pompe disease (GAA deficiency). 2. Acid alpha-glucosidase enzyme assay or genetic testing results to support diagnosis. 3. Patient age ≥ 8 years. 4. Patient does not have evidence of cardiac hypertrophy. 5. Prescribed by, or in consultation with a metabolic specialist and/or biochemical geneticist. 6. Approval Duration: 3 months.	1. Submission of chart notes documenting positive response to therapy (e.g., improvement stabilization, or slowing of disease progression for motor function, walking capacity, cardiorespiratory function, decrease in left ventricular mass index). 2. Approval duration: 6 months.
Allogeneic processed thymus tissue–agdc (**Rethymic**) **J3590** **NDC: 72359-0001-01** r	1. Ordered for an approved indication for use: • Transplantation of allogeneic processed thymic tissue-agdc (Rethymic®) may be considered medically necessary for the treatment of congenital athymia based on flow cytometry documenting fewer than 50 naïve T cells/mm3 (CD45RA+, CD62L+) in the peripheral blood or less than 5% of total T cells being naïve in phenotype when one of the following criteria are met: • Patient has congenital athymia associated with one of the following diagnoses:	**Not applicable. Maximum approval, one treatment course per lifetime.**

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	○ FOXN1 deficiency ○ Complete DiGeorge syndrome (cDGS), also referred to as complete DiGeorge anomaly (cDGA) ○ 22q11.2 deletion ○ CHARGE Syndrome AND ○ a circulating T cell count on flow cytometry demonstrating fewer than 50 naïve T cells/mm3 (CD45RA+ CD62L+) in the peripheral blood OR ○ less than 5% of the total T cells being naïve in phenotype. 2. Severe combined immunodeficiency (SCID) has been conclusively ruled out by the absence of SCID-causing genetic defects. 3. Heart surgery is not anticipated within 4 weeks prior to OR 3 months after Rethymic treatment. 4. Patient does not have HIV infection. 5. Patient is not a poor surgical candidate. 6. Patient has not previously received thymus tissue transplantation in their lifetime. 7. Dosage will not exceed a single, one-time dose not to exceed 42 slices (approximately 55,000 mm^2 of Rethymic).	

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Antihemophilia factor VIII (**Xyntha**) **J7185** **NDC:** **58394-0016-03** **58394-0022-03** **58394-0023-03,** **58394-0024-03** **58394-0025-03** **58394-0012-01** **58394-0013-01** **58394-0014-01** **58394-0015-01** r	1. Ordered for an approved indication for use: • treatment of adults and children with hemophilia A for control and prevention of bleeding. 2. Patient does not have von Willebrand's disease, and 3. Patient has one of the following: • Submission of documentation showing failure to meet clinical goals (e.g. continuation of spontaneous bleeds, inability to achieve appropriate trough level) after a trial of three of the following recombinant factor products: Advate, Kogenate FS, Kovaltry, NovoEight, Nuwiq, or Recombinate, OR • Submission of documentation showing history of hypersensitivity to three of the following recombinant factor products: Advate, Kogenate FS, Kovaltry, NovoEight, Nuwiq, or Recombinate, OR 4. Patient is at high risk for the development of inhibitors (e.g., family history of inhibitors and success with product, current treatment less than 50 days, high risk genetic mutation, history of initial intensive therapy > 5 days, or 5. Patient has developed inhibitors, or 6. Patient has undergone immune tolerance induction/immune tolerance therapy. 7. Approval Duration: 3 months due to clinical reporting requirements.	1. Documentation of positive clinical response to Xyntha therapy. 2. Not using for treatment of von Willebrand's disease. 3. Approval Duration: 3 months due to clinical reporting requirements.
Avalglucosidase alfa-ngpt (**Nexviazyme**) **J0219**	1. Ordered for an approved indication for use: • Treatment of patients ≥ 1 year of age with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency.	1. Initial criteria met **AND** 2. Chart notes documenting a positive response to therapy (e.g., improvement, stabilization, or slowing of disease

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NDC: 58468-0426-01 r	2. Patient aged 1 year or older. 3. Documented diagnosis of late-onset acid alpha-glucosidase deficiency (late-onset Pompe disease) established by ONE of the following: a. A laboratory test demonstrating deficient acid alpha-glucosidase activity in a dry blood spot, fibroblasts, lymphocytes, or muscle tissue. b. A molecular genetic test demonstrating biallelic pathogenic or likely pathogenic variants in the GAA gene. 4. Will not be used in combination with other enzyme replacement therapies (i.e., alglucosidase alfa). 5. Patient is not susceptible to fluid volume overload or has an acute underlying respiratory illness or compromised cardiac or respiratory function for whom fluid restriction is indicated. 6. Patient has documented baseline values for FVC and/or 6MWT. 7. Medication prescribed by, or in consultation with, a geneticist, neurologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of lysosomal storage disorders. 8. Quantity limit (max daily dose); 100 mg powder for injection, 23 vials every 14 days. Max units: 2300 mg every 14 days. 9. Initial approval duration is up to 3 months.	progression for motor function, walking capacity, respiratory function, muscle strength). 3. Approval duration: 3 months
Axicabtagene ciloleucel (**Yescarta**) Injection **Q2041**	1. Ordered for an approved indication for use: • treatment of adult patients with large B- cell lymphoma that is refractory to first-line chemotherapy. 2. The treatment facility that dispenses and administers Yescarta is enrolled and complies with the Risk Evaluation	**Not applicable. Maximum approval, one treatment course per lifetime.**

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NDC: **71287-0119-01** **71287-0119-02**	and Mitigation Strategy; AND 3. Patient age ≥ 18 years. 4. Patient has received prior treatment with first-line chemo-immunotherapy and has any of the following B-cell lymphoma sub-types: • Diffuse large B-cell lymphoma (DLBCL) • Primary mediastinal large B-cell lymphoma • High-grade B-cell lymphomas • HIV-related B-cell lymphomas • Monomorphic post-transplant lymphoproliferative B-cell type disorder 5. Patient does not have ANY of the following: • Primary CNS lymphoma • Previous treatment with Yescarta or other CD 19-directed chimeric antigen receptor (CAR) T-cell therapy. • ECOG performance status ≥ 3 (patient is not ambulatory, capable of self-care, or confined to bed or chair more than 50% of waking hours). • Inadequate or unstable kidney, liver, pulmonary, or cardiac function. • Active hepatitis B, active hepatitis C, or clinically active systemic infection. 6. Medication ordered by an Oncologist. 7. Approval duration: 3 months.	
Beremagene geperpavec (**Vyjuvek**)	1. Ordered for an approved indication for use: • Treatment of wounds in patients with diagnosis of dystrophic epidermolysis bullosa (DEB).	1. Patient has previously been treated with Vyjuvek therapy.

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J3401 **NDC: 82194-0510-02** r	2. Patient age ≥ 6 months. 3. Submission of medical records (e.g., chart notes, laboratory values) confirming a mutation in the collagen type VII alpha 1 chain (COL7A1) gene. 4. Patient has at least one recurrent or chronic open wound that meets all of the following: adequate granulation tissue, excellent vascularization AND no evidence of active wound infection. 5. No evidence or history of squamous cell carcinoma. 6. Prescribed by, or in consultation with, a dermatologist with expertise in the treatment of DEB. 7. Dosing is in accordance with FDA approved labeling. 8. Initial authorization limited to no more than 6 months and no more than 26 doses.	2. Patient had a positive clinical response to Vyjuvek therapy (e.g., decrease in wound size, increase in granulation tissue, complete wound closure). 3. Wound(s) being treated to meet all the following criteria: • Adequate granulation tissue • Excellent vascularization • No evidence of active wound infection • No evidence or history of squamous cell carcinoma • Dosing is in accordance with FDA approved labeling. 4. Reauthorization limited to no more than 6 months and no more than 26 doses.
Berotralstat (**Orladeyo**) capsules 110mg, 150mg **J3490, J8499** **NDCs:** **72769-0101-01** **72769-0102-01** r	1. Ordered for an approved indication for use: • prophylaxis to prevent attacks of hereditary angioedema (HAE) in adults and pediatric patients 12 years and older. 2. Patient age ≥ 12 years. 3. C1 inhibitor (C1-INH) antigenic level below the lower limit of normal as defined by the laboratory performing the test OR Normal X1-inh antigenic level and a low C1-INH functional level (functional C1-INH less than 50% or C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test. 4. Prescriber attestation that all baseline evaluations have been done, prophylactic therapy is medically necessary, and no	1. Member meets the criteria for initial approval. 2. Member has experienced a significant reduction in frequency of attacks (≥ 50%) since starting treatment. 3. Member has reduced the use of medications to treat acute attacks since starting treatment. 4. Prescriber attests that patient has had an annual evaluation for the continued need for long-term prophylaxis therapy AND 5. Prescriber attests a recent review of patient's current medication has been

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	contraindications to use. 5. Not used in combination with other approved products indicated for prophylaxis against HAE attacks (i.e., Cinryze, Haegarda, Takhzyro). 6. History of failure to BOTH of the following (document date of trial and list reason for therapeutic failure) Haegarda AND Takhzyro. Alternatively- could be failure of one of the following: Haegarda, Cinryze, Takhzyro. 7. Quantity limit of 1 capsule per day 8. Prescriber is a hematologist, immunologist, or allergist. 9. Initial approval duration: 3 months	completed and there is no concomitant use of P-gp inducers (e.g. rifampin, St John's wort), and dose adjustment has been made based on labeled recommendations for drug interactions if applicable. 6. Approval Duration: 3 months.
Betibeglogene autotemcel (**Zynteglo**) **J3590** **NDC: 73554-3111-01** r	1. Ordered for the treatment: • of adult or pediatric patients with Beta-thalassemia who require regular red blood cell (RBC) transfusions. 2. Patient aged ≥ 5 years and ≤ 50 years. 3. Patient has documented diagnosis of beta-thalessemia (excludes alpha-thalassemia and hemoglobin S/Beta-thalassemia variants) as defined by: • Confirmation by HBB sequence gene analysis showing biallelic pathogenic variants OR • Patient has severe microcytic hypochromic anemia, anisopoikilocytosis with nucleated red blood cells on peripheral blood smear, and hemoglobin analysis that reveals decreased amounts or complete absence of hemoglobin A & increased amounts of hemoglobin F. 4. Patient has transfusion-dependent disease defined as a history of transfusions of at least 100 mL/kg/year of packed	**Not applicable. Maximum approval, one treatment course per lifetime.**

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	red blood cells (RBCs) or with 8 or more transfusions of pRBCs per year in the two years preceding therapy. 5. Patient does **not** have any of the following: • Severely elevated iron in the heart (i.e., patient with cardiac T2* less than 10 msec by magnetic resonance imaging (MRI) • Advanced liver disease as defined by ○ Alanine transferases or direct bilirubin greater than 3 times the upper limit of normal (ULN). ○ Baseline prothrombin time or partial thromboplastin time greater than 1.5 times the ULN suspected of arising from liver disease. • Patients with MRI of the liver with results demonstrating liver iron content ≥ 15 mg/g (unless biopsy confirms absence of advanced disease). • Prior treatment with gene therapy • Prior allogeneic hematopoietic stem cell transplant (HSCT) • Positive for the presence of HIV type 1 or 2. • Prior malignancy or current malignancy (with the exception of adequately treated cone biopsied in situ carcinoma of the cervix uteri and basal or squamous cell carcinoma of the skin) or myeloproliferative or significant immunodeficiency disorder.	

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	• Concurrent use with Reblozyl (luspatercept-aamt subcutaneous injection). 6. Prescribed by hematologist or transplant specialist. 7. Approval: one treatment only.	
blinatumomab (**Blincyto**) Injection 35mcg **J9039** **NDC: 55513-0160-01** r	1. Ordered for an approved indication for use: • B-cell precursor acute lymphoblastic leukemia (ALL) in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1%. • Relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL). 2. Confirmation that drug carries current FDA-approval for indication. All other indications are considered experimental investigational and not medically necessary. 3. Testing or analysis confirming CD19 protein on the surface of the B cell. 4. The medication will be used as consolidation or maintenance therapy OR for relapsed or refractory disease. 5. Medication ordered by an Oncologist or hematologist. 6. Initial authorization limited to 3 months.	1. Clinical documentation (chart notes) for date-of-service within previous 3 months. 2. No evidence of unacceptable toxicity (e.g. Cytokine Release Syndrome (CRS), neurological toxicities, serious infections, pancreatitis etc.) disease progression while on current regimen. 3. Confirmation that drug carries current FDA-approval for indication. 4. Approval Duration: 3 months.
brentuximab (**Adcetris**) injection 50mg **J9042** **NDC: 51144-0050-01**	1. Prescribed for an approved indication for use: • Previously untreated Stage III or IV classical Hodgkin lymphoma (cHL), in combination with doxorubicin, vinblastine, and dacarbazine. • Classical Hodgkin lymphoma (cHL) at high risk of relapse or progression as post-autologous hematopoietic stem cell transplantation (auto-HSCT) consolidation.	1. Clinical documentation submitted for date-of-service within previous 3 months. 2. There is no evidence of unacceptable toxicity or disease progression. 3. Approval duration: 3 months.

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r	• Classical Hodgkin lymphoma (cHL) after failure of auto-HSCT or after failure of at least two prior multi-agent chemotherapy regimens in patients who are not auto-HSCT candidates. • Previously untreated systemic anaplastic large cell lymphoma (sALCL) or other CD30-expressing peripheral T-cell lymphomas (PTCL), including angioimmunoblastic T-cell lymphoma and PTCL not otherwise specified, in combination with cyclophosphamide, doxorubicin, and prednisone. • Systemic anaplastic large cell lymphoma (sALCL) after failure of at least one prior multi-agent chemotherapy regimen. • Primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30- expressing mycosis fungoides (MF) who have received prior systemic therapy. • In combination with lenalidomide and a rituximab product for adult patients with relapsed or refractory large B-cell lymphoma (LBCL), including diffuse B-cell lymphoma (DLBCL) not otherwise specified (NOS), DLBCL arising from indolent lymphoma, or high-grade B-cell lymphoma (HGBL), after two or more lines of systemic therapy who are ineligible for autologous hematopoietic stem cell transplantation (auto-HSCT) or CAR T-cell therapy. 2. Documentation of testing/analysis that confirms CD30 expression on the surface of the cell. 3. For B-cell lymphomas: patient is not a candidate for stem-cell transplant.	

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	4. Determine if patient is an appropriate candidate for Polivy (polatuzumab vedotin),a drug with similar mechanism of action, and is approved for both previously untreated patients and relapse/refractory patients. If patient is appropriate candidate for Polivy, MedStar may request redirect to Polivy. 5. Approval Duration: 3 months.	
burosumab-twza (**Crysvita**) injection 10mg/ml, 20mg/ml, 30mg/ml **J0584** **NDCs:** **69794-0304-01** **69794-0203-01** **69794-0102-01**	1. Ordered for an approved indication for use: • Treatment of X-linked hypophosphatemia (XLH) in adult and pediatric patients ≥ 6 months of age. • Treatment of FGF23-related hypophosphatemia in tumor-induced osteomalacia (TIO) associated with phosphaturic mesenchymal tumors that cannot be curatively resected or localized in adult and pediatric patients ≥ 2 years of age. 2. At least one of the following requirements satisfied: • Genetic testing results confirming pathogenic variant in PHEX (phosphate regulating gene with homology to endopeptidases located on the X chromosome) gene; OR • Genetic testing results confirming a likely pathogenic variant in PHEX gene; OR • Elevated FGF23 levels consistent with X-linked hypophosphatemia (i.e. above the normal reference range for the testing laboratory); OR • Pretreatment tubular reabsorption of phosphate corrected for glomerular filtration rate (TmP/GFR) below the normal range for age and gender. 3. <u>When used for the treatment of XLH:</u> • Elevated Serum fibroblast growth factor 23 (FGF23) level > 30 pg/ml; AND	1. Patient has previously received treatment with burosumab. 2. Patient has documented positive clinical response (e.g., enhanced height velocity, improvement in skeletal deformities, reduction in fractures, reduction in generalized bone pain). 3. Dosing is in accordance with FDA-approved labeling. 4. Authorization is limited to a maximum of 12-months.

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	• Serum phosphate < 3.0 mg/dL (0.97 mmol/L)
	• Serum Creatinine (SCr) below age adjusted upper limit of normal.
	• Serum 25(OH)D ≥ 16 mg/mL;
	• Dosing is in accordance with FDA-approved labeling.
	• If aged 6 months or greater, than the epiphyseal plate has not fused OR
	• All of the following:
	  ○ The patient's epiphyseal plate has fused; AND
	  ○ The patient is experiencing clinical signs and symptoms of the disease such as limited mobility, musculoskeletal pain and/or bone fractures; AND
	  ○ Failure, contraindication, or intolerance to vitamin D analog therapy (e.g., calcitriol, paricalcitiol, doxercalciferol) in combination with an oral phosphate agent (e.g., K-Phos, K-Phos Neutra).
	4. <u>When used for the treatment of TIO:</u>
	• Disease cannot be curatively resected or localized; and
	• Patient is aged 2 years or greater; and
	• Failure, contraindication, or intolerance to vitamin D analog therapy (e.g., calcitriol, paricalcitiol, doxercalciferol) in combination with an oral phosphate agent (e.g., K-Phos, K-Phos Neutra).
	• Dosing in accordance with FDA-approved labeling.
	5. Prescribed by, or in consultation with an endocrinologist,	

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	geneticist, nephrologist or specialist in either XLH or TIO. 6. Approval Duration: up to 12 months.	
c1 Inhibitor [Human] **cinryze** sol 500 unit **J0598** **NDC: 42227-0081-05** r **Haegarda** injection 2000unit, 3000unit **J0599** **NDCs:** **63833-0828-02** **63833-0829-02** r	1. Ordered for an approved indication for use: • Routine prophylaxis to prevent Hereditary Angioedema attacks in patients ≥ 6 years of age. 2. Cinryze will be considered for coverage when **ALL** of the criteria below are met and confirmed with medical documentation. • Diagnosis of hereditary angioedema (HAE) confirmed by one of the following: ○ Confirmed monoallelic mutation known to cause HAE in either the SERPING1 or F12 gene: OR ○ A C4 level below the lower limit of normal and either C1 inhibitor (C1-INH) antigenic level below the lower limit of normal or C1-INH functional level below the lower limit of normal; AND • Used for prophylaxis of acute HAE attacks: AND • Patient is at least 6 years of age; AND • Patient has experienced the following: ○ History of recurrent laryngeal attacks; OR ○ ≥ 2 severe episodes/month (ex. debilitating GI or cutaneous effects); OR ○ ≥ 5 days/month of debilitating symptoms; AND • Prescribed by an allergist, immunologist, hematologist, or other appropriate specialist; AND • Medications known to cause angioedema (ex. ACE-Inhibitors, estrogens, angiotensin II receptor blockers) have been evaluated and discontinued when appropriate.	1. All of the criteria for initial therapy must be met; **AND** 2. Clinical documentation (chart notes) for date-of-service within previous 3 months. 3. Provider attests to a positive clinical response. 4. Approval Duration: 3 months.

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	3. Approval Duration: 3 months when criteria are met.	
cabozantinib (**Cabometyx)** tablets 20mg, 40mg, 60mg **J8999** **e**	1. Ordered for an approved indication for use: • Patients with advanced renal cell carcinoma (RCC) • Patients with advanced renal cell carcinoma, as a first-line treatment in combination with nivolumab • Patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib. • Adult and pediatric patients ≥ 12 years of age with locally advanced or metastatic differentiated thyroid cancer (DTC) that has progressed following prior VEGFR-targeted therapy and who are radioactive iodine-refractory or ineligible (Cometriq). 2. Patients < 19 years of age shall be approved if the conditions above are met. 3. **Non-small cell lung cancer** has additional requirements: • Positive for RET gene rearrangements AND • Disease is either: recurrent, advanced, or metastatic 4. **Hepatocellular Carcinoma** has additional requirement: • History of contraindication, failure, or intolerance to Nexavar (sorafenib tosylate); **OR** • Child-Pugh Class A with unresectable disease **and** patient is not a transplant candidate; **OR** • Child-Pugh Class A **and** patient has metastatic disease or extensive liver tumor burden; **OR** • Child-Pugh Class A **and** patient has liver-confined disease that is inoperable due to performance status, comorbidity, or with minimal/uncertain extrahepatic disease. 5. **Osteosarcoma** has additional requirements:	1. Clinical documentation (chart notes) for date-of-service within previous 3 months. 2. Patient does not show evidence of disease progression while on Cabometyx therapy. 3. Approval Duration is for 12 months.

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	• Patient's disease has progressed on prior treatment; and • Patient has relapsed/refractory disease OR metastatic disease 6. Medication ordered by an Oncologist. 7. Approval Duration: 12 months.	
caplacizumab-yhdp (**Cablivi**) kit 11mg **C9047** **NDC: 58468-0225-01**	1. Ordered for an approved indication for use: • Treatment of adult patients with acquired thrombotic thrombocytopenic purpura (aTTP), in combination with plasma exchange and immunosuppressive therapy. 2. Diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP); **AND** 3. The patient received the requested medication with plasma exchange; **AND** **4.** Cablivi will be given in combination with immunosuppressive therapy; **AND** 5. The patient will not receive Cablivi beyond 30 days from the cessation of plasma exchange unless the patient has documented, persistent aTTP. 6. The patient has not experienced more than 2 recurrences of aTTP while on the requested medicaton. (A recurrence is when the patient needs to reinitiate plasma exchange, a 28-day extension of therapy is not considered a recurrence.) 7. Ordered by, or in consultation with a hematologist. 8. Approval duration: 30 days only.	1. A request for continuation of therapy is for extension of therapy after the initial course of Cablivi. The initial course is treatment with Cablivi during and 30 days after plasma exchange. 2. The patient has either of the following documented signs of persistent, underlying aTTP: • ADAMTS13 activity level of < 10%, **OR** • All of the following: ○ Microangiopathic hemolytic anemia (MAHA) documented by the presence of schistocytes on peripheral smear ○ Thrombocytopenia and ○ Elevated lactate dehydrogenase (LDH) level 3. Cablivi will be given in combination with immunosuppressive therapy. 4. The patient has not received a prior 28-day extension of therapy after the initial course of Cablivi. 5. The patient has not experienced more than

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		2 recurrences of aTTP while on Cablivi. (A recurrence is when the member needs to reinitiate plasma exchange. A 28-day extension of therapy does not count as a recurrence). 6. Approval duration: 28 days.
casimersen (**Amondys 45**) injection 50mg/ml **J1426** **NDC: 60923-0227-02** **r**	1. Ordered for an approved indication for use: • Treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 45 skipping. 2. Confirmed diagnosis of DMD with genetic confirmation of the DMD gene that is amenable to exon 45 skipping. 3. Provider attestation of baseline and subsequent evaluation and monitoring as appropriate such as hypersensitivity reactions and renal function. 4. Be on a stable dose of corticosteroid for ≥ 24 weeks. 5. Not ventilator dependent 6. Not receiving other RNA antisense therapy or gene therapy for DMD. 7. Maximum dose 30 mg/kg/dose once weekly 8. Prescribed by or in consultation with a pediatric neurologist with expertise in DMD. 9. Approval Duration: 3 months.	1. Clinical documentation (chart notes) for date-of-service within previous 3 months. 2. Not receiving other antisense therapy or gene therapy. 3. Not ventilator dependent. 4. Provider attestation of continued benefit without ADE 5. Max dose 30 mg/kg/dose/week 6. Duration: 3 months **<u>Limitations for use:</u>** This indication is approved under accelerated approval based on an increase in dystrophin production in skeletal muscle observed in patients treated with AMONDYS 45. Continued approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials.
Cerliponase alpha (**Brineura**) **J0567**	1. Ordered for an approved indication for use: • To slow the loss of ambulation in symptomatic pediatric patients ≥ 3 years of age with late infantile neuronal ceroid	1. Documentation that the patient's motor domain rating portion of the CLN2 Clinical Rating Score has remained stable or has not declined from baseline.

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NDCs: **68135-0495-04** **68135-0500-00** **68135-0811-02**	lipofuscinosis type 2 (CLN2), also known as tripeptidyl peptidase 1 (TPP1) deficiency. 2. Confirmation of diagnosis by submission of one of the following: • Laboratory testing demonstrating TPP1 enzyme activity; or • Molecular analysis that has detected two pathogenic variants or mutations in the TPP1/CLN2 gene. 3. Patient is age 3 years or older. 4. Meets all of the following scores on the Clinical Scoring System for LINCL:4: • Combined score of 3 to 6 in the motor and language domains • Score of at least 1 in the motor domain • Score of at least 1 in the language domain 5. Documentation indicates that there is ambulatory function that can be preserved (i.e., patient is not immobile). 6. Prescribed by, or in consultation with a neurologist with expertise in the treatment of CLN2. 7. Approval Duration: 6 months.	2. Patient has motor function that can be preserved, that is the patient is ambulatory and not immobile. 3. Approval Duration: 12 months.
Ciltacabtagene autoleucel (**Carvykti**) **Q2056** **NDCs:** **57894-0111-01** **57894-0111-02**	1. Ordered for the treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy including a proteasome inhibitor (e.g., bortezomib, etc), an immunomodulatory agent (e.g., lenalidomide, thalidomide, etc.), an anti-CD38 monoclonal antibody (e.g., daratumumab, isatuximab, etc). 2. Patient is ≥ 18 years of age. 3. Patient has histologically confirmed diagnosis of relapse or refractory multiple myeloma.	**Not applicable. Maximum approval, one treatment course per lifetime.**

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	4. Patient has not received prior CAR-T or B-cell maturation antigen (BCMA) targeted therapy. 5. Patient has not received prior allogeneic hematopoietic stem cell transplant within 6 months prior to therapy. 6. Patient does not have an active infection or inflammatory disorder. 7. Patient has not received live vaccines within 6 weeks prior to the start of lymphodepleting chemotherapy. 8. Patient has been screened for cytomegalovirus (CMV), hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines prior to collection of cells (leukapheresis); 9. Carvykti will be used as a single agent therapy. 10. Patient does not have known central nervous system (CNS) involvement with myeloma or a history or presence of clinically relevant, active, CNS pathology. 11. Patient does not have active or a history of plasma cell leukemia. 12. Approval limited to one dose of up to 100 million autologous CAR-positive viable T-cells.	
Cipaglucosidase-atga (**Pombiliti**) **J1203** **NDC: 71904-0200-01** **71904-0200-02** **71904-0200-03** **r**	1. Ordered for an approved indication for use: • In combination with Opfolda, for the treatment of adult patients with late-onset Pompe disease (lysosomal acid alpha-glucosidase [GAA] deficiency) weighing ≥ 40 kg and who are not improving on their current enzyme replacement therapy (ERT). 2. Patient is ≥ 18 years of age. 3. Patient weight is ≥ 40 kg.	1. Documentation submitted is dated within the previous 3 months. 2. Chart notes show a positive response to therapy (e.g., improvement, stabilization, or slowing of disease progression for motor function, walking capacity, respiratory function, muscle strength). 3. Medication with be taken in combination with Opfolda (miglustat).

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	4. Submission of acid alpha-glucosidase enzyme assay or genetic testing results supporting diagnosis. 5. Patient is not improving on current, first-line enzyme replacement therapy (ERT) (e.g., Lumizyme, Nexviazyme). 6. Opfolda (miglustat) will be given in combination with Pombiliti. 7. Documentation from provider is dated within previous 30 days 8. Approval Duration: 3 months.	4. Approval Duration: 3 months.
Coagulation factor IX (**Benefix**) recombinant **J7195** **NDC: 58394-0633-03** **58394-0634-03** **58394-0635-03** **58394-0636-03** **58394-0637-03** **r**	1. Ordered for an approved indication for use: • treatment of hemophilia B in adults and children for on-demand treatment and control of bleeding episodes or perioperative management of bleeding. Or in patients ≥ 16 years of age as routine prophylaxis to reduce the frequency of bleeding episodes. 2. Diagnosis of congenital factor IX deficiency confirmed by blood coagulation testing. 3. Not prescribed for use for induction of immune tolerance in patients with hemophilia B. 4. When prescribed for routine prophylaxis to prevent or reduce the frequency of bleeding episodes: o Patient must have severe hemophilia B (factor IX level of < 1%; OR o Patient must have at least two documented episodes of spontaneous bleeding into joints. 5. Dose is calculated per manufacturer guidelines:	5. Patient continues to meet all initial criteria. 6. Absence of unacceptable toxicity from the drug and development of neutralizing antibodies (inhibitors). 7. Any increases in dose must be supported by an acceptable clinical rationale (i.e., weight gain, half-life study results, increased breakthrough bleeding when patient is fully adherent to therapy. 8. The cumulative amount of medication the patient has on-hand does not exceed five doses. 9. Renewal approval duration: 3 months

<table>
<tr><th>Generic Medication (Brand Name)
Bolded medication specifies whether Brand or Generic is on Formulary with PA requirement</th><th>Approval Criteria & Submission Requirements</th><th>Renewal Criteria</th></tr>
<tr><td></td><td>
<table>
<tr><th>Indication</th><th>Dose</th></tr>
<tr><td>Control and prevention of bleeding episodes Hemophilia B

And

Perioperative management of Hemophilia B</td><td><u>Calculating the Initial Dose</u>
One unit per kilogram body weight increases the circulating Factor IX level by 1% (IU/dL).
– Adult & Child (≥12 years): Number of Factor IX IU required = body wt (kg) x Desired increase in Plasma Factor IX(percent) x 1.3 IU/kg;
– Child (<12 years): Number of Factor IX IU required = body wt (kg) x Desired increase in Plasma Factor IX(percent) x 1.4 IU/kg
<u>Minor</u>
Circulating Factor IX required (% of normal) = 20-30 IU/dL - Repeat every 12-24 hours as needed for 1-2 days
<u>Moderate</u>
Circulating Factor IX required (% of normal) = 25-50 IU/dL - Repeat every 12-24 hours as needed for 2-7 days
<u>Major</u>
Circulating Factor IX required (% of normal) = 50-100 IU/dL - Consider repeat dose after 12-24 hours as needed for 7- 10 days.</td></tr>
<tr><td>Routine prophylaxis Hemophilia B</td><td>For long term prophylaxis against bleeding, the recommended regimen is 100 IU/kg once weekly.
– Children (<12 years) have lower recovery, shorter half-life and higher clearance (based on per kg body weight) as compared to adolescents and adults.
– Adjust the dosing regimen (dose or frequency) based on the patient's clinical response.</td></tr>
</table>
6. Authorization duration: 3 months</td><td></td></tr>
<tr><td>cysteamine bitartrate (Procysbi)
25mg, 75mg capsules
75mg, 300mg granules

J8499

NDC: 75987-0101-08
r</td><td>1. Ordered for an approved indication for use:
• treatment of nephropathic cystinosis in adults and pediatric patients ≥ 1 years of age.
2. Patient age is ≥ 1 year.
3. Diagnosis of nephropathic cystinosis with documentation of assay detecting increased cystine concentration in leukocytes or genetic testing results supporting diagnosis.
4. Patient will not receive Procysbi in combination with Cystagon.
5. Approval duration: 3 months</td><td>1. Clinical documentation (chart notes) for date-of-service within previous 3 months.
2. Documentation of positive clinical response to Procysbi therapy (e.g., improvement, stabilization, or slowing of disease progression for serum creatinine, calculated creatinine clearance, leukocyte cystine concentration, or maintained growth [height]).</td></tr>
</table>

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is on Formulary with PA requirement	Approval Criteria & Submission Requirements	Renewal Criteria
		3. Absence of hypersensitivity or other adverse reaction. 4. Approval duration: 3 months
Deflazacort (**Emflaza**) **J3490, J8499** **NDC:** **52856-501-01** **52856-502-03** **52856-503-03** **52856-504-03** **52856-505-22**	1. Ordered for an approved indication for use: • treatment of Duchenne muscular dystrophy (DMD) in patients aged 2 years and older. 2. Patient age ≥ 2 years. 3. Patient is biologically male. 4. Prior trial of at least 6 months of continuous use of prednisone/prednisolone equivalent in previous 2 years and experience adverse effect (specifically uncontrolled weight gain). 5. Prescribed by, or in consultation with, a neurologist. 6. Dose limitations: • Tablet: 0.9 mg/kg once daily (round to nearest tablet dose) • Suspension: 0.9 mg/kg once daily (round to nearest tenth of a milliliter) 7. Approval Duration: 3 months	1. Obtain current weight to calculate dose. 2. Verify diagnosis, age, and prescriber specialty. 3. Verify claim for Emflaza in previous 90-days 4. Prescriber attestation of patient's clinical improvement, stabilization of disease, or significant limitation of disease progression (e.g., improved strength and timed motor function, pulmonary function, etc.). 5. Approval Duration: 6 months.
Delandistrogene moxeparvovec (**Elevidys**) **J1413** **NDCs:** **60923-0501-10,** **60923-0502-11** **60923-0503-12,**	1. Prescribed for treatment of Duchenne muscular dystrophy (DMD). 2. Prescribed by, or in consultation with, a pediatric neuromuscular specialist with expertise in the diagnosis of DMD. 3. Submission of medical records confirming both of the following: • A mutation in the DMD gene AND • The mutation is not a deletion in exon 8 or exon 9	**Not applicable. Maximum approval, one treatment course per lifetime.**

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60923-0504-13, **60923-0505-14 ,** **60923-0506-15** **60923-0507-16,** **60923-0508-17,** **60923-0509-18,** **60923-0510-19,** **60923-0511-20,** **60923-0512-21,** **60923-0513-22,** **60923-0514-23,** **60923-0515-24,** **60923-0516-25,** **60923-0517-26,** **60923-0518-27,** **60923-0519-28,** **60923-0520-29,** **60923-0521-30,** **60923-0522-31,** **60923-0523-32,** **60923-0524-33,** **60923-0525-34,** **60923-0526-35,** **60923-0527-36,** **60923-0528-37,** **60923-0529-38,** **60923-0530-39,** **60923-0531-40,** **60923-0532-41,**	4. Patient is aged 4 or 5 years of age. 5. Submission of documentation confirming that the patient is ambulatory without needing an assistive device (e.g., without side-by-side assist, cane, walker, wheelchair, etc.). 6. Patient does not have an elevated anti-AAVrh74 total binding antibody titer ≥ 1:400. 7. Patient will not receive exon-skipping therapies for DMD [e.g., Amondys (casimersen), Exondys 51 (eteplirsen), Viltepso (viltolarsen), Vyondys 53 (golodirsen)] concomitantly or following Elevidys treatment. 8. Patient has never received Elevidys treatment in their lifetime. 9. Dosing in accordance with FDA guidelines: 1.33×10^{14} vector genomes (vg)/kg. 10. Authorization will be issued for no more than one treatment per lifetime and for no longer than 30 days from approval or until 6 years of age, whichever is first.	

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60923-0533-42, **60923-0534-43,** **60923-0535-44,** **60923-0536-45,** **60923-0537-46,** **60923-0538-47,** **60923-0539-48,** **60923-0540-49,** **60923-0541-50,** **60923-0542-51,** **60923-0543-52,** **60923-0544-53,** **60923-0545-54,** **60923-0546-55,** **60923-0547-56,** **60923-0548-57,** **60923-0549-58,** **60923-0550-59,** **60923-0551-60,** **60923-0552-61,** **60923-0553-62,** **60923-0554-63,** **60923-0555-64,** **60923-0556-65,** **60923-0557-66,** **60923-0558-67,** **60923-0559-68,** **60923-0560-69,** **60923-0561-70**		

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Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is on Formulary with PA requirement	Approval Criteria & Submission Requirements	Renewal Criteria
r		
Dinutuximab (**Unituxin**) **J9999** **C9399 (hospital outpt use only)** **NDC: 66302-0014-01**	1. Ordered for an approved indication for use: • Treatment of pediatric patients with high-risk neuroblastoma who achieve at least a partial response to prior first-line multiagent, multimodality therapy; to be used in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF), interleukin-2 (IL-2) and 13-cis-retinoic acid (RA). 2. Patient age < 18 years. 3. Will not be used concurrently with other GD2-binding monoclonal antibodies (e.g., naxitamab, etc). 4. Dosing limitations: Unituxin 17.5 mg/5mL vials: 12 vials q28 days, Maximum units per dose and over time – 52.5 mg per day. 5. Approval Duration: 6 months (5 therapy cycles).	**Not applicable. Maximum approval, one treatment course per lifetime.**
Eculizumab (**Soliris**) injection 10mg/ml **J1300** **NDC: 25682-0001-01** r	1.Ordered for an approved indication for use: • treatment of adult and pediatric patients ≥ 1 month of age with paroxysmal nocturnal hemoglobinuria (PNH). • treatment of adult and pediatric patients ≥ 1 month of age with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy (TMA). • treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR+) antibody positive. • Treatment of neuromyelitis optica spectrum disorder (NMOSD). 2. FDA approved patient age.	1. Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit. 2. **PNH:** • Age ≥ 18 years • Decrease in serum LDH from pre-treatment baseline. • NO dual therapy with another PA medication for PNH (e.g., Empaveli, Fabhalta, or Ultomiris). **aHUS:**

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	3. Documentation to support diagnosis: **PNH:** • Flow cytometric confirmation of PNH type III red cells; AND • Patient had at least one transfusion in the preceding 24 months; OR • Documented history of major adverse thrombotic vascular events from thromboembolism; OR • Patient has high disease activity defined as lactic dehydrogenase (LDH) level ≥ 1.5 times the upper limit of normal with one of the following symptoms: weakness, fatigue, hemoglobinuria, abdominal pain, dyspnea, hemoglobin, 10 g/dL, a major vascular event, dysphagia, or erectile dysfunction. • History of failure to/contraindication or intolerance to Empaveli therapy; • Patient age < 18 years or currently pregnant. **aHUS:** • Common causes of aHUS have been ruled out, including infectious causes of HUS and thrombotic thrombocytopenic purpura (TTP). • Ultomiris is not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS). • Must present with the following symptoms: o Hemoglobin < 10 g/dL o Platlets, 150,000/mm^3 o Documented evidence of hemolysis, such as	• Decrease in serum LDH from pre-treatment baseline. • Patient does not have Shiga toxin E.coli related hemolytic uremic syndrome (STEC-HUS). • NO dual therapy with another PA medication for aHUS (e.g., Ultomiris). **gMG**: • Age ≥ 18 years • Improvement and maintenance of at least a 2-point improvement (reduction) in the MG-ADL score from pre-treatment baseline and reduction of signs and symptoms of MG required to show clinical benefit. • **NOTE:** dose escalation of immunosuppressive therapy, or additional rescue therapy from baseline to treat MG or exacerbation of symptoms during use is considered treatment failure. • Not receiving in combination with Empaveli, Fabhalta, or Ultomiris. **NMOSD:** • Documentation to demonstrate positive clinical response from baseline as demonstrated by both of the following:

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	elevated LDH levels, decreased haptoglobin level or schistocytosis. • Increased serum creatinine OR currently undergoing dialysis. **gMG:** • Patient has not failed previous course of Soliris or Ultomiris therapy; • Positive serologic test for anti-AChR antibodies; AND • One of the following: ○ History of abnormal neuromuscular transmission test demonstrated by single-fiber electromyography (SFEMG) or repetitive nerve stimulation OR ○ History of positive anticholinesterase test (e.g. edrophonium chloride test) OR ○ Pt has demonstrated improvement in MG signs on oral cholinesterase inhibitors as assessed by the treating neurologist; AND • Patient has MGFA clinical classification of II, III, or IV at initiation of treatment; AND • Patient has Myasthenia gravis-specific activities of daily living scale (MG-ADL) total score ≥ 6 at initiation of treatment; AND • One of the following: ○ History of failure to at least two immunosuppressive agents over the previous 12-months (e.g., azathioprine, mtx, cyclosporing, mycophenolate); OR ○ History of failure to at least one immunosuppressive therapy and has required four or more courses of	• Reduction in the number and/or severity of relapses or signs and symptoms of NMOSD; and • Maintenance, reduction or discontinuation of dose(s) of any baseline immunosuppressive therapy prior to starting Soliris. • **NOTE:** dose escalation of immunosuppressive therapy, or additional rescue therapy from baseline to treat MG or exacerbation of symptoms during use is considered treatment failure. • Not receiving Soliris therapy in combination with any of the following: Disease modifying therapies for the treatment of MS (e.g., Gilenya, Tecfidera, Ocrevus, etc.); Anti-IL6 therapy (e.g., Actemra, Enspryng), B-cell depletion therapy (e.g., rituximab, Uplizna). • Approval Duration: 3 months.

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	plasmapheresis/plasma exchanges, and/or intravenous immune globulin over the previous 12 months without symptom control; AND
	NMOSD:
	• Documentation to support diagnosis of NMOSD by a neurologist confirming:
	  ○ Optic neuritis; or
	  ○ Acute myelitis; or
	  ○ Area postrema syndrome: episode of otherwise unexplained hiccups or nausea and vomiting; or
	  ○ Acute brainstem syndrome; or
	  ○ Symptomatic cerebral syndrome with NMOSD-typical brain lesions; AND
	• Positive serologic test for anti-aquaporin-4 immunoglobulin G (AQP4-IgG)/NMO-IgG antibodies; and
	• Diagnosis of multiple sclerosis or other diagnoses have been ruled out; and
	• Patient has not failed a previous course of Soliris therapy; and
	• History of failure of, contraindication, or intolerance to rituximab therapy; and
	• History of at least two relapses in the previous 12-months; or
	• History of at least three relapses during the previous 24-months, at least one relapse withing the previous 12-months; and
	• Not receiving Soliris therapy in combination with any of the following: Disease modifying therapies for the treatment of	

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	MS (e.g., Gilenya, Tecfidera, Ocrevus, etc.); Anti-IL6 therapy (e.g., Actemra, Enspryng), B-cell depletion therapy (e.g., rituximab, Uplizna). 4. Recommended vaccinations at least 2 weeks prior to administration of first dose Soliris. 5. Cannot be used in combination with other medications in the same class, such as Ultomiris. 6. Medication ordered by Hematologist, Nephrologist, or Oncologist. 7. Approval Duration: 3 months	
Efgartigimod alfa-fcab (**Vyvgart**) I.V. injection 400mg/20ml **J9332** **NDC: 73475-3041-05** **Vyvgart Hytrulo - SQ** Efgartigimod alfa and hyaluronidase **J9334** **NDC:**	1. Ordered for an approved indication for use: • Treatment of adult patients with anti-acetylcholine receptor antibody positive (AChR+) generalized myasthenia gravis (gMG) as monotherapy or in combination with glucocorticoids in patients with glucocorticoid-resistant or glucocorticoid-dependent disease. 2. Patient age ≥ 18 years. 3. Patient has Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of Class II, III, or IV at initiation of therapy. 4. MG activities of daily living (MG-ADL) total score of ≥ 5. 5. Documentation of positive serologic test for anti-AChR antibodies. 6. Greater than 50% of baseline MG-ADL score is due to non-ocular symptoms.	1. Clinical documentation (chart notes) for date-of-service within previous 3 months. 2. Patient continues to meet initial approval criteria. 3. Patient has absence of toxicity to drug. 4. Patient has had an improvement (reduction) of at least 2-points from baseline in the Myasthenia Gravis-Specific Activities of Daily Living (MG-ADL) total score sustained for at least 4-weeks; and 5. Improvement in muscle strength testing with fatigue maneuvers as evidenced on neurologic examination when compared to baseline; and 6. Patient requires continuous treatment, after an initial beneficial response, due to new or worsening disease activity (Note: a minimum of 50 days must have elapsed

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73475-3102-03	7. Patient is currently receiving a stable dose of at least one gMG treatment (including cholinesterase inhibitors, corticosteroids, or non-steroidal immunosuppressants). 8. Documentation of patient's current weight for appropriate dosing. 9. Trial and failure, contraindication or documentation of intolerance to at least two of the following: • Rituximab or biosimilar (e.g., truxima) • Cyclophosphamide • Azathioprine • Mycophenolate mofetil 10. Not currently prescribed with other immunomodulatory therapies (e.g., eculizumab (Soliris)) 11. Medication ordered by or in consultation with a neurologist. 12. Approval Duration: 3 months	from the start of the previous treatment cycle). 7. Approval Duration: 3 months
Elacestrant (**Orserdu**) **J3490, J9999** **NDC:** **72187-0101-03** **72187-0102-03**	1. Ordered for an approved indication for use: • Treatment of postmenopausal women or adult men, with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative, *ESR1*-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy. 2. For patient aged < 19 years of age: • If criteria in #1 are met, approval shall be granted for 12 months. For patients ≥ 19 years of age: • Diagnosis of breast cancer that is either advanced or metastatic.	1. Clinical documentation (chart notes) for date-of-service within previous 3 months. 2. Patient does not show evidence of progressive disease while on Orserdu therapy. 3. Approval Duration: 12 months.

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	• The cancer is ER+, HER2(-) and has a confirmed *ESR1* gene mutation. • Patient is either male or a postmenopausal female. • Disease has progressed following at least one line of endocrine therapy. 3. Authorization Duration: 12 months.	
elapegademase-lvlr (**Revcovi**) Injection 1.6mg/ml **J3590, J3490** **NDC: 57665-0002-01** **r**	1. Ordered for an approved indication for use: • treatment of adenosine deaminase severe combined immune deficiency (ADA-SCID) in pediatric and adult patients. 2. Diagnosis of ADA-SCID confirmed by genetic testing. 3. Patient has failed bone marrow transplantation or is not a candidate for bone marrow transplantation. 4. Dose does not exceed 0.4 mg/kg per week. 5. Patient aged 3 months or older. 6. Prescribed by or in consultation with an immunologist. 7. Approval duration: 3 months	1. Patient continues to meet initial approval criteria. 2. Dose does not exceed 0.4 mg/kg per week. 3. Patient is responding positively to therapy (e.g., improvement in immune function (T cell, B cell, and natural killer lymphocytes; reduction in frequency/severity of opportunistic infections and decrease from baseline or maintenance of normal red cell dATP levels. 4. Approval duration limited to 3 months.
Elivaldogene autotemecel (**Skysona**) **J3590** **NDC: 73554-2111-01** **r**	1. Ordered for an approved indication for use: • To slow the progression of neurologic dysfunction in male patients aged 4 to 17 years with early, active cerebral adrenoleukodystrophy (CALD). Early, active CALD refers to asymptomatic or mildly asymptomatic (neurological function score ≤ 1) boys who have gadolinium enhancement on brain MRI and Loes scores of 0.5-9. 2. Patient is a male aged 4 to 18 years of age. 3. Diagnosis documented and defined by one or more of the following:	**Not applicable. Maximum approval, one treatment course per lifetime.**

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	○ Elevated very long chain fatty acids (VLCFA) value for ALL of the following: • Concentration of C26: 0 • Ratio of C24: 0 to C22: 0 • Ratio of C26: 0 to C22: 0 **OR** ○ Pathogenic variants in the ABCD1 gene detected by molecular genetic testing; AND 4. Patient has active CNS disease established by central radiographic review of brain MRI demonstrating both: • Loes score between 0.5 and 9 (inclusive) on a 34-point scale; and • Gadolinium enhancement on MRI of demyelinating lesions, and 5. Neurologic Function Score (NFS) ≤ 1 (asymptomatic or mildly symptomatic disease). 6. Patient does not have a full ABCD1-gene deletion. 7. Patient does not have trauma induced disease. 8. Patient is eligible to undergo hematopoietic stem cell transplant (HSCT) and has not had a prior allogeneic-HSCT. 9. Approval for one time only.	
Elosulfase alfa (**Vimizim**) injection 5mg/5ml **J1322** **NDC: 68135-0100-01** **r**	1. Ordered for an approved indication for use: • for patients with Mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome). 2. Documented diagnosis of MPS IVA with biochemical/genetic confirmation by one of the following: • Absence or marked reduction in N-acetylgalactosamine 6-sulfatase (GALNS) enzyme activity; OR • Sequence analysis and/or deletion/duplication analysis of	1. Clinical documentation (chart notes) for date-of-service within previous 3 months. 2. Documented clinically significant improvement or stabilization in symptoms 3. Approval Duration: 3 months

Generic Medication (Brand Name) **Bolded** medication specifies whether Brand or Generic is on Formulary with PA requirement	Approval Criteria & Submission Requirements	Renewal Criteria
	the GALNS gene for biallelic mutation. 3. Age ≥ 5 years. 4. Dosing and administration: 1.2 mg/kg IV over 3.5-4.5 hours once weekly. 5. Initial approval duration: 3 months	
Elranatamab-bcmm (**Elrexfio**) **J1323** **NDC:** **00069-2522-01** **00069-2522-02** **00069-4494-01** **00069-4494-02** **63539-0252-01** **63539-0252-02**	1. Ordered for an approved indication for use: • Treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. 2. Patient is aged 18 years or older. 3. Patient has received at least four prior therapies, including ALL of the following: • Proteasome inhibitor • Immunomodulatory agent • Anti-CD38 monoclonal antibody, and 4. Prescriber is certified with the Elrexfio REMS program. 5. Chart notes submitted are for a date of service within the previous 3 months. 6. Approval Duration: 3 months due to clinical reporting requirements.	1. Clinical documentation (chart notes) for date-of-service within previous 3 months. 2. Patient shows **no** disease progression or unacceptable toxicity. 3. Approval Duration: 3 months due to clinical reporting requirements.
Emicizumab (**Hemlibra**) **J7170** **NDC: 50242-0920-01**	1. Ordered for an approved indication for use: • Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients ages newborn or older with hemophilia A (congenital factor VIII deficiency) with or without factor VIII inhibitors. 2. Documented diagnosis of Hemophilia A; AND	1. Documentation with a date of service within previous 3 months that shows a positive clinical response to Hemlibra therapy. 2. Requested dose meets suggestion under "Least Wastage" when using the manufacturer provided dosing calculator

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50242-0921-01 **50242-0922-01** **50242-0923-01** **50242-0927-01** **50242-0930-01** r	3. Prescribed for the prevention of bleeding episodes (i.e., routine prophylaxis). 4. Chart notes submitted are for a date of service within the previous 3 months. 5. Requested dose meets suggestion under "Least Wastage" when using the manufacturer provided dosing calculator tool found at: https://www.hemlibra-hcp.com/dosing-and-administration/dosing-calculator.html 6. Ordered by, or in consultation with a Hematologist. 7. Approval Duration: 3 months due to clinical reporting requirements.	tool found at: https://www.hemlibra-hcp.com/dosing-and-administration/dosing-calculator.html 3. Ordered by, or in consultation with a Hematologist. 4. Approval Duration: 3 months due to clinical reporting requirements.
Epcoritamab **(Epkinly)** **J9321** **NDC:** **82705-0002-01** **82705-0010-01**	1. Ordered for an approved indication for use: • Treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from indolent lymphoma, and high-grade B-cell lymphoma after two or more lines of systemic therapy. 2. Verify indication continues to be approved by FDA. 3. Patient is ≥ 18 years of age. 4. Patient has diagnosis of CD20+ relapsed or refractory diffuse large B-cell lymphoma (DLBCL), including DLBCL arising from indolent lymphoma and high-grade B-cell lymphoma (HGBL) 5. Patient has received two or more prior lines of therapy, including at least one anti-CD20 monoclonal antibody. 6. Patient is using Epkinly as a single agent. 7. Patient has Eastern Cooperative Oncology Group (ECOG) status of 0-2 (i.e. ambulatory and capable of all self-care but	1. This indication is approved under accelerated approval based on response rate and durability of response. Please verify continued FDA approval for indication. 2. Patient continues to meet initial approval criteria such as monotherapy requirements, etc. 3. Clinical documentation for date-of-service within previous 3 months that patient shows positive clinical response as defined by stabilization of disease or decrease in size of tumor or tumor spread. 4. Patient has not experienced unacceptable toxicity from the drug (e.g., serious infections, cytokine release syndrome (CRS), or immune effector cell-associated

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	unable to work, up and about > 50% of waking hours or better). 8. Patient does NOT have CNS involvement of lymphoma. 9. Patient does not have ongoing active infection. 10. Patient does not have known impaired T-cell immunity. 11. Approval Duration: 6 months.	neurotoxicity syndrome (ICANS), serious tumor flare, etc.). 5. Approval Duration: 6 months
Etranacogene dezaparvocec (**Hemgenix**) **J1411** **NDCs: 0053-0099-01, 0053-0100-10, 0053-0110-11, 0053-0120-12, 0053-0130-13, 0053-0140-14 , 0053-0150-15, 0053-0160-16, 0053-0170-17, 0053-0180-18, 0053-0190-19, 0053-0200-20, 0053-0210-21, 0053-0220-22, 0053-0230-23, 0053-0240-24, 0053-0250-25, 0053-0260-26, 0053-0270-27, 0053-0280-28, 0053-0290-29, 0053-**	1. Ordered for an approved indication for use: • Treatment of adults with Hemophilia B (congenital Factor IX deficiency) who: ○ Currently use Factor IX prophylaxis therapy, or ○ Have current or historical life-threatening hemorrhage, or ○ Have repeated, serious spontaneous bleeding episodes. 2. Patient is ≥ 18 years of age. 3. Has either both: • Diagnosis of severe hemophilia B and • Documentation of endogenous Factor IX levels less than 1% of normal Factor IX (< 0.01 IU/ml); **OR** ALL of the following: • Diagnosis of moderately severe hemophilia B; and • Documentation of endogenous Factor IX levels ≥ 1% ≤ 2%; and • One of the following: ○ Current of historical life-threatening hemorrhage; or ○ Repeated, serious spontaneous bleeding episodes. AND	**Not applicable. Maximum approval, one treatment course per lifetime.**

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0300-30, 0053-0310-31, 0053-0320-32, 0053-0330-33 , 0053-0340-34, 0053-0350-35, 0053-0360-36, 0053-0370-37, 0053-0380-38, 0053-0390-39, 0053-0400-40, 0053-0410-41, 0053-0420-42, 0053-0430-43, 0053-0440-44, 0053-0450-45, 0053-0460-46, 0053-0470-47, 0053-0480-48 **r**	4. One of the following: • Patient currently uses Factor IX prophylaxis therapy; or • Patient has been determined an appropriate candidate for Hemgenix by the Hemophilia Treatment Center based on willingness to adhere to initial and long-term monitoring and management; AND 5. Patient has had a minimum of 150 exposure days to a Factor IX agent; and 6. Patient does not have a history of inhibitors to Factor IX ≥ 0.6 Bethesda units (BU); and 7. Patient does not screen positive for active Factor IX inhibitors as defined as ≥ 0.6 BU prior to administration of Hemgenix; and 8. Patient has not gone through Immune Tolerance Induction (ITI); 9. Liver health assessments including enzyme testing ALT, AST, ALP, total bilirubin and hepatic ultrasound and elastography are performed to rule out radiological liver abnormalities and/or sustained liver enzyme elevations; and 10. Documentation that the patient has been evaluated for the presence of preexisting neutralizing antibodies to the adenovirus vector (e.g., AAV-5) used to deliver therapy; and 11. Patient has had pre-existing anti-AAV5 neutralizing antibodies measured through the laboratory developed, CLIAvalidated AAV5 Neutralizing Antibody Test1 made available through CSL Behring; and	

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	12. Patient does not have high anti-AAV antibody (e.g., AAV-5) titers that may be associated with a lack of response to treatment. 13. Patient is HIV negative; or if patient is HIV+, and is virally suppressed with anti-viral therapy (i.e., < 200 copies of HIV per mL) and the patient's hepatitis B surface antigen is negative. 14. Patient's hepatitis C antibody is negative; OR if HCV antibody+, then HCV RNA is negative; and 15. Patient is not currently using antiviral therapy for Hep B or C; 16. Patient has not previously received treatment with Hemgenix and 17. Hemgenix will be administered within a Hemophilia Treatment Center (HTC) that holds Federal designation and is listed within the CDC's HTC directory; and 18. Dosed in accordance with the FDA-approved labeling; and 19. Authorization is for not longer than 45-days from approval and is limited to once per life-time.	
evinacumab-dgnb (**Evkeeza**) injection 345mg/2.3ml, 1200mg/8ml **J1305** **NDCs:** **61755-0010-01** **61755-0013-01** **r**	1. Ordered for an approved indication for use: • An adjunct to other low-density lipoprotein-cholesterol (LDL-C) lowering therapies for the treatment of adult and pediatric patients, ≥ 12 years of age, with homozygous familial hypercholesterolemia (HoFH). 2. Documented genetic test confirming homozygous familial hypercholesterolemia (HoFH). 3. Baseline laboratory information required (full lipid panel, genetic testing, negative pregnancy test and documentation	1. Meets all initial criteria. 2. Must provide documentation of laboratory information to support continued use (full lipid panel) and continued use of concurrent therapies to lower cholesterol with date-of-service within previous 3 months. 3. Renewal Approval Duration: 3 months

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	of use/counseling regarding contraception to prevent pregnancy 4. Prior trial/failure and/or documented intolerance to one high potency statin (atorvastatin, rosuvastatin) and concurrent ezetimibe. • Must provide laboratory data to support failure/intolerance (full lipid panel, creatinine kinase). • If failure, but no intolerance, lipid lowering therapy should be continued with aa statin and/or ezetimibe. 5. Dosing 15 mg/kg IV every 4 weeks. 6. Initial Approval Duration: 3 months.	
Exagamglogene autotemcel (**Casgevy**) **J3590** **NDC:** **51167-0290-01** **51167-0290-09**	1. Ordered for an approved indication for use: • Treatment of sickle cell disease (SCD) in patients ≥ 12 years of age with recurrent vaso-occlusive crises (VOCs). 2. Patient age ≥ 12 years. 3. Patient had inadequate response, intolerable side effects, or contraindication to hydroxyurea; AND 4. Patient has experienced at least four vaso-occlusive crises in the previous 24 months; AND 5. Patient is clinically stable and able to undergo myeloablative conditioning and hematopoietic stem cell transplantation; AND 6. Patient does not have a known 10/10 human leukocyte matched related donor willing to participate in an allogeneic hematopoietic stem cell transplant; AND 7. Patient has not previously received allogeneic hematopoietic stem cell transplantation; AND 8. Patient has not previously received gene therapy; AND	**Not applicable. Maximum approval, one treatment course per lifetime.**

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	9. Patient does not have a prior or current history of malignancy or immunodeficiency disorder (with the exception of non-melanoma skin cancers or an immediate family member with a known or suspected Familial Cancer Syndrome; AND 10. Patient does not have advanced liver disease (e.g., liver cirrhosis, active hepatitis, significant fibrosis, liver iron concentration ≥ 14 mg/g); AND 11. Patient does not have evidence of CKD; AND 12. Patient does not have history or presence of Moyamoya disease; AND 13. Patient does not have any of the following: • HIV-1 or HIV-2 • Hepatitis C (HCV) OR undetectable hepatitis C viral load if patient is positive for HCV antibodies. • Hepatitis B (HBV) unless one of the following: ▪ Patient has received previous hepatitis B vaccination AND has negative markers of Hepatitis B ▪ Patient has previous HVB exposure AND is negative for HBV DNA 14. Prescribed by, or in consultation with, a hematologist or transplant specialist. 15. Approval: one-time, single-dose treatment	
factor VIIa, recombinant human (**NovoSeven RT**) injection 1mg, 2mg, 5mg, 8mg	1. Ordered for an approved indication for use: • treatment of bleeding episodes and perioperative management in adults and children with hemophilia A or B with inhibitors, congenital Factor VII (FVII) deficiency, and Glanzmann's thrombasthenia with refractoriness to platelet transfusions, with or without antibodies to	1. Patient continues to meet indication-specific criteria and chart notes submitted are for a date-of-service within the previous 3 months. 2. Absence of unacceptable toxicity from drug; and

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J7189 **NDC: 00169-7201-01** **r**	platelets. • treatment of bleeding episodes and perioperative management in adults with acquired hemophilia. 2. Diagnosis of congenital factor VIII deficiency confirmed by blood coagulation testing. 3. Confirmation that patient has acquired inhibitors to Factor VIII 4. Used as treatment in at least one of the following: • Control and prevention of acute bleeding episodes; or • Perioperative management; or • Routine prophylaxis to prevent or reduce the frequency of bleeding episodes when the following criteria are also met: ○ Patient has at least two documented episodes of spontaneous bleeding into joints; or ○ Patient has documented trial and failure of Immune Tolerance Induction (ITI). 5. When ordered for Hemophilia B: • Diagnosis of congenital Factor IX deficiency has been confirmed by blood coagulation testing; and • Confirmation that patient has acquired inhibitors to Factor IX. 6. When ordered for Congenital Factor VII Deficiency: • Diagnosis confirmed by blood coagulation testing. 7. When ordered for Glanzmann's Thromboasthnia: • Diagnosis confirmed by blood coagulation testing; and • The use of platelet transfusions is known or suspected to be ineffective or contraindicated. 8. Medication ordered by, or in consultation with a	3. Any dose increases must be supported by an acceptable clinical rationale (i.e., weight gain, half-life study results, increase in break-through bleeding when patient is fully adherent to therapy, etc). 4. The cumulative amount of medication that the patient has on-hand will be considered. The authorization will allow up to 5 doses on hand for the treatment of acute bleeding episodes as needed for the duration of the authorization. 5. Renewal duration: 3 months.

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	Hematologist. 9. Approval Duration: • For perioperative management of bleeding: 1 month. • All other indications: up to 3 months.	
Factor VIII, recombinant human with VWF fusion **(Altuviiio)** **J7214** **NDCs:** **71104-0978-01** **71104-0979-01** **71104-0980-01** **71104-0981-01** **71104-0982-01** **71104-0983-01** **71104-0984-01** r	1. Ordered to treat an approved indication: • Routine prophylaxis to reduce the frequency of bleeding episodes. • On-demand treatment and control of bleeding episodes • Perioperative management of bleeding Altuviiio is not indicated for the treatment of von Willebrand disease. 2. Diagnosis of hemophilia A. 3. Patient is not a suitable candidate for treatment with shorter acting half-life Factor VIII (recombinant) products [e.g., Advate, Kogenate FS, Kovaltry, Novoeight, Nuwiq, or Recombinate] as attested by the prescribing physician. 4. Both of the following: (1) Dose does not exceed 50 IU/kg - AND- Patient is infusing no more frequently than every 7 days. 5. Authorization of therapy will be issued for 3 months.	1. Documentation of positive clinical response to Altuviiio therapy and chart notes have a date-of-service within 3 months of request. 2. Dose does not exceed 50 IU/kg 3. Patient is infusing no more frequently than every 7 days. 4. Duration of therapy will be issued for 3 months.
factor VIII, recombinant human pegylated (**Jivi**) injection 500 unit, 1000unit, 2000unit, 3000unit **J7208**	1. Ordered for an approved indication for use: • On-demand treatment and control of bleeding episodes in adults and adolescents ≥ 12 years with hemophilia A. • Perioperative management of bleeding. • Routine prophylaxis to reduce the frequency of bleeding episodes. 2. Patient age is ≥ 12 years; AND 3. Patient has diagnosis of hemophilia A; AND	1. Documentation of positive clinical response to Jivi therapy with chart notes having a date-of-service within the previous 3 months. 2. Chart documentation submitted is for date-of-service within previous 3 months. 3. Patient is not receiving routine infusions more frequently than 2 times per week.

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NDC: 00026-0426-02 **00026-3942-XX** **00026-3944-XX** **00026-3946-XX** **00026-3948-XX** **00026-4942-XX** **00026-4944-XX** **00026-4946-XX** **00026-4948-XX** r	4. Patient has previously received Factor VIII replacement therapy; AND 5. Not for the treatment of von Willebrand disease; AND 6. Patient is not a suitable candidate for treatment with a shorter acting half-life Factor VIII (recombinant) products [Advate, Kogenate FS, Kovaltry, Novoeight, Nuwiq, or Recombinate] as attested by the prescriber; AND 7. Patient is not to receive routine infusions more frequently than 2 times per week. 8. Chart documentation submitted is for date-of-service within previous 3 months. 9. Medication ordered by a Hematologist. 10. Authorization Duration: 3 months.	4. Authorization Duration: 3 months.
Factor VIII rec, Fc fusion prot (**Eloctate**) **J7205** **NDC:** **71104-0801-01** **71104-0802-01** **71104-0803-01** **71104-0805-01** **71104-0806-01** **71104-0807-01** **71104-0808-01** **71104-0809-01** **71104-0810-01**	1. Ordered for an approved indication for use: • Treatment of adults and children with Hemophilia A (congenital Factor VIII deficiency) for: ○ On-demand treatment and control of bleeding episodes. ○ Perioperative management of bleeding; ○ Routine prophylaxis to reduce the frequency of bleeding episodes. 2. Patient is not being treated for von Willebrand disease. 3. Patient is not a suitable candidate for treatment with shorter acting half-life Factor VIII products (e.g., Novoeight) as attested by the prescribing physician. 4. Dose does not exceed 50 IU/kg **AND** 12.5 IU/kg/day **AND** patient is infusing no more frequently than every 4 days **UNLESS**:	1. Documentation of positive response to Eloctate therapy by submission of chart notes having a date-of-service within the previous 3 months. 2. Dosing is within guidelines for initial authorization. 3. Approval Duration: 3 months.

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r	5. Patient is less than 6 years of age; and • Pharmacokinetic testing (PK) results suggest that dosing more intensive than 50 IU/kg is required: OR • PK testing results suggest that dosing more frequent than every 3.5 days is required; OR • PK testing results suggest that dosing more intensive than 14.5 IU/kg/day is required. 6. Authorization duration: 3 months.	
Fosdenopterin (**Nulibry**) injection 9.5mg **J3490** **NDC: 73129-0001-01**	1. Ordered for an approved indication for use: • To reduce mortality risk in patients with molybdenum cofactor deficiency (MoCD) Type A. • Diagnosis confirmed by genetic testing. 2. Will not be used in combination with other substrate replacement therapy (e.g., recombinant cyclic pyranopterin monophosphate, etc.); AND 3. Must be prescribed by, or in consultation with, a specialist in medical genetics or pediatric neurology. 4. Diagnosis of MoCD Type A is confirmed by molecular genetic testing, by a mutation in the *MOCS1* gene suggestive of disease. 5. Patient has biochemical features suggestive of MoCD Type A (i.e., elevated sulfites in urine, low serum uric acid, elevated urinary xanthine and hypoxanthine) and will be treated presumptively while awaiting genetic confirmation; and 6. Patient has baseline values for the following: • Elevated urinary s-sulfocysteine (SSC) normalized to creatinine; and • Clinical notes regarding signs and symptoms of	1. Patient continues to meet initial approval criteria as listed. 2. Absence of unacceptable toxicity from the drug (e.g., severe phototoxicity, clinically significant infection) as evidenced by chart notes submitted with a date-of-service within the previous 3 months. 3. Disease response compared to pre-treatment baseline as evidenced by the following: • Reduction in urinary SSC normalized to creatinine; and • Stabilization or improvement in one or more signs and symptoms of disease including, but not limited to, seizure frequency/duration, growth, achievement of developmental milestones; OR

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r	disease which may include, but are not limited to, seizure frequency/duration, growth, and developmental milestones. 7. Approval Duration: 3 months	4. Patient initiated therapy as an inpatient based on presumptive diagnosis of MoCD Type A which was subsequently confirmed by genetic testing; AND patient is responding to therapy compared to one or more pre-treatment baseline parameters which prompted the workup for MoCD. 5. Approval Duration: 3 months
Givosiran (**Givlaari**) **J0223** **NDC: 71336-1001-01** r	1. Ordered for an approved indication for use: • Treatment of adults with acute hepatic porphyria (AHP). 2. Diagnosis of acute hepatic AHP (i.e., acute intermittent porphyria, hereditary coproporphyria, variegate porphyria, ALA dehydratase deficient porphyria. 3. One of the following: • Patient has active disease as defined in the clinical trial by having at least two documented porphyria attacks within the previous 6 months; or • Patient is currently receiving treatment with prophylactic hemin to prevent porphyria attacks; and 4. Provider attestation that the patient's baeline (pre-treatment) hemin administration requirements and rate and/or number of porphyria attacks has been documented; and 5. Patient has not had a liver transplant; and 6. Patient will not receive concomitant prophylactic hemin treatment while on Givlaari; and	1. Patient has previously received Givlaari for the treatment of AHP; and continues to meet initial approval criteria. 2. Documentation that the patient has experienced a positive clinical response by submission of chart notes with a date-of-service within the previous 3 months, while on Givlaari by demonstrating all of the following from pre-treatment baseline: • Reduction in hemin administration requirements. • Reduction in the rate and/or number of porphyria attacks • Improvement in signs and symptoms of AHPs (pain, neurological, gastrointestinal, renal, quality of life, etc). 3. Authorization Duration: 3 months.

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	7. Prescribed by, or in consultation with, a hematologist, or a specialist with expertise in the diagnosis and management of AHPs; and 8. Dosing is in accordance with FDA-approved labeling. 9. Authorization Duration: 3 months.	
Glofitamab (**Columvi**) **J9286** **NDC:** **50242-0125-01** **50242-0127-01**	1. Ordered for an approved indication for use: • Treatment of adult patients with relapsed or refractory large B-cell lymphoma, not otherwise specified (DLBCL, NOS) or large B-cell lymphoma (LBCL) arising from follicular lymphoma, after two or more lines of systemic therapy. 2. Verify that FDA indication has continued approval for use. 3. Patient ≥ 18 years of age. 4. Patient has relapsed or refractory disease, and has been previously treated with at least two prior lines of systemic therapy. 5. Patient does not have clinically significant active systemic infection. 6. Patient does not have primary CNS lymphoma or CNS involvement of disease. 7. Patient has not received a prior allogeneic hematopoietic stem cell transplant (HSCT). 8. Patient does not have a history of refractoriness to Obinutuzumab and will be pretreated with Obinutuzumab prior to treatment with glofitamab. 9. Patient will receive tumor lysis syndrome prophylaxis during therapy (e.g., anti-hyperuricemics and adequate hydration). 10. Approval Duration: 6 months.	1. This indication is approved under accelerated approval based on response rate and durability of response. Please verify continued FDA approval for indication. 2. Patient continues to meet initial approval criteria such as concomitant therapy requirements, etc. 3. Clinical documentation that patient shows positive clinical response as defined by stabilization of disease or decrease in size of tumor or tumor spread. 4. Patient has not experienced unacceptable toxicity from the drug (e.g., serious infections, cytokine release syndrome (CRS), or immune effector cell-associated neurotoxicity syndrome (ICANS), serious tumor flare, etc.). 5. Approval Duration: 6 months not to exceed 12 treatment cycles total per lifetime.

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glycerol phenylbutyrate (**Ravicti**) Liquid 1.1grams/ml **J8499** **NDC: 75987-0050-06** r	1. Ordered for an approved indication for use: • chronic management of patients with urea cycle disorders (UCDs) who cannot be managed by dietary protein restriction and/or amino acid supplementation alone. 2. Confirmed diagnosis of urea cycle disorders (UCD's) as evidenced by plasma ammonia concentration of 150 micromole/L or higher associated with a normal anion gap and a normal plasma glucose concentration; and molecular genetic testing or measurement of enzyme activity. 3. Verification that requested drug still carries FDA approval for indication 4. Age ≥ 2 years of age. 5. Patient must have tried and failed Buphenyl® as evidenced by unmanaged chronic hyperammonia over a 12-month period. 6. Patient must have history of inadequate response to either dietary protein restriction or amino acid supplementation AND must be actively on dietary protein restriction. 7. Prescriber is a geneticist or other experienced clinician familiar with the management of UCD's. 8. Authorization Duration: 3 months.	1. All initial criteria are met; and 2. Verification that Ravicti maintains FDA approval for requested indication; and 3. Documentation of positive clinical response to Ravicti therapy by submission of chart notes with a date-of-service within the previous 3 months; and 4. Patient is actively on dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements) 5. Approval Duration: 3 months.
Golodirsen (**Vyondys 53**) injection 100mg/2ml **J1429** **NDC: 60923-0465-02**	1. Ordered for an approved indication for use: • treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. 2. Genetic testing must confirm patient's DMD gene is amenable to exon 53 skipping.	1. All initial criteria are met; and 2. Patient has experienced a benefit from therapy, is tolerating therapy, AND medical records documenting that the patient is maintaining ambulatory status by submission of chart notes with a date-of-service within the previous 3 months.

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r	3. Patient is older than 6 years of age or older, but age ≤ 15 years at therapy initiation. 4. Be on stable dose of corticosteroid for ≥ 24 weeks; and 5. Not ventilator dependent; and 6. Not receiving other RNA antisense therapy or gene therapy for DMD. 7. Baseline renal function test (GFR) and Urine protein-to-creatinine ratio prior to starting treatment. 8. Documented baseline function testing using a tool to demonstrate physical functions, including, but not limited to: Brooke Upper Extremity Scale, Baseline 6-minute walk test, Pediatric Evaluation of Disability Inventory. 9. Prescribed by or in consultation with a neurologist with expertise in DMD. 10. Maximum dose 30 mg/kg/dose once weekly. 11. Initial authorization period: 3 months.	**3. Total course of therapy has not exceeded 12 months.** 4. Approval Duration: 3 months
Human plasma-derived plasminogen (**Ryplazim**) **J2998** **NDCs:** **70573-0099-01** **70573-0099-02**	1. Ordered for an approved indication for use: • Treatment of patients with plasminogen deficiency type 1 (hypoplasminogenemia). 2. Patient has symptomatic internal or external lesions consistent with plasminogen deficiency Type 1 (i.e., ligeneous conjunctivitis, ligeneous gingivitis, and/or pseudomembranous lesions on mucus membranes (middle ear, respiratory tract, GI tract); and 3. The patient's baseline (pre-treatment) plasminogen activity has been assessed; and	1. The patient continues to meet the criteria for initial approval. 2. The patient has at least one of the following as evidenced by the submission of chart notes with a date-of-service within the previous 3 months: • At least a 10% increase in plasminogen activity from baseline. • At least a 50% improvement in symptomatic internal or external lesion numbers or size from baseline; or

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r	4. Prescribed by, or in consultation with, a specialist in the area of the patient's diagnosis (e.g., ophthalmologist, specialist from a hemophilia and thrombosis treatment center). 5. Approval Duration: 3 months.	• Information has been provided to support the continued use of Ryplazim. 3. Approval Duration: 3 months.
idecabtagene vicleucel (**Abecma**) injection **Q2055** **NDCs:** **59572-0515-01** **59572-0515-02** **59572-0515-03**	1. Ordered for an approved indication for use: • To treat relapsed or refractory multiple myeloma in adults after ≥4 prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. 2. Verification that product continues to carry FDA-approved indication for use. 3. Lymphodepleting chemotherapy (with fludarabine and cyclophosphamide) is ordered for administration for 3 days followed by Abecma dose infusion 2 days after completion of lymphodepleting therapy. 4. Diagnosis of relapsed or refractory multiple myeloma (MM) 5. Age ≥ 18 years 6. Must have received at least 4 prior MM therapies (induction with or without hematopoietic stem cell transplant with or without maintenance therapy is considered a single regimen) 7. Must have received an immunomodulatory drug (iMiD), proteasome inhibitor (PI), and an anti-CD38 antibody 8. ECOG performance status of 0 or 1 9. HBV, HCV, and HIV screening within previous 30 days. 10. Provider attestation: Drug specific baseline evaluation and monitoring completed according to package insert (CBC/CMP, screening for HBV, hepatitis C, HIV), patient is not	**Not applicable. Maximum approval, one treatment course per lifetime.**

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	pregnant and is using effective contraception, counseling/assessment of recent live vaccine use. 11. Monitor immunoglobulin levels, blood counts, and for cytokine release syndrome during and after therapy. 12. Patient has not received prior CAR-T or B-cell maturation antigen (BCMA) targeted therapy. 13. Patient has not received prior allogeneic hematopoietic stem cell transplant. 14. Medication ordered by Hematologist or Oncologist enrolled in ABECMA REMS and compliance with REMS program criteria. 15. Approval Duration: 1 treatment course, cannot be renewed.	
idursulfase (**Elaprase**) injection 6mg/3ml **J1743** **NDC: 54092-0700-01**	1. Ordered for an approved indication for use: • Patients with Hunter syndrome (Mucopolysaccharidosis II, MPS II). 2. Patient age ≥ 16 months; and 3. Patient has absence of severe cognitive impairment. 4. Diagnosis confirmed by one of the following: • Deficient iduronate 2-sulfatase (I2S) enzyme activity in white cells, fibroblasts, or plasma in the presence of normal activity of at least one other sulfatase; OR • Detection of pathogenic mutations in the IDS gene by molecular genetic testing; AND 5. Documented baseline value for urinary glycosamnoglycan (uGAG); and 6. Documented baseline values for one or more of the following: • **Patients ≥ 5 years of age:** 6-minute walk test (6-MWT), percent predicted forced vital capacity (FVC), joint	1. Patient meets criteria for initial approval; and 2. Absence of unacceptable toxicity from the drug (e.g., anaphylactic reactions, antibody development, acute respiratory complications, etc.) as evidenced by submission of chart notes with a date-of-service within the previous 3 months; and 3. Patient does not have progressive or irreversible severe cognitive impairment. 4. Patient has documented reduction in uGAG levels; 5. Patient has demonstrated positive clinical response to therapy compared to pre-treatment baseline in one or more of the following:

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	range of motion, left ventricular hypertrophy, quality of life (CHAQ/HAQ/MPS HAQ); or • **Patients < 5 years:** spleen volume, liver volume, FVC, and/or 6-MWT. 7. Approval Duration: 12 months	• **Patients ≥ 5 years:** stabilization or improvement in percent predicted FVC and/or 6-MWT, increased joint range of motion, decreased left ventricular hypertrophy, improved growth, improved QOL; OR • **Patients < 5 years:** spleen volume, and/or liver volume or stabilization/improvement in FVC and/or 6-MWT. 6. Approval Duration: 12 months.
imiglucerase (**Cerezyme**) injection 400 unit **J1786** **NDC: 58468-4663-01**	1. Ordered for an approved indication for use: • Treatment of adults and pediatric patients 2 years of age and older with Type 1 Gaucher disease that results in one or more of the following conditions: anemia, thrombocytopenia, bone disease, hepatomegaly, or splenomegaly. • Administration under the supervision of a health care provider experienced in the treatment of Gaucher disease. 2. Diagnosis of Type 1 Gaucher disease confirmed by enzyme assay demonstrating a deficiency of beta-glucocerebrosidase enzyme activity or by genetic testing. 3. Symptoms of one of the following complications associated with Type 1 Gaucher disease: • Anemia • Thromobocytopenia • Bone disease • Hepatomegaly	1. Patient meets criteria for initial approval. 2. Patient has documentation of beneficial response (e.g., reduced severity or resolution of anemia, thrombocytopenia, bone disease, hepatomegaly or splenomegaly. 3. Patient is not experiencing an inadequate response or any intolerable adverse events from therapy. 4. Approval Duration: 12 months.

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	• Splenomegaly 4. Patient ≥ 2 years of age. 5. Quantity limited to no more than three times weekly administration. 6. Approval Duration: 12 months.	
interferon gamma-1b (**Actimmune)** injection 2 million IU/0.5ml **J9216** **NDCs:** **75987-0111-11** **75987-0111-10** **r**	1. Ordered for an approved indication for use: • To reduce frequency and severity of serious infections associated with chronic granulomatous disease (CGD). • To delay time to disease progression in patients with severe, malignant osteopetrosis (SMO). 2. Patient age is less than 19 years. 3. When prescribed for: • Chronic Granulomatous Disease (CGD); • Osteopetrosis; or • Primary Cutaneous Lymphomas when the patient has a diagnosis of: ○ Mycosis fungoides (MF) or ○ Sezary Syndrome (SS) 4. Approval Duration: 3 months.	1. Patient does not show evidence of progressive disease while on Actimmune. 2. Reauthorization is for 3 months. 3. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.
Ipilimumab (**Yervoy**) injection 50mg, 200mg **J9228** **NDC: 00003-2328-22**	1. Ordered for an approved indication for use. 2. Patient is at least 18 years of age. 3. Criteria as outlined below for specific indications. **<u>Ampullary Adenocarcinoma:</u>** • Patient disease is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) disease; and • Used in combination with nivolumab; and used as first-line therapy for unresectable or metastatic intestinal type disease or used as subsequent therapy for disease	1. Patient continues to meet requirements of initial approval. 2. Absence of unacceptable toxicity. 3. Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread. **4. COVERAGE CAN NOT BE RENEWED FOR THE FOLLOWING INDICATIONS:** • Ampullary Adenocarcinoma

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	progression. **<u>Biliary Tract Cancers (Gallbladder Cancer or Intra/Extra-hepatic Chloangiocarcinoma</u>** • Patient has tumor mutational burden-high (TMB-H) [≥ 10 mutations/megabase (mut/Mb)] disease as determined by an FDA-approved or CLIA-compliant test; and • Used as subsequent treatment for progression on or after systemic treatment for unresectable, resected gross residual (R2), or metastatic disease; and • Used in combination with nivolumab. **<u>Bone Cancer</u>** • Patient has one of the following: Ewing sarcoma, Chondrosarcoma (excluding mesenchymal chondrosarcoma), Osteosarcoma, or Chordoma; and • Patient has TMB-H disease as determined by FDA-approved or CLIA-compliant test; and • Used in combination with nivolumab; and • Patient has unresectable or metastatic disease that progressed following prior treatment; and • Patient has no satisfactory alternative treatment options. **<u>CNS Cancer</u>** • Used for the treatment of brain metastases in patients with BRAF non-specific melanoma; and • Used as initial treatment in patients with small asymptomatic brain metastases; or • Relapsed limited brain metastases with either stable systemic disease or reasonable systemic treatment options; or	• Colorectal Cancer • Appendiceal Adenocarcinoma • CNS metastases from Melanoma • Hepatocellular Carcinoma • Renal Cell Carcinoma • Cutaneous Melanoma (either 1st line or subsequent therapy or adjuvant therapy in combination with nivolumab). • Small Bowel Adenocarcinoma • Uveal Melanoma **5. COVERAGE RENEWABLE IF THE PATIENT HAS NOT EXCEEDED A MAXIMUM OF TWO YEARS OF THERAPY:** • Biliary Tract Cancer • Bone Cancer • Esophageal and Esophagogastric/Gastroesophageal Junction Cancer • Kaposi Sarcoma • Malignant Peritoneal Mesothelioma • Malignant Pleural Mesothelioma • Non-Small Cell Lung Cancer 6. Cutaneous Melanoma (single agent adjuvant treatment – maintenance therapy is limited to a maximum of three years of therapy.

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	• Recurrent extensive brain metastases with stable systemic disease or reasonable systemic treatment options. **Colorectal Cancer** • Patient is at least 12 years of age; and • Has MSI-H or dMMR disease; and • Patient has not previously received treatment with a checkpoint inhibitor (e.g., nivolumab, pembrolizumab, etc.; • Used in combination with nivolumab*; AND • Used as subsequent therapy; AND • Patient has metastatic, unresectable, or medically inoperable disease, OR • Used as primary treatment; AND • Used as neoadjuvant therapy for clinical T4b colon cancer; or • Used as neoadjuvant therapy of resectable liver and/or lung metastases, OR • Used for isolated pelvic/anastomotic recurrence of rectal cancer, OR • Patient has metastatic, unresectable, or medically inoperable disease; or • Single agent nivolumab should be used in patients who are not candidates for intensive therapy. **Cutaneous Melanoma**	

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	• Used as a first line therapy for unresectable or metastatic disease in combination with nivolumab; OR
	• Used as initial therapy for limited resectable local satellite/in-transit recurrence AND used as a single agent in patients with previous exposure to anti-PD-1 therapy; OR
	• Used as subsequent therapy for unresectable or metastatic disease; AND
	  ○ Used after disease progression or maximum clinical benefit from BRAF-targeted therapy (e.g., dabrafenib/trametinib, vemurafenib/cobimetinib, encorafenib/binimetinib, etc); and
	  ○ Used as a single agent in patients of at least 12 years of age if not previously used along or in combination with anti-PD-1 immunotherapy; OR
	  ○ In combination with nivolumab if not previously used for patients who progress on a single agent anti-PD-1 therapy; OR
	  ○ In combination with pembrolizumab, if not previously used, for patients who progress on single agent anti-PD-1 therapy; OR
	• Used as reinduction therapy in patients who experienced disease control from prior use, but subsequently have disease progression/relapse > 3 months following treatment discontinuation; or
	• Used as a single agent for adjuvant therapy; and
	  ○ Patient has pathologic involvement of regional lymph nodes of more than 1 mm and has	

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	undergone complete resection including total lymphadenectomy; OR ○ Patient has prior exposure to anti-PD-1 therapy (e.g., nivolumab or pembrolizumab); AND • Patient has local satellite/intransit recurrence and no evidence of disease after complete excision; or • Patient has undergone complete therapeutic lymph node dissection and/or complete resection of nodal recurrence; OR • Patient has oligometastatic disease and no evidence of disease following metastasis-directed therapy or systemic therapy. **<u>Appendiceal Adenocarcinoma – Colon Cancer</u>** • Patient has MSI-H or dMMR disease; and • Patient not previously treated with a checkpoint inhibitor (e.g., nivolumab, pembrolizumab, etc.); and • Used in combination with nivolumab and a candidate for intensive therapy; and • Used for advanced or metastatic disease. **<u>Esophageal Cancer and Esophagogastric/Gastroesophageal Junction Cancers</u>** • Patient has esophageal squamous cell carcinoma (ESCC); and • Patient not previously treated with a checkpoint inhibitor; • Used as a first-line treatment in combination with nivolumab; • Patient is not a surgical candidate or has unresectable	

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	advanced, recurrent, or metastatic disease. **Hepatocellular Carcinoma** • Used in combination with nivolumab; and • Used as subsequent therapy for progressive disease; and • Patient has Child-Pugh Class A hepatic impairment; and • Patient was previously treated with sorafenib; or • Patient has unresectable disease and is not a transplant candidate; or • Patient has liver-confined disease that is inoperable by performance status, comorbidity, or with minimal or uncertain extrahepatic disease; or • Patient has metastatic disease or extensive liver tumor burden. **Kaposi Sarcoma** • Used in combination with nivolumab as subsequent therapy; • Patient has classic disease; and • Used for relapsed/refractory advanced cutaneous, oral, visceral, or nodal disease; and • Disease has progressed on or not responded to first-line therapy and has progressed on an alternate first-line therapy. **Renal Cell Carcinoma (RCC)** • Used in combination with nivolumab for clear cell histology; AND • First line therapy in patients with advanced, relapsed or stage IV disease with poor or intermediate risk; OR • First line therapy in patients with relapsed or stage IV	

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	disease with favorable risk; OR • Subsequent therapy in patients with relapsed or stage IV disease. **Malignant Peritoneal Mesothelioma (MPeM)** • Used in combination with nivolumab; and • Used as subsequent therapy (if chemotherapy was administered first line); OR • Used as first line therapy AND patient has unresectable diffuse disease; OR • Patient has unresectable recurrent benign multi-cystic or well-differentiated papillary disease. • May also be used for pericardial mesothelioma and tunica vaginalis testis mesothelioma. **Malignant Pleural Mesothelioma (MPM)** • Used in combination with nivolumab; and • Used as subsequent therapy (if chemotherapy was administered first line); OR • Used as first line therapy AND patient has stage IIIB or IV disease; OR • Patient has sarcomatoid or biphasic histology; OR • Disease is medically inoperable or unresectable; OR • Patient has stage I-IIIA disease with epithelioid histology and did not receive induction therapy. • May also be used for pericardial mesothelioma and tunica vaginalis testis mesothelioma. **Uveal Melanoma** • Patient has metastatic or unresectable disease. **Merkel Cell Carcinoma**	

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	• Used for M1 disseminated disease; and • Patient progressed on anti-PD-L1 or anti-PD-1 therapy OR anti-PD therapies are contraindicated. **<u>Non-Small Cell Lung Cancer (NSCLC)</u>** If first line therapy, one of the following criteria: • Patients with a performance status (PS) of 0-1 who have tumors that are negative for actionable molecular biomarkers and PD-L1 < 1% • Patients with PS 0-1 who are positive for one of the following biomarkers: EGFR exon 20, KRAS G12C, BRAF V600E, NTRK 1/2/3 gene fusion, MET exon 14 skipping, or RET rearrangement. • PD-L1 expression positive (PD-L1 ≥ 1%) tumors, as detected by an approved FDA or CLIA compliant test that are negative for actionable molecular biomarker AND used in combination with nivolumab +/- platinum-doublet chemotherapy. If used as subsequent therapy, one of the following criteria: • Patients with PS 0-1 who received prior targeted therapy for one of the following molecular biomarkers: EGFR S768I, L861Q, and/or G719X, or ROS1 rearrangement. • Patients with PS 0-1 who are positive for one of the following molecular biomarkers BRAF V600E, NTRK 1/2/3 gene fusion, MET exon 14 skipping, or RET rearrangement; AND • Used in combination with nivolumab +/- pemetrexed and either carboplatin or cisplatin for non-squamous cell histology.	

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	Small Bowel Adenocarcinoma (SBA) • Patient has advanced or metastatic disease that is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); and • Patient has not previously received treatment with a check-point inhibitor (e.g., nivolumab, pembrolizumab, etc); and • Used as initial therapy in combination with nivolumab; OR • Used as subsequent therapy for patients with no prior oxaliplatin exposure in the adjuvant treatment setting and no contraindication to oxaliplatin therapy. **Soft Tissue Sarcoma** • Used in combination with nivolumab • Used as subsequent therapy • Patient has no satisfactory treatment alternatives • Patient has myxofibrosarcoma, undifferentiated pleomorphic sarcoma (UPS), dedifferentiated liposarcoma, cutaneous angiosarcoma, or undifferentiated sarcomas **OR** • Patient has tumor mutational burden-high (TMB-H) [≥ 10 mutations/megabase (mut/Mb)] disease as determined by an FDA-approved or CLIA-compliant test. 4. Medication ordered by an Oncologist. 5. Approval Duration: 6 months.	
Iptacopan (**Fabhalta**) **J8499**	1. Ordered for an approved indication for use: • Treatment of adults with paroxysmal nocturnal hemoglobinuria (PNH). 2. Patient aged ≥ 18 years.	1. Documentation of positive clinical response to Fabhalta therapy as evidenced by increased or stabilization of hemoglobin levels, reduction in

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NDC: 00078-1189-20 r	3. Submission of medical records documenting the diagnosis of PNH as confirmed by both of the following: • Flow cytometry analysis confirming presence of PNH clones; **AND** • Laboratory results, signs, and/or symptoms attributed to PNH (e.g., abdominal pain, anemia, dyspnea, extreme fatigue, smooth muscle dystonia, unusual thrombosis, hemolysis, hemoglobinuria, kidney disease, PAH, etc.) 4. One of the following: • Will not be concurrently prescribed with another complement inhibitor used for the treatment of PNH (e.g., Empaveli, Soliris, Ultomiris, etc.); **OR** • Patient is currently receiving another complement inhibitor which will be discontinued and Fabhalta will be initiated in accordance with FDA approved labeling. 5. Prescribed by, or in consultation with a Hematologist or Oncologist. 6. Approval Duration: 3 months due to clinical reporting requirements.	transfusions, improvement in hemolysis decrease in LDH, increased reticulocyte counts, etc with a date-of-service within the previous 90-days. 2. Patient is not receiving Fabhalta in combination with another complement inhibitor used for the treatment of PNH (e.g., Empaveli, Soliris, Ultomiris). 3. Prescribed by, or in consultation with a Hematologist or Oncologist. 4. Updated office visit notes within previous 3 months. 5. Approval Duration: 3 months due to clinical reporting requirements.
Inavolisib (**Itovebi**) 3 mg, 9 mg tablets **NDC: 50242-0079-08** **50242-0079-86** **50242-0084-08**	1. Ordered for an approved indication for use: • The treatment of adults with endocrine-resistant, PIK3CA-mutated, hormone-receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, **locally advanced or metastatic cancer**, as detected by an FDA-approved test, when used in combination with palbociclib and fulvestrant, following recurrence on or after completing adjuvant endocrine therapy. 2. Patient is ≥ 18 years of age; AND	1. Documentation of positive clinical response as defined as: no evidence of unacceptable toxicity or disease progression while on current regimen. 2. Initial criteria continue to be met, (e.g. inavolisib is concurrently administered in conjunction with palbociclib and fulvestrant; pre- and peri-menopausal females and males are administered

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	3. Meets one of the following: • Patient is a post-menopausal female, or • Patient is a pre- or peri-menopausal female, or a male that meets ONE of the following: ○ Patient is receiving a gonadotropin-releasing hormone (GnRH) agonist, (e.g. leuprolide IM injection, triptorelin pamoate IM injection, goserelin SQ injection); OR ○ Patient has had surgical bilateral oophorectomy or ovarian irradiation (females) or orchiectomy (males). 4. Patient has locally advanced or metastatic hormone receptor (HR)-positive disease; AND 5. Patient has human epidermal growth factor receptor 2 (HER2)-negative disease; AND 6. Patient has PIK3CA-mutated breast cancer as confirmed by an FDA-approved test; AND 7. Patient meets <u>one</u> of the following: • Patient has disease progression while on adjuvant endocrine therapy; OR • Patient has had disease recurrence within 12 months after completing adjuvant endocrine therapy (e.g. tamoxifen, anastrozole, letrozole, exemestane, toremifene); AND 8. Itovebi will be used in combination with palbociclib and fulvestrant. 9. Pre-treatment optimization of blood glucose has occurred and A1c lab results within previous 30 days. 10. Dosing is in accordance with FDA-approved labeling.	luteinizing hormone-releasing hormone (LHRH) agonist in accordance with local clinical practice). 3. Patient has not experienced fasting glucose > 500 mg/dL twice within 30 days, which requires permanent drug discontinuation. 4. A1c is monitored no less than every 3 months. 5. Patient has not experienced Grade 4 stomatits, Grade 4 diarrhea, or any other Grade 4 adverse effect as defined in the package insert. 6. Approval Duration: 12 months.

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	11. Prescribed by or in consultation with an oncologist. 12. Approval Duration: 3 months.	
Lanadelumab-flyo (**Takhzyro**) injection 300mg/2ml **J0593** **NDC: 47783-0644-01** **r**	1. Ordered for an approved indication for use: • hereditary angioedema (HAE) prophylaxis in adult and pediatric patients ≥ 12 years of age. 2. Prescribed by or in consultation with a specialist in allergy, immunology, hematology, pulmonology, or medical genetics. 3. Patient aged 12 years or older. 4. History of one of the following criteria for long-term HAE prophylaxis: • History of two or more severe HAE attacks per months (i.e., airway swelling, debilitating cutaneous or GI episodes. • Patient is disabled by HAE more than 5 days per month. • History of at least one laryngeal attack caused by HAE AND 5. Treatment with "on-demand" therapy (e.g., Kalbitor, Firazyr, Ruconest or Berinert) did not provide satisfactory control or access to "on-demand therapy is limited" AND 6. Not used in combination with C1 inhibitor prophylaxis (e.g., Cinryze, Haegarda, or Orladeyo) AND 7. Confirmation that patient is avoiding the following triggers for HAE attacks: • Estrogen-containing oral contraceptive agents AND hormone replacement therapy • Antihypertensive agents containing ACE inhibitors. 8. Approval Duration: 3 months.	7. Documentation of positive clinical response from Takhzyro therapy with submission of chart notes with a date-of-service within the previous 3 months. 8. Not used in combination with other products indicated for prophylaxis against HAE attacks (Cinryze, Haegarda, Orladeyo). 9. Approval Duration: 3 months.

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Leniolisib (**Joenja**) **J8499** **NDC: 71274-0170-60** r	1. Prescribed for an approved indication for use; treatment of activated phosphoinositide 3-kinase delta (PI3Kδ) syndrome (APDS) in adult and pediatric patients 12 years of age and older. 2. Diagnosis confirmed by the presence of an APDS-associated genetic variant in either PIK3CD or PIK3R1. 3. Patient aged ≥ 12 years. 4. Patient weight is ≥ 45 kg. 5. Documentation of other clinical findings and manifestations consistent with APDS (e.g., recurrent respiratory tract infections, recurrent herpesvirus infections, lymphadenopathy, hepatosplenomegaly, autoimmune cytopenia). 6. Patient has a history of trial and failure, intolerance, or contraindication to current standard of care for APDS (e.g., antimicrobial prophylaxis, immunoglobulin replacement therapy, immunosuppressive therapy). 7. Prescribed by, or in consultation with a hematologist or immunologist. 8. Approval duration: 3 months.	1. Documentation of positive clinical response to Joenja therapy (e.g., reduced lymph node size, increased naïve B-cell percentage, decreased frequency or severity of infections, decreased frequency of hospitalizations) by submission of chart notes with a date-of-service within the previous 3 months. 2. Patient weight is ≥ 45 kg. 3. Prescribed by, or in consultation with a hematologist or immunologist. 4. Approval duration: 3 months.
lisocabtagene maraleucel (**Breyanzi**) injection **Q2054** **NDC: 73153-0900-01**	1. Ordered for an approved indication for use: • Treatment of adult patients with large B-cell lymphoma (LBCL) including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B, who have:	**Not applicable. Maximum approval, one treatment course per lifetime.**

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	a. refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy; or b. refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age; or c. relapsed or refractory disease after two or more lines of systemic therapy. 2. Age ≥ 18 years of age. 3. Prescriber attestation that all baseline evaluations have been done, and no contraindications to use are present. 4. Prescriber attests that subsequent appropriate evaluation and monitoring will be done based on the package insert. 5. Dose: 50-110 x 10^6 CAR positive viable T cells, one time dose. 6. NOT for the treatment of patients with primary central nervous system lymphoma. 7. Medication ordered by an Oncologist or Hematologist. 8. Approval limited to once per lifetime.	
Lomitapide (**Juxtapid**) Capsules 5 mg, 10 mg, 20 mg, 30 mg **J8499**	1. Ordered for an approved indication for use: • An adjunct to a low-fat diet and other lipid-lowering treatments, including LDL apheresis where available, to reduce LDL-C, total cholesterol, apolipoprotein B, and non-HDL-C in patients with homozygous familial hypercholesterolemia. 2. Patient age ≥ 18 years.	1. Meets all initial approval criteria. 2. Attestation of continued benefit without significant adverse drug effects. 3. Laboratory data (full lipid panel) submitted to support continued use. 4. Renewal Duration: 12 months

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	3. Documentation of baseline LFTs (including ALT, AST, alkaline phosphatase and total bilirubin) prior to initiation of treatment. 4. Prescriber attestation that a low-fat diet (<20% of energy from fat) has been initiated. 5. Prior trial, failure, insufficient response, and/or documented intolerance to preferred lipid lowering treatments including statin + ezetimibe, or Praluent. 6. Medication ordered by a REMS registered cardiologist or endocrinologist. 7. Approval Duration: 12 months.	
Loncastuximab tesirine-lpyl (**Zynlonta**) solution 10mg **J9359**	1. Ordered for an approved indication for use: • the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, DLBCL arising from low-grade lymphoma, and high-grade B-cell lymphoma. 2. Patient is at least 18 years of age. 3. Used as a single-agent therapy. 4. Patient has not received prior anti-CD19 therapy (e.g., tafasitamab, CAR-T) or patient previously received anti-CD19 therapy and re-biopsy indicates CD-19 positive disease; and 5. Patient does not have graft-versus-host disease; and 6. Patient has not had an autologous stem cell transplant (ASCT) within 30 days or allogeneic stem cell transplant within 60 days prior to start of therapy; and 7. Medication ordered by an Oncologist. 8. Approval Duration: 6 months	1. Patient continues to meet initial criteria for use. 2. Positive disease response from treatment defined as stabilization of disease or decrease in size of tumor or tumor spread. 3. Absence of unacceptable drug toxicity. 4. Approval Duration: 6 months.

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Lumasiran (**Oxlumo**) injection 94.5mg/0.5ml **J0224** **NDC: 71336-1002-01** **r**	1. Ordered for an approved indication for use: • treatment of primary hyperoxaluria type 1 (PH1) to lower urinary and plasma oxalate levels in pediatric and adult patients. 2. Diagnosis of primary lyperoxaluria type 1 (PH1) confirmed by documentation of genetic test results showing a mutation in the alanine:glyoxylate aminotransferase (AGXT) gene OR liver enzyme analysis demonstrating absent or significantly reduced alanine: glyoxylate aminotransferase (AGT) activity. 3. Metabolic testing demonstrating one of the following: • Increased urinary oxalate excretion (e.g., > 1 mm/1,73 m^2 per day [90 mg/1.73 m^2]), increased urinary oxalate: creatinine ratio relative to normative values for age OR • Increased plasma oxalate and glyoxylate concentrations. 4. Patient has not received a liver transplant. 5. Prescribed by or in consultation with a nephrologist or other provider (i.e., geneticist, urologist) with experience in treating PH1. 6. Approval Duration: 3 months.	1. All initial approval criteria is met, and 2. Submission of medical records documenting a positive clinical response to therapy from pre-treatment baseline. 3. Approval Duration: 3 months.
Maralixibat (**Livmarli**) **J8499** **NDC: 79378-0110-01** **r**	1. Diagnosis of Alagille syndrome (ALGS) confirmed by genetic testing with the presence of a mutation in JAG1 or NOTCH2 deletion or mutation. 2. Patient is experiencing cholestatic pruritus associated with ALGS. 3. Patient has serum bile acid concentration above upper limit of normal reference range. 4. Patient age ≥ 3 months of age.	1. Documentation of positive clinical response to Livmarli therapy as evidenced in chart notes with a date-of-service within the previous 3 months. 2. Patient does not have cirrhosis, portal hypertension or history of hepatic decompensation event. 3. Documentation of patient's current weight in kg.

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	5. Failure of at least two systemic medications for Alagille syndrome unless contraindicated (e.g., cholestyramine, rifampicin, or ursodeoxycholic acid aka ursodiol). 6. Patient does not have cirrhosis, portal hypertension or history of a hepatic decompensation event. 7. Documentation of patient's current weight in kg. 8. Maximum dose 380 mcg/kg/day, not to exceed 28.5 mg (3 ml) per day. 9. Prescribed by or in consultation with a hepatologist or gastroenterologist. 10. Approval Duration: 3 months.	4. Maximum dose 380 mcg/kg/day, not to exceed 28.5 mg (3 ml) per day. 5. Approval duration: 3 months
Mecasermin (**Increlex**) **J2170** **NDCs: 15054-1040-05**	1. Ordered for an approved indication for use: • Treatment of growth failure in pediatric patients ≥ 2 years of age with severe primary insulin-like growth factor-1 (IGF-1) deficiency or with growth hormone (GH) gene deletion who have developed neutralizing antibodies to GH. 2. Severe primary IGF-1 deficiency is defined by (pretreatment): • Height standard deviation (SD) score ≤ -3.0 AND • Basal IGF-1 SD score ≤ -3.0 AND • Normal or elevated GH 3. Pediatric GH deficiency has been ruled out with a provocative GH test (i.e., peak GH level ≥ 10 ng/ml) 4. Epiphyses are open. 5. All other indications are considered experimental and not medically necessary. Increlex is NOT a substitute to GH for approved GH indications. Increlex is not indicated for use in patients with secondary forms of IGF-1 deficiency, such as	1. The patient's growth rate is > 2 cm/year or there is a documented clinical reason for lack of efficacy (e.g., on treatment for < 1 year, nearing final adult height/late stages of puberty). 2. Epiphyses are open (confirmed by X-ray). 3. Approval Duration: 12 months.

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	GH deficiency, malnutrition, hypothyroidism, or chronic treatment with pharmacologic doses of anti-inflammatory corticosteroids. 6. Approval Duration: 12 months.	
Metreleptin (**Myalept**) injection 11.3mg **J3490, J3590** **NDC: 76431-0210-01** r	1. Ordered for an approved indication for use: • An adjunct to diet as replacement therapy to treat the complications of leptin deficiency in patients with congenital or acquired generalized lipodystrophy. 2. Diagnosis of congenital or acquired generalized lipodystrophy associated with leptin deficiency. 3. Myalept is being used as an adjunct to diet modification. 4. Prescribed by an endocrinologist. 5. Patient has at least ONE of the following: • Diabetes mellitus or insulin resistance with persistent hyperglycemia (A1c > 7.0) despite BOTH of the following: ○ Dietary intervention ○ Optimized insulin therapy at maximum tolerated doses; OR • Persistent hypertriglyceridemia (TG > 250) despite BOTH of the following: ○ Dietary intervention ○ Optimized therapy with at least TWO triglyceride-lowering agents from different classes (e.g., fibrates, statins) at maximum tolerated doses. 6. Approval Duration: 3 months.	1. Documentation of positive clinical response to Myalept therapy as evidenced in chart notes submitted with date-of-service within the previous 3 months. 2. Myalept is being used as an adjunct to diet modification. 3. Prescribed by an endocrinologist. 4. Approval Duration: 3 months.
mifepristone (Korlym) tablets Korlym-300mg ONLY	1. Ordered for an approved indication for use: • Control of hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who	1. Documentation of one of the following as evidenced by submission of chart notes

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J8499 **NDCs:** **00591-4390-96** *Brand NDC's should not be used when generic available:* *76346-0073-01* *76346-0073-02*	have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery. 2. Patient is ≥ 18 years of age. 3. Diagnosis of endogenous Cushing's syndrome (i.e., hypercortisolism is not a result of chronic administration of high dose glucocorticoids). 4. Patient has type 2 diabetes mellitus OR the patient has glucose intolerance as defined by a 2-hour glucose tolerance test value of 140-199 mg/dL. 5. The patient has either failed surgery or is not a candidate for pituitary surgery. 6. No other indications are approved, redirect requests for Mifeprex brand to appropriate formulary alternatives. 7. Prescribed by or in consultation with an endocrinologist. 8. The dose does not exceed 20 mg/kg/day. 9. Approval Duration: 3 months.	with a date-of-service within the previous 3 months: • Patient has improved glucose tolerance while on Korlym therapy; or • Patient has stable glucose tolerance while on Korlym therapy. 2. Dose does not exceed 20 mg/kg/day. 3. Approval duration: 3 months per authorization.
Mirvetuximab (**Elahere**) **J9063** **NDC: 72903-0853-01**	1. Prescribed for an approved indication for use: treatment of adult patients with folate receptor alpha (FRα)–positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. 2. Patient is ≥ 18 years of age. 3. Verification that the FDA indication remains valid. 4. Confirmation that patient has folate receptor alpha positive disease. 5. Patient does not have moderate or severe hepatic impairment. 6. Patient has platinum-resistant disease.	1. Disease response with treatment as defined by stabilization of disease or decrease in tumor size or tumor spread as evidenced in chart notes submitted with a date-of-service within the previous 3 months. 2. There is no evidence of unacceptable toxicity or disease progression. 3. The patient does not have moderate or severe hepatic impairment. 4. Approval duration: 3 months.

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	7. Patient has tried at least one systemic regimen (e.g., bevacizumab, cyclophosphamide, docetaxel, etoposide, gemcitabine, paclitaxel, carboplatin, Lynparza (Olaparib) or Zejula (niraparib). 8. Prescribed by or in consultation with an oncologist. 9. Dosing is up to 6 mg/kg adjusted ideal body weight dosed once every 3-weeks. 10. Approval duration: 3 months.	
Mogamulizumab-kpkc (**Poteligeo**) injection 20mg/5ml **J9204** **NDC: 42747-0761-01**	**1.** Ordered for an approved indication for use: • the treatment of adult patients with relapsed or refractory mycosis fungoides or Sézary syndrome after at least one prior systemic therapy. 2. Patient is ≥ 18 years of age. 3. Poteligeo is used as a single-agent therapy. 4. Patient has relapsed or refractory disease. 5. Approval Duration: 6 months.	1. Disease response with treatment as defined by stabilization of disease or decrease in tumor size or tumor spread. 2. No evidence of disease progression or unacceptable toxicity 3. Renewal Duration: 6 months.
Mosunetuzumab-axgb (**Lunsumio**) **J9350** **NDC: 50242-0142-01** **50242-0159-01**	1. Ordered for an approved indication for use: • Treatment of adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy. 2. Documentation of at least two lines of systemic therapy including an anti-CD20 monoclonal antibody (e.g. rituximab) and an alkylating agent (e.g. bendamustine). 3. Patient age ≥ 18 years. 4. Patient does not have central nervous system (CNS) lymphoma; AND 5. Used for histologically confirmed grades 1-3a disease; AND	1. Patient continues to meet the requirements for initial approval. 2. Patient has absence of unacceptable toxicity from the drug. 3. Patient achieved a partial response or has stable disease as evidenced by metabolic and radiologic response criteria. 4. Confirmation that drug continues to carry FDA-approval for indication. 5. Patient has not exceeded a maximum total of 17 cycles. 6. Approval for up to eight, 21-day cycles.

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	6. Patient has an Eastern Cooperative Oncology Group (ECOG) performance status of 0-1. 7. Confirmation that drug continues to carry FDA-approval for indication. 8. Coverage for eight, 21-day cycles.	
Nanoparticle albumin bound sirolimus (**Fyarro**) **J9331** **NDC: 80803-0153-50**	1. Ordered for the treatment of adult patients with locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa). 2. Patient age ≥ 18 years 3. Medication used as a single agent. 4. Patient does not have severe hepatic impairment. 5. Dosage is 100 mg/m2 on days 1 and 8 of each 21-day cycle until disease progression or unacceptable toxicity. 6. Initial approval: 6 months	1. No evidence of disease progression or unacceptable toxicity 2. Renewal Duration: 6 months.
Naxitamab (**Danyelza**) **J9348** **NDC:73042-0201-01** **r**	1. Ordered for an approved indication for use: • In combination with granulocyte-macrophage colony-stimulating factor (GM-CSF), for the treatment of pediatric patients ≥ 1 year of age and adult patients with relapsed or refractory high-risk neuroblastoma in the bone or bone marrow who have demonstrated a partial response, minor response, or stable disease prior to therapy. 2. Patient age ≥ 1 year with relapsed or refractory disease in the bone or bone marrow. 3. The patient has demonstrated a partial or minor response or stable disease with prior therapy. 4. Danyelza will be used in combination with GM-CSF (e.g., sargramostim). 5. Prescribed by or in consultation with an oncologist.	1. No evidence of disease progression or unacceptable toxicity as evidenced by chart notes submitted with a date-of-service within the previous 3 months. 2. Approval Duration: 3 months.

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	6. Approval Duration: 3 months.	
Nirogacestat (**Ogsiveo**) tablets 150 mg **J8999**	1. Ordered for an approved indication for use: • Treatment of Desmoid Tumors (aggressive fibromatosis) in adult patients. 2. Patient is aged 18 years or older. 3. Patient has been diagnosed with progressing desmoid tumors as defined as ≥ 20% progression within 12 months, AND 4. The desmoid tumors are not amenable to surgery or radiotherapy, AND 5. The patient requires systemic treatment. 6. Quantity Limits: 2 tablets daily, not to exceed 150 mg BID. 7. Approval Duration: 12 months.	1. Patient does not show evidence of progressive disease while on Ogsiveo therapy. 2. Approval Duration: 12 months
Nitisinone (Orfadin) capsules Nitisinone is preferred for 2mg, 5mg 10mg **Orfadin** 20mg **J8499** **NDC: 66658-0204-90**	1. Ordered for an approved indication for use: • treatment of adult and pediatric patients with hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine. 2. Diagnosis of type 1 tyrosinemia by biochemical or DNA testing. 3. Patient adherent to dietary restrictions of tyrosine and phenylalanine. 4. Patient is under the care of a nutritionist. 5. Dose not to exceed 2 mg/kg/day. 6. Patient is not enrolled in any study involving the requested drug. 7. PA form completed completely. 8. Approval Duration: 3 months	ORFADIN PRIOR AUTH FORM 1. Meets all initial approval criteria. 2. MDH provided PA form completed with all required documentation. 3. Approval duration: 3 months.
Nusinersen (**Spinraza**)	1. Ordered for an approved indication for use: • Diagnosis of SMA Type I, II, or III.	1. Cannot be used in combination with Zolgensma (onasemnogene abeparvovec).

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J2326 **NDC: 64406-0058-01** r	• Diagnosis by a neurologist with expertise in the diagnosis of SMA; 2. Genetic testing confirming both: • 5q SMA homozygous gene deletion, homozygous gene mutation, or compound heterozygous mutation: AND • At least 2 copies of SMN2 3. AND • Patient is not dependent on invasive ventilation or tracheostomy. • Patient is not dependent on non-invasive ventilation beyond use for naps and nighttime sleep; • Patients with Type II and III SMA must have some functional upper extremity use. 4. **Initial therapy** • Medical records must be submitted documenting all of the above criteria; • Medical records must be submitted documenting a baseline motor examination utilizing at least one of the following exams (based on patient age and motor ability) to establish baseline motor ability. • Hammersmith infant neurological exam (HINE); • Hammersmith Functional Motor Scale Expanded (HFMSE); • Upper Limb Module Test (non-ambulatory; or • Childrens Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND) 5. Prescribed by a neurologist with expertise in the treatment of SMA.	2. Each Spinraza maintenance dose must be preauthorized; 3. Chart notes submitted should have a date-of-service within the previous 3 months. 4. Approval period is 3 months. 5. All the criteria for initial therapy must be met: • Medical records must be submitted that document repeat motor testing since the most recent Spinraza® dose using the same motor test done to establish baseline motor ability, unless it is determined that the original test is no longer appropriate. • Repeat motor testing must document a response to treatment as defined by the following: **HINE:** 1. Improvement or maintenance of previous improvement of at least 2 points (or max score of 4) in ability to kick (improvement in at least 2 milestones); **OR** 2. Improvement or maintenance of previous improvement of at least 1 point increase in motor milestones of head control, rolling, sitting, crawling, standing, or walking (consistent with improvement by at least 1 milestone); **AND**

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	6. Spinraza must be given according to the current FDA labelling guidelines for dosage and timing; 7. Must be administered intrathecally by a physician or other healthcare professional experienced in performing lumbar punctures. 8. Initial and Renewal Approval Duration: 4 loading doses for initiation, 3 months each approval period thereafter.	3. Improvement or maintenance of previous improvement in more HINE motor milestones. **HFMSE:** 1. Improvement or maintenance of improvement of at least a 3-point increase in score; **ULM:** 1. Improvement or maintenance of previous improvement of at least 2-point increase in score; **CHOP-INTEND:** 1. Improvement or maintenance of previous improvement of at least a 4-point increase in score.
Odevixibat (**Bylvay**) **J8499** **NDCs:** **74528-0040-01** **74528-0120-01** r	1. Prescribed for an approved indication for use: • Treatment of pruritus in patients ≥ 3 months of age with progressive familial intrahepatic cholestasis (PFIC) type 1, 2, or 3. 2. Patient age ≥ 3 months. 3. Patient does not have concomitant liver disease (e.g., biliary atresia, benign recurrent intrahepatic cholestasis (BRIC), liver cancer, alternate non-PFIC related etiology of cholestasis). 4. Genetic testing results confirming a diagnosis of progressive familial intrahepatic cholestasis. Coverage will not be provided for patients with PFIC type 2 with variants in the ABCB11 gene that predict non-functional or complete absence of bile salt export pump protein (BSEP-3).	1. Chart notes or medical records documenting a benefit from therapy (e.g., improvement in pruritis) with a date-of-service within the previous 3 months. 2. Liver function tests are monitored, and treatment is interrupted if new onset liver test abnormalities occur, or symptoms consistent with clinical hepatitis are observed. 3. Patient has not experienced hepatic decompensation (e.g., variceal hemorrhage, ascites, hepatic encephalopathy).

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	5. Provider attestation of drug specific baseline evaluation and monitoring with subsequent evaluation and monitoring performed as required. 6. Prior or continued use of ursodiol. 7. Prescribed by or in consultation with a prescriber with experience working with PFIC, hepatologist or gastroenterologist. 8. Dosing 40 mcg/kg once daily for first 3 months. May increase in 40 mcg/kg increments to maximum daily dose of 6 mg. 9. Initial Approval Duration: 3 months.	4. Approval Duration: 3 months.
Olipudase alfa (**Xenpozyme**) **J0218** **NDC: 58468-0050-01** **r**	2. Prescribed for an approved indication for use; treatment of non-central nervous system manifestations of acid sphingomyelinase deficiency (ASMD) in adult and pediatric patients. 3. Acid sphingomyelinase enzyme assay (as measured in peripheral leukocytes, cultured fibroblasts, or lymphocytes) or genetic testing results documenting a mutation in the sphingomyelin phosphodiesterase-1 (SMPD1) gene. 4. Prior to initiation of Xenpozyme, baseline transaminase (alanine aminotransferase [ALT] and aspartate aminotransferase [AST]) levels recorded within past 30 days. 5. Documentation of patient's current weight. 6. Prescribed by or in consultation with a metabolic disease specialist or geneticist. 7. Dose does not exceed 3 mg/kg IV every 2 weeks. 8. Approval duration: 3 months	1. Documented response to therapy improvement or stabilization in disease (e.g., improvement in lung function, reduction in spleen volume, reduction in liver volume, improvement in platelet count, improvement in linear growth progression) with chart notes submitted with date-of-service within previous 3 months. 2. Documentation of patient's current weight. 3. Dose does not exceed 3 mg/kg IV every 2 weeks. 4. Approval duration: 3 months.
Onasemnogene abeparvovec-xioi	1. Ordered for an approved indication for use:	**Not applicable. Maximum approval, one treatment course per lifetime.**

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(**Zolgensma**) injection **J3399** **NDCs: 71894-0120-02 71894-0121-03 71894-0122-03, 71894-0123-03, 71894-0124-04, 71894-0125-04, 71894-0126-04, 71894-0127-05, 71894-0128-05, 71894-0129-05, 71894-0130-06, 71894-0131-06, 71894-0132-06, 71894-0133-07 71894-0134-07, 71894-0135-07, 71894-0136-08, 71894-0137-08, 71894-0138-08, 71894-0139-09, 71894-0140-09, 71894-0141-09** r	• treatment of pediatric patients < 2 years of age with spinal muscular atrophy (SMA) with bi-allelic mutations in the survival motor neuron 1 (SMN1) gene. 2. Genetic testing confirming bi-allelic mutations in the SMN1 gene on chromosome 5q 3. Patient age less than 2 years 4. Prescriber attests that baseline evaluation has been done and there are no contraindications to use. 5. Prescriber attests that subsequent appropriate evaluation and monitoring will be done based on package insert. 6. Continued approval for this medication may be contingent upon verification of clinical benefit in confirmatory trials. 7. Patient is not receiving concomitant SMA disease modifying therapy (e.g., Spinraza). 8. Use of Zolgensma in patients with advanced SMA (e.g. complete limb paralysis, permanent ventilator dependence) has not been evaluated. 9. Prescribed by a pediatric neurologist with experience in the diagnosis of SMA. 10. One time approval only	
Palovarotene (**Sohonos**) **J8499** **NDC: 15054-0010-01 15054-0015-01**	1. Ordered for an approved indication for use: • Treatment for the reduction in volume of new heterotopic ossification in adults and female children aged ≥ 8 years and older or male children with fibrodysplasia ossificans progressive (FOP). 2. Documentation supporting the diagnosis of FOP; **AND**	1. Documentation for a date-of-service within the previous 30 days; **AND** 2. Documentation shows a positive clinical response (e.g., reduction in new HO volume, improved CAJIS and FOP-PFQ scores, improved quality of life); **AND**

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15054-0025-01 **15054-0050-01** **15054-0100-01** r	3. Diagnosis has been confirmed by the presence of a mutation in the activin receptor IA (ACVR1) gene; **AND** 4. Patient has heterotopic ossification as confirmed by radiologic testing; **AND** 5. Patient satisfies one of the criteria below: BOTH of the following: • Patient is female; **AND** • Patient is aged ≥ 8 years; **OR** BOTH of the following: • Patient is male; **AND** • Patient is aged ≥ 10 years; **AND** 6. Sohonos is being used to reduce the volume of new heterotopic ossification (HO); **AND** 7. Prescribed by, or in consultation with an FOP expert (e.g., endocrinologist, geneticist, pediatric orthopedist, or pediatric rheumatologist). 8. Sohonos is NOT being prescribed for COPD or Osteochondroma(s). 9. Approval Duration: 3 months due to clinical reporting requirements.	3. Prescribed by, or in consultation with an FOP expert (e.g., endocrinologist, geneticist, pediatric orthopedist, or pediatric rheumatologist). 4. Approval Duration: 3 months due to clinical reporting requirements.
Patisiran (**Onpattro**) Solution 10mg/5ml **J0222** **NDC: 71336-1000-01**	1. Ordered for an approved indication for use: • Treatment of polyneuropathy in adults with hereditary transthyretin-mediated (hATTR) amyloidosis. 2. Patient age ≥ 18 years. 3. Medication ordered by a rheumatologist, neurologist, or a specialist in the treatment of amyloidosis.	1. Patient continues to meet the initial approval criteria. 2. Documentation of therapeutic response as evidenced by chart notes with a date-of-service within the previous 6 months demonstrating the stabilization or improvement from baseline in one of the following:

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	4. Diagnosis of hATTR with polyneuropathy confirmed by the presence of a transthretin (TTR) gene mutation (e.g., V30M, A97S, T60A, E89Q, S50R). 5. Documentation of one of the following baseline tests: • Modified Neuropathy Impairment Scale +7 (mNIS+7) composite score. • Polyneuropathy disability (PND) score of ≤ IIIb • Familial amyloid polyneuropathy (FAP) Stage 1 or 2 6. Patient has clinical signs and symptoms of polyneuropathy (i.e., weakness, sensory loss, decreased motor strength, decreased gait speed) 7. Other causes of peripheral neuropathy have been assessed and ruled out. 8. Patient will not be receiving Onpattro in combination with oligonucleotide agents (Onpattro, Tegsedi) 9. Prescribed by, or in consultation with, a neurologist, geneticist, or physician specializing in the treatment of amyloidosis. 10. Approval Duration: 12 months	• mNIS+7 score • polyneuropathy disability (PND) score ≤ IIIb • familial amyloid polyneuropathy (FAP) Stage 1 or 2. 3. Approval Duration: 12 months.
Pegcetacoplan (**Empaveli**) injection 1080mg **J3490, J3590, C9399** **NDC: 73606-0010-01**	1. Ordered for an approved indication for use: • Treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH). 2. Documentation supporting diagnosis of PNH as confirmed by both of the following: • Flow cytometry analysis confirming presence of PNH clones; and • Laboratory results, signs and/or symptoms attributed to PNH (e.g., abdominal pain, anemia, dyspnea, extreme	1. Documentation of positive clinical response to Empaveli therapy (e.g, increased or stabilization of hemoglobin levels, reduction in transfusions, improvement in hemolysis, decrease in LDH, increased reticulocyte count, etc.) 2. Patient is not receiving Empaveli in combination with another complement

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	fatigue, smooth muscle dystonia, unexplained or unusual thrombosis, hemolysis/hemogobinuria, kidney disease, pulmonary hypertension, etc.) 3. Patient age ≥ 18 years. 4. Patient is not receiving Empaveli in combination with another complement inhibitor used for the treatment of PNH (e.g., Fabhalta, Soliris, Ultomiris); OR 5. Patient is currently receiving Soliris (eculizumab) which will be discontinued after an initial 4-week overlap period with Empaveli; OR 6. Patient is currently receiving Ultomiris (ravulizumab-cwvz) which will be discontinued and Empaveli will be initiated no more than 4 weeks after the last dose. 7. Prescribed by either a hematologist or oncologist. 8. Approval Duration: 6 months.	inhibitor used for the treatment of PNH (e.g., Fabhalta, Soliris, Ultomiris). 3. Prescribed by or in consultation with an oncologist or hematologist. 4. Approval Duration: 12 months.
pegloticase (**Krystexxa**) injection 8mg/ml **J2507** **NDC: 75987-0080-10** **r**	1. Ordered for an approved indication for use: • Treatment of chronic gout in adults refractory to conventional therapy. 2. Verified there is no G6PD deficiency prior to therapy initiation. 3. Patient aged 18 years or older. 4. Krystexxa will not be used concomitantly with oral urate-lowering therapies. 5. The patient has had at least 2 gout flares per year that were inadequately controlled by colchicine or NSAIDs or at least 1 gout tophus or gouty arthritis. 6. Patient has had an inadequate response to or clinical reason for not completing at least a three-month trial with the following medications at the medically appropriate doses:	1. Patient must have taken Krystexxa for less than 18 months of cumulative therapy. 2. Patient meets ALL initial authorization criteria. 3. Patient has NOT had 2 consecutive uric acid levels above 6 mg/dl since starting Krystexxa. 4. Documentation submitted showing improvement from therapy, meaning chart notes and lab test results showing response to therapy (e.g., serum uric acid levels < 6 mg/dL, reduction of tophi, reduction of symptoms and/or flares). 5. Renewal duration: 3 months.

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	• Allopurinol or febuxostat • Probenecid (alone or in combination with allopurinol or febuxostat). • Clinical reasons for not completing a 3-month trial with allopurinol, febuxostat, and probenecid may include: allergic reaction to drug, toxicity from drug, intolerance to drug therapy, drug-drug interactions with current drug therapy, severe renal dysfunction (allopurinol), known blood dyscrasias or uric acid kidney stones (probenecid), end-stage renal impairment (febuxostat), history of CVD or new CV event (febuxostat). 7. Not for the treatment of asymptomatic hyperuricemia. Patient must experience symptomatic gout. 8. Prescriber agrees to monitor serum uric acid levels prior to subsequent infusions and consider discontinuing treatment if levels rebound and exceed 6 mg/dl. 9. Medication ordered by Rheumatologist, Nephrologist or Podiatrist. 10. Approval duration: 3 months.	
Pegunigalsidase alfa (**Elfabrio**) **J2508** **NDCs:** **10122-0160-02** **10122-0160-05** **10122-0160-10**	1. Ordered for an approved indication for use: 2. Treatment of adults with confirmed Fabry disease 3. Patient aged 18 years or older. 4. Submission of alpha-glactosidase enzyme assay or genetic testing results to support diagnosis by one of the following: • a*galactosidase A (a*Gal A) activity in plasma, isolated leukocytes, and/or cultured cells (males only) **OR** • Detection of pathogenic mutations in the GLA-gene by molecular genetic testing **AND**	1. Patient continues to meet criteria for initial approval, **AND** 2. Absence of unacceptable toxicity from drug such as anaphylaxis, severe hypersensitivity reactions, severe infusion-associated reactions, glomerulonephritis AND 3. Disease response with treatment as shown in chart notes submitted with date-

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	• Baseline value for plasma GL-3 and/or inclusions, plasma or urinary globotriaosylceramide (Gb_3/GL-3); or plasma globotriaosylsphingosine (lyso* Gb_3). 5. The medication with not be used in combination with Galafold, migalastat or agalsidase beta. 6. Quantity limits: 6 vials q14 days, max: 120 mg q14 days. 7. Approval Duration: 3 months	of-service within the previous 3 months and defined by a reduction or stabilization in one or more of the following as compared to pre-treatment baseline: • Reduction in Plasma GL-3 and/or GL-3 inclusions • Reduction in plasma or urinary Gb_3/GL-3. • Improvement and/or stabilization in renal function, pain reduction. 4. Renewal duration: 3 months
Pozelimab (**Veopoz**) **J3590** **NDC: 61755-0014-00** **61755-0014-01** **r**	1. Ordered for an approved indication for use: • Treatment of adult and pediatric patients 1 year of age and older with CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease. 2. Patient aged ≥ 1 year. 3. Documentation (lab results) confirming biallelic CD55- loss-of-function mutation; **AND** 4. Hypoalbuminemia (serum albumin concentration ≤ 3.2 g/dL; **AND** 5. Patient has one or more of the following signs and symptoms of CD-55 PLE: • abdominal pain • diarrhea • peripheral edema; or • facial edema 6. Documentation for criteria #5 above for date-of-service within previous 2 months.	1. Chart notes for a date-of-service within previous 90-days that provide documentation supporting a positive clinical response to treatment (e.g., normalization of serum albumin, improvement in signs and symptoms of disease, and/or a decrease in the number of hospitalizations and infections). 2. Patient has not experienced unacceptable toxicity or disease progression while on current regimen. 3. Approval Duration: 3 months due to clinical reporting requirements.

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	7. Approval Duration: 3 months due to clinical reporting requirements.	
Ravulizumab-cwvz **(Ultomiris)** injection 100mg/ml 300mg/30ml **J1303** **NDCs:** **25682-0022-01** **25682-0025-01** **25682-0028-01**	1. Ordered for an approved indication for use: • treatment of adult and pediatric patients ≥ 1 month of age with paroxysmal nocturnal hemoglobinuria (PNH). • treatment of adult and pediatric patients ≥ 1 month of age with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy (TMA). • treatment of adult patients with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR+) antibody positive. 10. FDA approved patient age. 11. Documentation to support diagnosis: **PNH:** • Flow cytometric confirmation of PNH type III red cells; AND • Patient had at least one transfusion in the preceding 24 months; OR • Documented history of major adverse thrombotic vascular events from thromboembolism; OR • Patient has high disease activity defined as lactic dehydrogenase (LDH) level ≥ 1.5 times the upper limit of normal with one of the following symptoms: weakness, fatigue, hemoglobinuria, abdominal pain, dyspnea, hemoglobin, 10 g/dL, a major vascular event, dysphagia, or erectile dysfunction. • History of failure to/contraindication or intolerance to	1. Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit. 2. **gMG**: Improvement and maintenance of at least a 2-point improvement (reduction) in the MG-ADL score from pre-treatment baseline and reduction of signs and symptoms of MG required to show clinical benefit. 3. **NOTE:** dose escalation of immunosuppressive therapy, or additional rescue therapy from baseline to treat MG or exacerbation of symptoms during use is considered treatment failure. 4. Not receiving in combination with Empaveli, Fabhalta, or Soliris. 5. Approval Duration: up to 12 months.

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	Empaveli therapy; • Patient age < 18 years or currently pregnant. **aHUS:** • Common causes of aHUS have been ruled out, including infectious causes of HUS and thrombotic thrombocytopenic purpura (TTP). • Ultomiris is not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS). • Must present with the following symptoms: o Hemoglobin < 10 g/dL o Platlets, 150,000/mm^3 o Documented evidence of hemolysis, such as elevated LDH levels, decreased haptoglobin level or schistocytosis. • Increased serum creatinine OR currently undergoing dialysis. **gMG:** • Patient has not failed previous course of Soliris or Ultomiris therapy; • Positive serologic test for anti-AChR antibodies; AND • One of the following: o History of abnormal neuromuscular transmission test demonstrated by single-fiber electromyography (SFEMG) or repetitive nerve stimulation OR o History of positive anticholinesterase test (e.g. edrophonium chloride test) OR	

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	○ Pt has demonstrated improvement in MG signs on oral cholinesterase inhibitors as assessed by the treating neurologist; AND • Patient has MGFA clinical classification of II, III, or IV at initiation of treatment; AND • Patient has Myasthenia gravis-specific activities of daily living scale (MG-ADL) total score ≥ 6 at initiation of treatment; AND • One of the following: ○ History of failure to at least two immunosuppressive agents over the previous 12-months (e.g., azathioprine, mtx, cyclosporin, mycophenolate); OR ○ History of failure to at least one immunosuppressive therapy and has required four or more courses of plasmapheresis/plasma exchanges, and/or intravenous immune globulin over the previous 12 months without symptom control; AND 12. Recommended vaccinations at least 2 weeks prior to administration of first dose Ultomiris. 13. Cannot be used in combination with other medications in the same class, such as Soliris. 14. Medication ordered by Hematologist, Nephrologist, or Oncologist registered with Ultomiris REMS program. 15. Approval Duration: 12 months.	
Rozanolixizumab (**Rystiggo**) **J9333**	1. Ordered for an approved indication for use: • Treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or	1. Patient demonstrates a positive response to therapy (e.g., improvement in MG-ADL score, changes compared to baseline in

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NDC: **50474-0980-79**	anti-muscle-specific tyrosine kinase (MuSK) antibody positive. 2. Patient age ≥ 18 years. 3. Patient is anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive. 4. Myasthenia Gravis Foundation of America (MGFA) clinical classification II to IV-a. 5. MG activities of daily living (MG-ADL) total score of 3 or more with at least 3 points from non-ocular symptoms. 6. On a stable dose of at least one of the following: • Acetylcholinesterase inhibitors (e.g., pyridostigmine) • Steroids (at least one month of treatment) • Nonsteroidal immunosuppressive therapy (NSIST) (at least 6 months of treatment) e.g., azathioprine, mycophenolate mofetil). 7. Approval Duration: 6 months.	Quantitative Myasthenia Gravis (QMG) total score). 2. Patient has no evidence of unacceptable toxicity or disease progression while on the current regimen. 3. Approval Duration: 6 months.
Sastralizumab-mwge (**Enspryng**) injection **J3590**	1. Ordered for an approved indication for use: • Treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive. 2. Must submit FDA-approved testing showing antibody positive. 3. Age ≥ 18 years. 4. Prescriber attests that baseline evaluation has been done and there are no contraindications to use (e.g., Hep B, TB, LFT's, live or live-attenuated vaccines 4 weeks prior or 2 weeks for non-live vaccines). 5. Prescriber attests that subsequent appropriate evaluation and monitoring will be done based on the package insert (e.g.,	1. Meets all initial criteria, AND 2. Provider attestation of continued benefit. 3. Use in caution if ALT/AST > 1.5 x ULN. 4. Contraindicated in patients with active hepatitis B infection or active or untreated latent tuberculosis. 5. Approval duration: 12 months

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	infections, LFT's, CBCs – neutrophils) 6. Medication ordered by neurologist, immunologist, or ophthalmologist experienced in treatment of this disease. 7. Approval Duration: 12 months.	
Sodium phenylbutyrate (**Olpruva**) Suspension **J8499** **NDC: 72542-0002-01** **72542-0200-02** **72542-0200-09** **72542-0003-01** **72542-0300-XX** **72542-0400-XX** **72542-0500-XX** **72542-0600-XX** **72542-0367-01** **72542-0667-02** **72542-0667-18** r	1. Ordered for an approved indication for use: • As an adjunctive therapy to the stand of care, in the chronic management of adult and pediatric patients, weighing ≥ 20 kg and a BSA of 1.2 m^2 or greater, with urea cycle disorders (UCDs), involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccinic acid synthetase (AS). 2. Not prescribed for the treatment of acute hyperammonemia. 3. Documentation submitted to confirm diagnosis of UCD via enzymatic, biochemical or genetic testing. 4. Olpruva is being used as an adjunctive therapy along with dietary protein restriction. 5. The patient cannot be managed by dietary protein restriction or amino acid supplementation alone. 6. The patient has had a failed trial of/or contraindication to generic sodium phenylbutyrate power; OR the patient is unable to swallow Buphenyl (sodium phenylbutyrate) tablets. 7. Approval duration: 3 months.	1. Patient continues to meet initial criteria for approval. 2. The patient has a documented clinical benefit from baseline (e.g., normal fasting glutamine, low-normal fasting ammonia levels, improved mental status clarity) as shown in chart notes submitted with date-of-service within the previous 3 months. 3. Approval Duration: 3 months.
Talquetamab-tgvs (**Talvey**) 3 mg/1.5 ml 40 mg/ml	8. Ordered for an approved indication for use: • Treatment of adult patient with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a	1. Patient shows clinical positive response to treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread, as shown in chart notes

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J3055 **NDC:** **57894-0469-01** **57894-0470-01**	proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody. • Confirmation that the contingent approval which was gained under accelerated approval based on response rate and durability of response remains intact. 2. Patient is at least 18 years of age, and 3. Patient does not have an active infection, including clinically important localized infections, and 4. Patient does not have active CNS involvement or clinical signs of meningeal involvement of multiple myeloma, and 5. Patient has not had an allogenic stem cell transplant within the previous six months or an autologous stem cell transplant within the previous 12 weeks, and 6. Patient weight and signs of oral and skin toxicity will be monitored at baseline and periodically during therapy, and 7. Talvey will be used as a single-agent therapy, and 8. Patient has relapsed or refractory disease, and 9. Patient has received at least four prior therapies, including a proteasome inhibitor (e.g. bortezomib, etc.), and immunomodulatory agent (e.g. lenalidomide, thalidomide etc.), and an anti-CD38 monoclonal antibody (e.g. daratumumab, isatuximab, etc.) 10. Prescriber is enrolled in the Tecvayli-Talvey REMS program, and 11. Used as continuation therapy following inpatient administration of all of the step-up doses, and	submitted with a date-of-service within the previous 3 months; and 2. Absence of unacceptable toxicity from the drug, e.g. several oral toxicity and weight loss, serious life-threatening infections, severe cytopenias, severe dermatologic toxicity, hepatoxicity, neurologic toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), cytokine release syndrome (CRS), etc. 3. Approval Duration: 3 months due to clinical reporting requirements.

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	12. Patient had an absence of unacceptable toxicity while on inpatient administration of step-up titration doses, and 13. Quantity Limits: • Talvey 3 mg/1.5 ml solution for injection in a single-use vial: 3 vials per week. • Talvey 40 ml/1 ml solution for injection in a single-dose vial: 3 vials per week. 14. Maximum Units (per dose over time) • Titration: 3 mg on day one, 9 mg on day four and 40 mg on day seven. • Maintenance: 40 mg weekly 15. Approval Duration: 3 months due to clinical reporting requirements.	
Tebentafusp (**Kimmtrak**) **J9274** **NDC: 80446-0401-01** r	1. Prescribed for an approved indication for use: • Treatment of HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma. 2. Patient has HLA-A*02:01 genotype positive disease as determined by an FDA-approved or CLIA compliant test. 3. Patient is at least 18 years of age. 4. Verification of non-pregnant status for females. 5. Patient does not have symptomatic or untreated brain metastases. 6. Patient does not have: • clinically significant cardiac disease or impaired cardiac function (i.e., CHF (NYHA grade ≥ 2) • uncontrolled hypertension or • clinically significant arrhythmia requiring medical treatment.	1. Patient has received the first 3 infusions (i.e., Day 1, 8, and 15) in an appropriate healthcare setting and did not experience any Grade 2 or worse hypotension (hypotension requiring medical intervention). 2. Patient has not had disease progression or unacceptable toxicity (e.g., persistent/severe cytokine release syndrome, severe dermatological reactions, severe elevated liver enzymes). 3. Disease response with treatment as defined by stabilization of disease or decrease in the size of tumor or tumor spread as evidenced in the chart notes

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	• Acute myocardial infarction or unstable angina pectoris < 6 months prior to the start of therapy. 7. Quantity limits: 1 vial per 7 days, max 68 mcg/week 8. Approval Duration: 1 month	submitted with a date-of-service within the previous 3 months. 4. Renewal Duration: 3 months
Teclistamab (**Tecvayli**) **J9380** **NDCs:** **57894-0449-01** **57894-0450-01**	1. Prescribed for an approved indication: treatment of adult patients with relapsed or refractory multiple myeloma. 2. Confirmation of current FDA approved indications due to this medication receiving accelerated approval. Indications are contingent upon verification and description of clinical benefit in confirmatory trials. 3. Patient age ≥ 18 years. 4. Patient has had at least four prior therapies, including an anti-CD38 monoclonal antibody (e.g., daratumumab), a proteasome inhibitor (e.g., bortezomib, ixazomib, or carfilzomib) and an immunomodulatory agent (e.g., lenalidomide or pomalidomide) 5. Patient has had no prior treatment with any B cell maturation antigen (BCMA) targeted therapy. 6. Patient does not have any of the following comorbidities: stroke, seizure, CNS involvement or clinical signs of meningeal involvement of multiple myeloma. 7. Patient has not had an allogenic stem cell transplant within the previous six months or an autologous stem cell transplant within the previous 12 weeks. 8. Prescribed by or in consultation with a hematologist or oncologist. 9. Approval duration: 3 months	1. Patient continues to meet all of the initial criteria. 2. Documented response with treatment as defined by stabilization of disease or decrease in size of tumor/tumor spread as evidenced by chart notes submitted with a date-of-service within the previous 3 months. 3. Absence of unacceptable toxicity from the drug (e.g., Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), severe infusion-related reactions, cytokine release syndrome (CRS), hepatotoxicity, neutropenia, etc. 4. Approval duration: 3 months.

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teduglutide (**Gattex**) **J3490** **NDCs:** **68875-0101-01** **68875-0102-01** **68875-0103-01** **r**	1. Ordered for an approved indication for use: • the treatment of adults and pediatric patients ≥ 1 year of age with Short Bowel Syndrome (SBS) who are dependent on parenteral support. 2. 200 cm or less of remaining small intestine 3. Chart notes documenting the use of parenteral nutrition, including recent PN orders specifying frequency of Phosphatidylserine (PS), caloric requirements, fluid and electrolyte needs, current volume of PS per week and duration of use of PS. 4. Patient weight over 22 pounds (10 kg) 5. Adult patients must have coloscopy with polyp removal within past 6 months. 6. Pediatric patients must have fecal occult blood testing, with follow up colonoscopy/sigmoidoscopy if unexplained blood in stool. 7. Must have recommended lab values checked every 6 months: bilirubin, alkaline phosphatase, and amylase levels 8. Approval Duration: 3 months	1. Chart notes documenting at least a 20% reduction in parental nutrition use from baseline as shown in chart notes with a date-of-service within the previous 3 months. 2. Submission of recent PN orders required. 3. Attestation of continued benefit 4. Free from intestinal obstruction 5. Repeat colonoscopy after initial 1 year of treatment shows no signs of intestinal malignancy. 6. No significant changes in bilirubin, alkaline phosphatase, or amylase levels 7. Approval duration: 3 months.
Teplizumab (**Tzield**) **J9381** **NDCs:** **73650-0316-01** **73650-0316-10** **73650-0316-14**	1. Ordered for an approved indication for use: • To delay the onset of Stage 3 type 1 diabetes (T1D) in adults and pediatric patients aged 8 years and older with stage 2 T1D. 2. Patient is ≥ 8 years of age. 3. Documentation of stage 2, T1D confirmed by: • Presence of two or more of the following pancreatic islet cell autoantibodies: ○ Glutamic acid decarboxylase 65 (GAD)	**Not applicable. Maximum approval, one treatment course per lifetime.**

Updated: March 2025

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	autoantibodies; ○ Insulin autoantibody (IAA); ○ Insulinoma-associated antigen 2 autoantibody (IA-2A); ○ Zinc transporter 8 autoantibody (ZnT8A); ○ Islet cell autoantibody (ICA) 4. Dysglycemia on an oral glucose-tolerance test 5. May NOT be approved for patients with: • Stage 3 T1D; or • Clinical history consistent with T2D; or • Serious infection or chronic infection, including, but not limited to Epstein-Barr virus or cytomegalovirus. 6. Approval Duration: one treatment course per lifetime.	
Teprotumumab-trbw (**Tepezza**) injection 500mg **J3241** **NDC: 75987-0130-15**	1. Ordered for an approved indication for use: • treatment of Thyroid Eye Disease (TED). 2. Requested dose and frequency in accordance with FDA-approved labeling. 3. Is age-appropriate according to FDA-approved labeling. 4. Adult patient > 18 years of age. 5. Patient has clinical diagnosis of Grave's disease. 6. Must be euthyroid or have thyroxine and free triiodothyronine levels less than 50% above or below normal limits within previous 2 months. 7. Must have a Clinical Activity Score ≥ 4 within previous 2 months. 8. Onset of TED symptoms within past 9 months. 9. Must provide documentation that member has tried and failed and/or has intolerance or contraindication to at least one of	**Not applicable. Maximum approval, one treatment course per lifetime.**

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	the following: • Intravenous Corticosteroids • Rituximab or any of its biosimilars • Surgical management 10. Approval duration: limited to 8 infusions.	
Tisotumab vedotin-tftv (**Tivdak**) injection 40mg **J9273**	1. Ordered for an approved indication for use: • the treatment of adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy. 2. Patient is ≥ 18 years of age. 3. Member does not have active ocular surface disease or history or cicatricial conjunctivitis AND 4. Member has not had prior Steven-Johnson syndrome AND 5. Member does not have Grade ≥ 2 peripheral neuropathy AND 6. Member does not have known coagulation defects leading to increased risk of bleeding AND 7. Member has had an ophthalmic exam at baseline, and as clinically indicated AND 8. Tivdak is used as a single agent therapy. 9. Ordered by or in consultation with an oncologist. 10. Approval Duration: 6 months	1. Initial criteria continue to be met. 2. Disease response with treatment as defined by stabilization of disease or decrease in tumor size or tumor spread. 3. Absence of unacceptable toxicity from the drug (e.g., peripheral neuropathy, hemorrhage, recurrent or persistent grade 2 or higher pneumonitis, keratitis, conjunctival ulceration, etc). 4. Approval Duration: 6 months.
Trofinetide (**Daybue**) **J8499** **NDC: 63090-0660-01** **r**	1. Prescribed for an approved indication for use: • Treatment of Rett syndrome in adults and pediatric patients 2 years of age or older. 2. Patient aged 2 years or older. 3. Documentation of mutation of the MECP2 gene. 4. Quantity limited to 24 bottles per 90-days. 5. Approval Duration: 3 months.	1. Documentation of clinical benefit from therapy (e.g., slowed decline in the severity in signs and symptoms) as shown in chart notes submitted with a date-of-service within the previous 3 months. 2. Approval duration: 3 months

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Valoctocogene roxaparvovec (**Roctavian**) **J1412** **NDC: 68135-0927-01** **68135-0927-48** **r**	1. Prescribed for the treatment of Hemophilia A (Factor VIII Deficiency). 2. Patient is ≥ 18 years of age. 3. Patient has diagnosis of severe Hemophilia A with documentation of endogenous Factor VIII levels < 1% of normal Factor VIII (< 0.01 IU/ml, < 1 IU/dL). 4. One of the following: • Currently receiving chronic prophylactic Hemlibra (emicizumab) therapy; OR • BOTH of the following: ○ Currently uses Factor VIII prophylaxis therapy; AND ○ Has had a minimum of 150 exposure days to a Factor VIII agent; OR • Determined to be an appropriate candidate for therapy by the Hemophilia Treatment Center based on patient willingness to adhere to initial and long-term monitoring. 5. Patient does not have a history of inhibitors to Factor VIII ≥ 0.6 Bethesda units (BU). 6. Patient does not screen positive for active Factor VIII inhibitors as defined as ≥ 0.6 BU prior to administration of Roctavian. 7. Patient does not have pre-existing immunity to the AAV5 capsid as detected by FDA-approved test. 8. Patient has not Immune Tolerance Induction (ITI). 9. Liver function testing, hepatic ultrasound, and elastography have been performed to rule-out radiological liver abnormalities and/or sustained liver enzyme elevations. 10. One of the following:	**Not applicable. Maximum approval, one treatment course per lifetime.**

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	• Patient is not HIV+; or • Patient is HIV+ and is virally suppressed with anti-viral therapy (i.e., < 200 copies of HIV/mL). 11. The patient's hepatitis B surface antigen is negative. 12. One of the following: • The patient's hepatitis C virus (HCV) antibody is negative, OR • The patient's HCV antibody is positive, and the HCV RNA is negative. 13. The patient is not currently using antiviral therapy for either hepatitis B or C. 14. The patient has not previously received treatment with Roctavian or other gene therapy for hemophilia during their lifetime. 15. Treatment is administered within a Hemophilia Treatment Center (HTC) that holds Federal designation as evidenced by being listed within the CDC's HTC directiory. 16. Prescriber attests that patient will be able to adhere to weekly monitoring for at least 26 weeks following administration and regularly thereafter as recommended in the package insert. 17. Prescriber attests that patient has received counseling to abstain from alcohol for at least one year after administration and regarding how much alcohol may be acceptable thereafter. 18. Dosing is in accordance with FDA-approved labeling. 19. Authorization is for a single administration only.	
Vamorolone (**Agamree**)	1. Ordered for an approved indication for use:	1. Patient has demonstrated positive response to therapy (e.g., improved motor

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J3490, J8499 **NDC:** **69616-0264-38** **69616-0265-38**	• treatment of Duchenne muscular dystrophy (DMD) in patients ≥ 2 years of age. 2. Patient is ≥ 2 years of age. 3. Patient's diagnosis of DMD is confirmed by one of the following: • Genetic testing with a confirmed pathogenic variant in the dystrophin gene, OR • Muscle biopsy showing the absence of, or marked decrease in dystrophin protein. 4. The patient has tried prednisone or prednisolone for ≥ 6 months and had at least one of the following significant intolerable adverse effects: • Cushingoid appearance • Central (truncal) obesity • Undesirable weight gain (≥ 10% body weight increase within 6 months). • Diabetes and/or hypertension that is difficult to manage according to the provider. 5. Prescribed by, or in consultation with, a physician who specializes in the treatment of DMD and/or neuromuscular disorders. 6. Approval Duration: 12 months.	function, muscle strength, and/or improved pulmonary function). 2. Approval Duration: 12 months.
Velmanase alfa (**Lamzede**) **J0217** **NDCs:**	1. Prescribed for an approved indication: • treatment of non-central nervous system manifestations of alpha-mannosidosis (AM) in adult and pediatric patients. 2. Confirmation of diagnosis by enzyme assay demonstrating alpha-mannosidase activity < 10% of normal in blood	1. Patient has demonstrated response to therapy (e.g., improvement in the 3-minute stair climbing test (3MSCT) from baseline, improvement in 6-minute walking test (6MWT) from baseline, improvement in forced vital capacity (FVC, % predicted),

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10122-0180-02 **10122-0180-05** **10122-0180-10** **r**	leukocytes or fibroblasts or genetic testing confirmation of a mutation in the MAN2B1 gene. 3. Patient age ≥ 3 years. 4. Verification for female patients of non-pregnant status. 5. Patient does not have a history of HSCT or bone marrow transplant. 6. Patient is not wheelchair bound due to illness. 7. Prescribed by, or in consultation with a geneticist, metabolic disease sub-specialist, or physician who specializes in the treatment of lysosomal storage disorders. 8. Approval Duration: 3 months.	reduction in serum or urine oligosaccharide concentration from baseline). 2. Approval Duration: 3 months
Vestronidase alpha (**Mepsevii**) **J3397** **NDCs:** **69794-0001-01**	1. Ordered for an approved indication for use: • Treatment of Mucopolysaccardiosis VII (MPS VII, Sly syndrome) in pediatric and adult patients. 2. Patient ≥ 5 months of age. 3. Patient must have documented diagnosis of MPS VII confirmed by both: • Beta-glucuronidase enzyme deficiency in peripheral blood leukocytes, AND • Detection of pathogenic mutations in the GUSB gene by molecular genetic testing. 4. Patient must have documented baseline value for at least ONE of the following: • 6-minute walk test (6MWT) and/or motor function (e.g., Bruininks-Oseretsky Test of Motor Proficiency (BOT-2), or • Liver and/or spleen volume, or • Urinary excretion of glycosaminoglycans (GAGs) such as chondroitin sulfate and dermatan sulfate, or	1. Patient has demonstrated response to therapy compared to pretreatment baseline in at least ONE of the following: • Stability or improvement in 6MWT and/or motor function, or • Reduction in liver and/or spleen volume, or • Reduction in urinary excretion of glycosaminoglycans (GAGs), or • Stability of skeletal disease, or • Stability or improvement in pulmonary function tests. 2. Patient has absence of unacceptable toxicity from the drug, including any of the following: anaphylaxis or severe allergic reactions. 3. Approval Duration: 6 months.

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	• Skeletal involvement, or • Pulmonary function tests. 5. Prescribed by, or in consultation with, a metabolic or generic specialist. 6. Approval duration: 6 months	
Viltolarsen (**Viltepso**) 50 mg/ml solution **J1427** **NDC: 73292-0011-01** r	1. Ordered for an approved indication for use: • treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping. 2. Genetic testing must confirm patient's DMD gene is amenable to exon 53 skipping. 3. Current patient weight, including date weight was obtained and within 30 days of requested date. 4. Baseline renal function test (GFR) and Urine protein-to-creatinine ratio prior to starting treatment. 5. Documented baseline function testing using a tool to demonstrate physical functions, including, but not limited to: Brooke Upper Extremity Scale, Baseline 6-minute walk test, Pediatric Evaluation of Disability Inventory. 6. Stable dose of glucocorticoid for at least 3 months. 7. Confirmation that drug continues to carry FDA-approval for indication. 8. Prescribed by a neurologist with expertise in treatment of DMD. 9. Approval duration: 3 months	1. Documentation and provider attestation of continued benefit, including respiratory status assessment, without adverse effects based on chart notes submitted with date-of-service within the previous 3 months. 2. Not receiving another antisense therapy or gene therapy. 3. Verification that drug continues to carry FDA-approval for indication. 4. Approval duration: 3 months
Voretigene neparvovec (**Luxturna**)	1. Prescribed for an FDA-approved indication: • Treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy.	**Not applicable. Maximum approval, one treatment course per eye LIFETIME**

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J3398 **NDCs:** **71394-0065-01** **71394-0415-01** **71394-0716-01**	2. Patients must have viable retinal cells as determined by the treating physician(s). 3. Clinical documentation submitted to confirm genetic diagnosis of pathogenic/likely pathogenic biallelic RPE65 gene mutations. 4. The RPE65 gene mutations classifications are based on the current American College of Medical Genetics and Genomics (ACMG) standards and guidelines for interpretation. 5. Pathogenic/likely pathogenic classification of RPE65 mutations has been affirmed within the previous 12 months. 6. Patient is at least 12 months of age, but < 65 years of age. 7. Patient has viable retinal cells in each eye to be treated as determined by optical coherence tomography (OCT) and/or ophthalmoscopy; AND one of the following: • An area of retina within the posterior pole of greater than 100 µm of thickness shown on OCT; • ≥ 3 disc areas of retina without atrophy or pigmentary degeneration within the posterior pole; • Remaining visual field within 30 degrees of fixation as measured by a III4e isopter or equivalent. 8. Patient has not received previous treatment for requested eye. 9. Approval Limitations: 1 treatment per eye lifetime.	
Vutrisiran (**Amvuttra**) **J0225** **NDC: 71336-1003-01**	1. Prescribed for an FDA-approved indication: • treatment of polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults. (ICD-10: E85.1) 2. Documentation is provided that the patient has a TTR mutation confirmed by genotyping.	1. Patient must have met all initial authorization criteria. 2. Patient must have demonstrated a beneficial response to therapy with Amvuttra compared to baseline (e.g.,

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	3. Documentation is provided that the patient has associated mild to moderate polyneuropathy. 4. Prescribed by or in consultation with a neurologist, geneticist, or physician specializing in the treatment of amyloidosis. 5. **Cannot** be approved if the patient has any of the following: • History of liver transplant, or moderate or severe hepatic impairment • Has severe renal impairment or end-stage renal disease • NYHA class III or IV heart failure • Sensorimotor or autonomic neuropathy not related to aATTR amyloidosis (including, but not limited to monoclonal gammopathy, autoimmune disease). 6. Amvuttra will not be used in combination with inotersen (Tegsedi), patisiran (Onpattro) or tafamidis (Vyndaqel, Vyndamax) 7. Quantity limited to one Amvuttra 25 mg/0.5 ml syringe per 3 months. 8. Initial approval duration: 3 months.	improvement of neuropathy severity and rate of disease progression as demonstrated by the modified Neuropathy Impairment Scale+7 (mNIS+7) composite score, the Norfolk Quality of Life Diabetic Neuropathy (QoL-DN) total score, polyneuropathy disability (PND) score, FAP disease stage, manual grip strength). Documentation from the medical record must be provided and have a date-of-service within the previous 3 months. 3. Approval duration: 3 months.
Zilucoplan (**Zilbrysq**) **J3490, J3590, C9399** **NDC: 50474-0990-80** **50474-0991-80** **50474-0992-80**	1. Ordered for an approved indication for use: • Treatment of adult patients with anti-acetylcholine receptor antibody positive (AChR+) generalized myasthenia gravis (gMG). 2. Patient age ≥ 18 years. 3. Cannot be approved for investigational conditions, including but not limited to: ocular myasthenia gravis, myasthenia gravis MUSK antibody positive or other antibodies that are not AChR, postural orthostatic tachycardia syndrome, primary	1. Patient is not continuing therapy based off being established on therapy through samples, manufacturer coupons or otherwise. If they have, initial policy criteria must be met to qualify for approval. 2. Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical

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	immune. thrombocytopenia, paroxysmal nocturnal hemoglobinuria. 4. Patient has Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of Class II, III, or IV at initiation of therapy, meaning patient is not intubated and is not being treated for ocular gMG. 5. MG activities of daily living (MG-ADL) total score of ≥ 6. 6. Documentation of positive serologic test for anti-AChR antibodies. 7. Greater than 50% of baseline MG-ADL score is due to non-ocular symptoms. 8. Patient is currently receiving a stable dose of at least one gMG treatment (including cholinesterase inhibitors, corticosteroids, or non-steroidal immunosuppressants). 9. Documentation of patient's current weight for appropriate dosing. 10. Patient has received or is currently receiving two different immunosuppressant therapies for ≥ 1 year; OR patient had inadequate efficacy, a contraindication, or significant intolerance to two different immunosuppressant therapies (e.g., azathioprine, cyclosporine, mycophenolate mofetil, methotrexate, pyridostigmine, tacrolimus, cyclophosphamide); AND 11. Patient has evidence of unresolved symptoms of gMG including difficulty swallowing, difficulty breathing, and a functional disability resulting in the discontinuation of physical activity (e.g., double vision, talking, impaired mobility).	benefit (e.g., improvements in speech, swallowing, mobility or respiratory functioning) and must have a date-of-service within the previous 3 months. 3. Improvement and maintenance of at least a 2-point improvement (reduction) in the MG-ADL score from pre-treatment baseline and reduction of signs and symptoms of MG required to show clinical benefit. 4. Zilbrysq cannot be concurrently prescribed with maintenance immunoglobulin therapy (IVIG), rixtuximab, or other biologic for gMG (e.g., Soliris, Ultomiris, Vyvgart/Vyvgart Hytrulo, or Rystiggo). 5. Approval Duration: 3 months.

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	12. Not prescribed in combination with another complement inhibitor, a neonatal Fc receptor blocker, or a rituximab product (e.g., Soliris (eculizumab), Ultomiris (ravulizumab), Rystiggo (rozanolixzumab-noli), Vyvgart/Vyvgart Hytrulo (efgartigimod alfa products)). 13. Prescribed by, or in consultation with a neurologist or rheumatologist. 14. Approval Duration: 3 months.	