Appendix Z

COLORADO
Department of Health Care Policy & Financing

Inpatient and Outpatient Hospital Specialty Drug Prior Authorization Procedures, Coverage Policies and Drug Utilization Criteria for the Health First Colorado Medical Benefit

Inpatient (IP) and Outpatient (OP) Hospital Specialty Drugs which are carved out from the All-Patient Refined Diagnosis Related Group (APR-DRG) and the Enhanced Ambulatory Patient Group (EAPG) payment methodologies, respectively, are listed in this document. A member-specific prior authorization (PA) is required for Health First Colorado medical benefit coverage. PA criteria is based on FDA product labeling, CMS approved compendia, clinical practice guidelines, and peer-reviewed medical literature.

Hospital Specialty Drug utilization criteria listed on Appendix Z apply specifically to medications billed on the UB-04/837I through the Health First Colorado medical benefit.

All Coverage Standards listed in Appendix Z will continue to be reviewed and evaluated for any applicable changes due to the evolving nature of factors including disease course, available treatment options and available peer-reviewed medical literature and clinical evidence. If request is for use outside of stated coverage standards, support with peer reviewed medical literature and/or subsequent clinical rationale shall be provided and will be evaluated at the time of request.

For the corresponding Healthcare Common Procedure Coding System (HCPCS) codes and National Drug Code (NDC) numbers for use in billing, please refer to Appendix X: The HCPCS/NDC Crosswalk.

Policy effective dates are listed on Appendix Z for both Inpatient Hospital (IP) and Outpatient Hospital (OP), as applicable.

Prior Authorization Procedures

- Complete and submit the Request Form to HCPF_PharmacyPAD@state.co.us
    - All Spinraza requests, including the Health First Colorado Spinraza Request Form and supporting clinical documentation, must be submitted to the following inbox: HCPF_Nusinersen@state.co.us
- PA forms can be signed by anyone who has authority under Colorado law to prescribe the medication. Assistants of authorized persons cannot sign the PA form.
- All PA requests are coded online into the PA system.

HCPCS	Drug	Effective Date	Coverage Standards
J0225	**Amvuttra (vutrisiran)**	**OP 04/03/2024 – 12/31/9999** **IP 04/03/2024 – 12/31/9999**	**Amvuttra** (vutrisiran) may be approved if all the following criteria are met: 1. Member has one of the following diagnosis: 1. Polyneuropathy of hereditary transthyretin-mediated amyloidosis as documented by genetic testing demonstrating mutations in the transthyretin (*TTR*) gene OR 2. Cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis with documented heart failure and at least one prior hospitalization for heart failure or clinical evidence of heart failure 2. Member is 18 years of age or older 3. Provider attests that member will be taking Vitamin A supplementation 4. Member does not have a history of liver transplant or severe hepatic impairment 5. Member is not concomitantly using a TTR-lowering agent or a TTR-stabilizing agent 6. Medication is being prescribed by, or in consultation with, a neurologist Reauthorization may be approved with documentation of improvement, stabilization, or slowing of disease progression based on assessment of signs and symptoms of disease Maximum dose: 25mg every 3 months
Q2058	**Aucatzyl** (obecabtagene autoleucel)	**OP 07/01/2025 – 12/31/9999** **IP 07/01/2025 – 12/31/9999**	Chimeric Antigen Receptor (CAR) T-Cell treatment is a multi-step process including collection, infusion, and recovery. Treatment will only be approved once per member lifetime. Requests will be evaluated for medical necessity and reviewed on a case-by-case basis. **Aucatzyl** (obecabtagene autoleucel) may be approved if all the following criteria are met: 1. Member has a diagnosis of CD19 positive relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) with the following: a. Member with philadelphia chromosome (Ph) positive disease has tried and failed two lines of any tyrosine kinase inhibitors (TKIs) or failed one second-generation TKI OR b. Member has philadelphia chromosome (Ph) negative disease 2. Member is 18 years and older 3. Member has adequate baseline renal, hepatic, pulmonary, and cardiac function 4. Member has been informed of anticipated benefits, risks, and expectations with treatment 5. Member does not have any of the following:

HCPCS	Drug	Effective Date	Coverage Standards
			a. Prior treatment with CAR T-cell immunotherapy b. Active infection or inflammatory disorder c. Primary central nervous system lymphoma d. Administration of live virus vaccination to member at least 6 weeks prior to therapy, during therapy, and until recovery of immune system post-CAR-T therapy
J9229	**Besponsa (inotuzumab ozogamicin)**	**OP 11/22/2023 – 12/31/9999** **IP 01/01/2024 – 12/31/9999**	**Besponsa** (inotuzumab ozogamicin) may be approved if all the following criteria are met: 1. Member has a documented diagnosis of relapsed or refractory CD22-positive B-cell precursor acute lymphoblastic leukemia (ALL) 2. Member has no prior treatment with inotuzumab ozogamicin 3. Member has all of the following documented prior to treatment a. Baseline electrocardiograms (ECGs) within normal limits b. Baseline electrolytes c. Baseline complete blood count (CBC) d. Baseline liver function tests (including ALT, AST, total bilirubin, and alkaline phosphatase) e. Member has been informed of anticipated benefits, risks, and expectations with treatment f. Treatment plan with the intended duration of treatment with inotuzumab ozogamicin g. Member of childbearing potential or with partners of childbearing potential has been counseled regarding the use of highly effective contraceptive methods while receiving treatment with inotuzumab ozogamicin and for at least 8 months or at least 5 months after the last dose, respectively. 4. Treating and prescribing provider(s) attests that post-infusion the following are completed a. Monitor complete blood counts and liver function tests b. Monitor for at least 1 hour post infusion
Q2054	**Breyanzi (lisocabtagene maraleucel)**	**OP 10/09/2023 - 12/31/9999** **IP 01/01/2024 - 12/31/9999**	Chimeric Antigen Receptor (CAR) T-Cell treatment is a multi-step process including collection, infusion, and recovery. Treatment will only be approved once per member lifetime. Requests will be evaluated for medical necessity and reviewed on a case-by-case basis. **Breyanzi** (lisocabtagene maraleucel) may be approved if all the following criteria are met: 1. Medical records and treating hematologist/oncologist provide testing and documentation to confirm member has the following diagnoses and prior treatment experience:

HCPCS	Drug	Effective Date	Coverage Standards
			a. Member is 18 years of age or older with a diagnosis of large B-cell lymphoma, including diffuse large B-cell lymphoma not otherwise specified, high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B who have one of the following: i. Refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy OR ii. Refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation due to comorbidities or age OR iii. Relapsed or refractory disease after two or more lines of systemic therapy 2. Prior to treatment: a. Member will receive lymphodepleting (LD) chemotherapy regimen appropriate for specified diagnosis i. Provide LD chemotherapy that member will receive including drug, dose, route frequency and duration prior to treatment with Breyanzi b. Member has been screened for hepatitis B virus, hepatitis C, and HIV c. Member has been informed of anticipated benefits, risks, and expectations with treatment including but not limited to the following i. Remission, post treatment occurrence of secondary malignancy, cytokine release syndrome, neurologic toxicity, and hypogammaglobulinemia 3. Treating and prescribing provider(s) attest to the following: a. Provider is a hematologist or oncologist experienced in treating with CAR-T therapy b. The hospital or associated clinic where the treatment will occur is specially certified per the drug manufacturer and in compliance with the Breyanzi REMS program for the treatment i. Treatment location for administration of requested medication is provided (inpatient or outpatient hospital) 4. Member must *not* have any of the following: a. Primary central nervous system lymphoma b. Prior treatment with CAR T-cell immunotherapy c. Active infection or inflammatory disorder d. Administration of live virus vaccination to member at least 6 weeks prior to therapy, during therapy, and until recovery of immune system post-CAR-T therapy

HCPCS	Drug	Effective Date	Coverage Standards
J0567	**Brineura (cerliponase alfa)**	**OP 01/01/2019 - 12/31/9999** **IP 01/01/2024 - 12/31/9999**	**Brineura** (cerliponase alfa) may be approved if all the following criteria are met: 1. Member has a diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2) 2. Medical records and/or genetic testing confirm: a. Member has mutations in TPP1 (tripeptidyl peptidase 1) gene AND b. Member has a diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2), also known as: i. Tripeptidyl peptidase 1 (TPP1) deficiency ii. Jansky-Bielschowsky disease c. Member has mild to moderate disease documented by a two-domain score of 3- 6 on motor and language domains of the Hamburg Scale, with a score of at least 1 in each of these two domains 3. Member is 3 years or older at time of Brineura administration 4. Treating and prescribing provider(s) attest to the following: a. Physician is experienced in intraventricular administration b. Member or member's caregiver has been counseled on the potential risks and potential benefits of all components of treatment c. Treatment is 10mL (300mg) Brineura followed by 2mL of intraventricular electrolytes administered once every other week by intraventricular infusion using the appropriate Brineura Administration Kit d. First dose occurs at least 5-7 days after intraventricular device implantation (most recent device, if replaced) e. Prior to each infusion: i. Sample of cerebrospinal fluid is obtained for cell count and culture (to identify any device-related infection) ii. Pretreatment with antihistamines +/- antipyretics or corticosteroids given 30-60 min prior to the start of infusion (unless clinically contraindicated) f. Post infusion: i. Monitor and assess vital signs (such as, blood pressure and heart rate); signs and symptoms of anaphylaxis ii. ECG performed at least every 6 months g. Treating and prescribing provider(s) attest to the following: i. Member will be assessed by the following exam scales or other validated assessment tool at baseline and during all subsequent office visits, completed at least every 6

HCPCS	Drug	Effective Date	Coverage Standards
			months AND will provide results to Health First Colorado via email (HCPF_PharmacyPAD@state.co.us). 1. Baseline clinical and neurological exam results will be provided including the name, score and date of the assessment tool a. Motor and language domains of the Hamburg CLN2 Clinical Rating Scale (efficacy for the Language domain cannot be established) 2. Member is able and willing to be compliant to treatment and treatment requirements 5. Member must not have any of the following: a. Any sign of acute, unresolved infection on or around the device insertion site, suspected or confirmed CNS infection b. Any acute intraventricular access device related complication c. Ventriculoperitoneal shunts d. Any other inherited neurologic disease e. Any contraindication to MRI scans or neurosurgery f. Pregnancy 6. Initial approval may be approved for 7 months to allow for additional, on treatment clinical and neurological exam results at six months. Subsequent approvals may be approved for 12 months. For reauthorization (after 7 or 12 months), if there has been a decline in motor domain, noted by ≥ 2 point loss in the motor domain of the CLN2 CRS, rationale and additional supporting documentation is provided.
Q2056	**Carvykti (ciltacabtagene autoleucel)**	**OP** **06/01/2023 - 12/31/9999** **IP** **01/01/2024 - 12/31/9999**	CAR T-Cell treatment is a multi-step process including collection, infusion, and recovery. Treatment will only be approved once per member lifetime. CAR-T requests will be evaluated for medical necessity and reviewed on a case-by-case basis. **Carvykti** (ciltacabtagene autoleucel) may be approved if all the following criteria are met: 1. Medical records and treating hematologist/oncologist provide testing to confirm member has one of the following diagnoses and prior treatment experience has been documented: a. Member is 18 years and older with a diagnosis of relapsed or refractory multiple myeloma, after one or more prior lines of therapy, defined by any of the following: i. Serum monoclonal paraprotein (M-protein) ≥ 1 g/dL OR ii. Urine M-protein level ≥ 200 mg/24 h

HCPCS	Drug	Effective Date	Coverage Standards
			iii. Serum free light chain ≥ 10 mg/dL and abnormal immunoglobulin kappa lambda free light chain ratio b. Prior treatment must include ALL the following: i. Proteasome inhibitor ii. Immunomodulatory agent iii. Anti-CD38 monoclonal antibody 2. Treating and prescribing provider(s) attest to the following: a. Provider is a hematologist/oncologist experienced in treating with CAR-T therapy b. The hospital or associated clinic where the treatment will occur is specially certified per the drug manufacturer and in compliance with the CARVYKTI REMS program for the treatment i. Treatment location for administration of requested medication is provided (inpatient, outpatient hospital). 3. Prior to treatment a. Member will receive lymphodepleting (LD) chemotherapy regimen appropriate for specified diagnosis i. Provide LD chemotherapy that member will receive including drug, dose, route frequency and duration prior to treatment with Carvykti. b. Member has adequate kidney, liver, cardiac, and pulmonary function (must meet established criteria/measures) to receive full therapy. c. Member has been screened for hepatitis B virus, hepatitis C virus, and HIV d. Member has been informed of anticipated benefits, risks and expectations with treatment including but not limited to the following i. Remission, post treatment occurrence of secondary malignancy, cytokine release syndrome, neurologic toxicity, and hypogammaglobulinemia 4. Member must not have any of the following: a. Primary central nervous system lymphoma b. Active infection or inflammatory disorder c. Administration of live virus vaccination to member at least 6 weeks prior to therapy, during therapy, and until recovery of immune system post-CAR-T therapy d. Prior treatment with a therapy targeted to B-cell maturation antigen (BCMA)

HCPCS	Drug	Effective Date	Coverage Standards
J3392	**Casgevy (exagamglogene autotemcel)**	**OP 01/01/2025 – 12/31/9999** **IP 01/01/2025 – 12/31/9999**	The Colorado Department of Health Care Policy and Financing / Colorado Medicaid participates in the Centers for Medicare & Medicaid Services (CMS) Center for Medicare and Medicaid Innovation (CMMI) Cell and Gene Therapy Access Model. Under this model, treatment centers that provide gene therapies for sickle cell disease (gene therapies for beta-thalassemia are not included at this time) must be members of the CMS Designated Registry through the Center for International Blood and Marrow Transplant Research (CIBMTR). Treatment centers must be enrolled in CIBMTR before administering gene therapies for sickle cell disease to Colorado Medicaid recipients. **Casgevy** (exagamglogene autotemcel) may be approved if all the following criteria are met: 1. Member has a confirmed diagnosis of one of the following: a. Sickle cell disease (SCD) with recurrent vaso-occlusive crises (VOCs) b. Transfusion-dependent beta-thalassemia (TDT) 2. Member is 12 years of age or older (for diagnosis of either SCD or TDT) 3. Member is clinically stable and eligible for transplantation (for diagnosis of either SCD or TDT) 4. Member with SCD has a documented history of at least two VOCs per year within the prior two years, based on provider attestation (for diagnosis of SCD only) 5. Member has trial and failure with hydroxyurea (for diagnosis of SCD only) a. Failure is defined as lack of efficacy, allergy, intolerable side effects, contraindications to therapy or significant drug-drug interactions 6. Prescribed by or in consultation with a board-certified hematologist with sickle cell disease expertise
J9286	**Columvi (glofitamab-gxbm)**	**OP 02/14/2024 – 12/31/9999** **IP 02/14/2024 – 12/31/9999**	**Columvi** (glofitamab-gxbm) may be approved if all the following criteria are met: 1. Member has a documented diagnosis of relapsed or refractory diffuse 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. Member is 18 years of age or older 3. Member has no active or previous central nervous system (CNS) lymphoma or CNS disease, acute infection, recent infection requiring antibiotics or prior allogeneic hematopoietic stem cell transplant (HSCT) 4. Member has been informed of anticipated benefits, risks, and expectations with treatment 5. Provider and member are aware that continued US FDA approval of Columvi (glofitamab-gxbm) may be contingent upon verification and description of clinical benefit in confirmatory trial(s). 6. Maximum of 12 dosage cycles will be approved

HCPCS	Drug	Effective Date	Coverage Standards
J9348	**Danyelza (naxitamab-gqgk)**	**OP 07/01/2021 - 12/31/9999** **IP 01/01/2024 - 12/31/9999**	**Danyelza** (naxitamab-gqgk) requests will be evaluated for medical necessity and reviewed on a case by case basis for all Health First Colorado Members when used in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF) for the diagnosis of relapsed or refractory high-risk neuroblastoma in the bone or bone marrow based on ALL the following: 1. Member is 1 year of age or older 2. Member's medical records indicate that the neuroblastoma has demonstrated a partial response, minor response, or stable disease with prior therapy. 3. Treating and prescribing provider(s) attest to the following: a. Treatment with naxitamab-gqgk and GM-CSF will be discontinued for disease progression b. Member or member's caregiver has been counseled on the potential risks and potential benefits of all components of treatment c. Member is able and willing to be compliant to treatment and treatment requirements d. Prior to each infusion: i. Pretreatment with clinically appropriate prophylactic medication for neuropathic pain ii. Pretreatment with antihistamines, H2 antagonist, acetaminophen and an antiemetic 30 minutes prior to each infusion iii. Pretreatment with intravenous corticosteroids given 30 minutes to 2 hours prior to the start of first infusion e. Post infusion: i. Monitor member for signs and symptoms of infusion reactions during infusion and for a minimum of 2 hours following each infusion
J1413	**Elevidys (delandistrogene moxeparvovec-rokl)**	**OP 01/01/2024 - 12/31/9999** **IP 01/01/2024 - 12/31/9999**	**Elevidys** (delandistrogene moxeparvovec-rokl) may be approved if all the following criteria are met: 1. Member is aged 4 through 5 years AND 2. Member has a diagnosis of Duchenne Muscular Dystrophy (DMD) with a confirmed mutation in the *DMD* gene AND 3. Member is ambulatory and provider has performed and documented a functional level determination of baseline assessment of ambulatory function AND 4. Member does not have either of these conditions: a. Elevated anti-AAVrh74 total binding antibody titers (≥1:400) based on ELISA testing b. Any deletion in exon 8 and/or exon 9 in the *DMD* gene 5. Requested medication is being prescribed by or in consultation with a neurologist or a provider who specializes in treatment of DMD (such as a pediatric neurologist, cardiologist, physical medicine and rehabilitation specialist, or pulmonary specialist) AND

HCPCS	Drug	Effective Date	Coverage Standards
			6. Provider attests that baseline liver function (clinical exam, GGT, total bilirubin), platelet count, and troponin-I will be assessed prior to Elevidys infusion and also monitored following the infusion according to product labeling AND 7. The member must be on corticosteroids at baseline or prescriber provides clinical rationale for not using corticosteroids AND 8. Provider has evaluated, and member has received, all age-appropriate vaccinations as recommended by current immunization guidelines prior to initiation of the corticosteroid regimen AND 9. Provider and patient or caregiver are aware that continued US FDA approval of Elevidys (delandistrogene moxeparvovec) for Duchenne muscular dystrophy (DMD) may be contingent upon verification and description of clinical benefit in confirmatory trial(s). Maximum dose: one kit containing 70 single-dose 10 mL vials Approval will be placed to allow for one treatment course
Q2042	**Kymriah (tisagenlecleucel)**	**OP** **01/01/2019 - 12/31/9999** **IP** **01/01/2024 - 12/31/9999**	Chimeric Antigen Receptor (CAR) T-Cell treatment is a multi-step process including collection, infusion, and recovery. Treatment will only be approved once per member lifetime. Requests will be evaluated for medical necessity and reviewed on a case-by-case basis. **Kymriah** (tisagenlecleucel) may be approved if all the following criteria are met: 1. Medical records and treating hematologist/oncologist provide testing to confirm member has one of the following diagnoses and prior treatment experience has been documented: a. For member age 18 years and older, Large B-cell lymphoma relapsed or refractory (r/r) disease after two or more lines of systemic therapy (including an anti-CD20 antibody and an anthracycline), including one of the following (i.-iii.), OR relapsed after autologous hematopoietic stem cell transplantation (HSCT) i. Diffuse large B-cell lymphoma (DLBCL), not otherwise specified ii. High grade B-cell lymphoma iii. DLBCL arising from follicular lymphoma b. For member age less than age 26 years B-cell precursor acute lymphoblastic leukemia (ALL), refractory or in second or later relapse 2. Prior to treatment: a. Member will receive Lymphodepleting (LD) chemotherapy:

HCPCS	Drug	Effective Date	Coverage Standards
			i. Provide LD chemotherapy that member will receive including drug, dose, route frequency and duration prior to treatment with Kymriah. b. Member's parent or caretaker/guardian has been informed of anticipated benefits, risks and expectations with treatment including, but not limited to the following: i. Remission, Cytokine Release Syndrome (CRS), neurological toxicities, serious infections, hypogammaglobulinemia, prolonged cytopenia, and manufacturing failure c. Member has adequate organ, cardiac, and pulmonary function (must meet established criteria/measures) to receive full therapy d. Member has been screened for hepatitis B virus, hepatitis C virus, and HIV 3. Treating and prescribing provider(s) attest to the following: a. Provider is a hematologist/oncologist experienced in treating with CAR-T therapy b. The hospital or associated clinic where the treatment will occur is specially certified per the drug manufacturer and in compliance with the KYMRIAH REMS program for the treatment (including immediate on-site access to tocilizumab) c. Member has appropriate labs completed prior to Kymriah treatment for monitoring during and after treatment 4. Treatment location for administration of Kymriah is provided (inpatient, outpatient hospital). 5. Member must not have any of the following: For adult members with Large B-cell lymphoma r/r, member does not have active central nervous system malignancy
J3394	**Lyfgenia** (lovotibeglogene autoemcel)	**OP** **07/01/2024 – 12/31/9999** **IP** **07/01/2024 – 12/31/9999**	**Lyfgenia** (lovotibeglogene autotemcel) may be approved if all the following criteria are met: 1. Member is 12 years of age or older at the expected time of gene therapy administration 2. Member has a confirmed, with genetic testing, diagnosis of sickle cell disease 3. Member is clinically stable and fit for transplantation 4. Member has documented history of at least four vaso-occlusive events (VOEs) within the prior two years, as determined by the provider, or is currently receiving chronic transfusion therapy for recurrent vaso-occlusive events (VOEs) 5. Member has tried and failed hydroxyurea or has experienced intolerance to hydroxyurea (defined as being unable to take hydroxyurea per health care professional judgment) at any point in the past 6. Medication is prescribed by or in consultation with a board-certified hematologist with expertise in sickle cell disease

HCPCS	Drug	Effective Date	Coverage Standards
J9038	**Niktimvo** (azatilimab)	**OP 04/03/2025 – 12/31/9999** **IP 04/03/2025 – 12/31/9999**	**Niktimvo** (axatilimab) may be approved if all the following criteria are met: 1. Member has recurrent or refractory chronic graft-versus-host disease (cGVHD) defined as failure of at least two prior lines of systemic therapy 2. Member weighs at least 40 kg 3. Member is post allogeneic hematopoietic stem cell transplant (generally 3 or more months) 4. Medication is used alone or in combination with a systemic corticosteroids, calcineurin inhibitors (CNI) or mammalian target of repamycin (mTOR) inhibitors 5. Members of childbearing potential have been counseled on the potential risk to a fetus and to use of effective contraception 6. Member does not have any of the following: a. History or evidence of current uncontrolled infection b. History of acute or chronic pancreatitis c. Hepatitis B or Hepatitis C
J7352	**Scenesse (afamelanotide)**	**OP 01/21/2024 – 12/31/9999** **IP 01/21/2024 – 12/31/9999**	**Scenesse** (afamelanotide) may be approved if all the following criteria are met: 1. Member is ≥18 years of age and has a documented diagnosis of erythropoietic protoporphyria as defined by the following: a. Increased total erythrocyte protoporphyrin AND b. Marked elevation of erythrocyte metal-free protoporphyrin (≥ 50 percent) AND c. Genetic sequencing demonstrating pathogenic or likely pathogenic variant in *FECH* gene AND 2. Member has documented baseline whole body skin examination. 3. Member does <u>not</u> have any of the following: a. Current or history of Bowen's disease, basal cell carcinoma, squamous cell carcinoma, melanoma, dysplastic nevus syndrome or other malignant or premalignant skin lesions b. History of any other photodermatosis such as polymorphic light eruption, discoid lupus erythematosus, or solar urticaria c. Currently pregnant or lactating <u>Reauthorization</u> may be approved with documentation of improvement or stability in disease state based on assessment of decrease in phototoxic reactions and increase in sun exposure time without phototoxic reaction based on lack of new lesion development with skin exams.

HCPCS	Drug	Effective Date	Coverage Standards
			Maximum dosage: 1 implantation every 2 months
J2326	**Spinraza (nusinersen)**	**OP 08/11/2018 - 12/31/9999** **IP 01/01/2024 - 12/31/9999**	**Spinraza** (nusinersen) requests will be reviewed on a case by case basis for all Health First Colorado members with a diagnosis of Spinal Muscular Atrophy (SMA) and may be approved for members meeting all of the following: 1. Member must have SMA documented by gene testing showing the following: a. SMN1 mutation AND more than two SMN2 gene copies must be specified. 2. Treatment naïve Members must meet all the requirements below to begin Spinraza treatment. Clinical documentation must include the following: a. Demonstrated SMA symptoms documented by a Neurologist using a motor exam. b. Acceptable motor exams include at least one of the following: i. For Members ≤ 2 years old: Hammersmith Infant Neurological Examination Section 2 (HINE-2), ii. For Members ≥ 3 years old: Hammersmith Functional Motor Scale Expanded (HFMSE) for ambulatory beneficiaries or Upper Limb Module (ULM) for non-ambulatory beneficiaries. c. Be free from permanent ventilation or requiring a maximum of 16 hours of assisted ventilation per 24 hours. d. Stable baseline labs including, but not limited to, a PT, PTT, platelets, and quantitative spot-urine protein testing prior to beginning treatment and prior to each subsequent Spinraza dose. 3. Members must meet all the requirements below to continue Spinraza treatment: a. Documentation of previous Spinraza doses including any doses received as part of an SMA clinical trial. b. Be assessed utilizing the same motor exam unless otherwise indicated. c. Has shown no adverse events to prior Spinraza treatment. d. Be free of permanent ventilation (16 hours or greater per 24 hours) or an increased number of hours of assisted ventilation. e. Stable laboratory values including, at a minimum, PT, PTT, platelets, and quantitative spot-urine protein testing prior to each dose.

HCPCS	Drug	Effective Date	Coverage Standards
			f. Demonstrated response to treatment by showing significant clinical improvement documented using quantitative scores using the same motor function test(s) used prior to initiating Spinraza treatment. g. Improvement of SMA related symptoms must be compared to the baseline assessment and motor function must be measured against the degenerative effects of SMA. i. An explanation must be submitted if a provider other than the one who initially performed the motor exam completes any follow-up exam(s). ii. Documentation of clinical improvement must include, at a minimum, the following: 1. At least a two (2) point increase inability to kick or a one (1) point increase in head control, rolling, sitting, crawling, standing, or walking inHINE-2; 2. At least a three (3) point increase in HFMSE; 3. At least a two (2) point increase in ULM. All Spinraza requests, including the Health First Colorado Spinraza Request Form and supporting clinical documentation, must be submitted to the following inbox: HCPF_Nusinersen@state.co.us
Q2053	**Tecartus (brexucabtagene autoleucel)**	**OP** **10/10/2022 - 12/31/9999** **IP** **01/01/2024 - 12/31/9999**	Chimeric Antigen Receptor (CAR) T-Cell treatment is a multi-step process including collection, infusion, and recovery. Treatment will only be approved once per member lifetime. Requests will be evaluated for medical necessity and reviewed on a case-by-case basis. **Tecartus** (brexucabtagene autoleucel) may be approved if all the following criteria are met: 1. Medical records and treating hematologist/oncologist provide testing to confirm member meets the following diagnosis specific criteria: a. Diagnosis for member aged 18 years and older i. Relapsed or refractory mantle cell lymphoma (MCL). (This indication is approved under accelerated approval based on overall response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial) 1. Prior treatment must include ALL of the following: a. Anthracycline or bendamustine-containing chemotherapy AND b. Anti-CD20 monoclonal antibody therapy (e.g. rituximab) AND c. Bruton's tyrosine kinase (BTK) inhibitor (e.g. Ibrutinib, acalabrutinib, zanubrutinib) AND

HCPCS	Drug	Effective Date	Coverage Standards
			2. Member has at least one measurable lesion AND 3. Member has adequate bone marrow reserve defined by all the following: a. Absolute neutrophil count (ANC) ≥ 1000 cells/µL b. Absolute lymphocyte count (ALC) ≥ 100 cells/µL c. Platelet count ≥ 75,000/µL ii. Relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) defined as one of the following 1. Primary refractory disease 2. First relapse if first remission ≤ 12 months 3. Relapsed or refractory disease after 2 or more lines of systemic therapy 4. Relapsed or refractory disease after allogeneic transplant provided individuals is at least 100 days from stem cell transplant at the time of enrollment 2. Prior to treatment: a. Member will receive lymphodepleting (LD) chemotherapy regimen appropriate for specified diagnosis i. Provide LD chemotherapy that member will receive including drug, dose, route frequency and duration prior to treatment with Tecartus. b. Member has adequate kidney, liver, cardiac, and pulmonary function (must meet established criteria/measures) to receive full therapy. c. Member has been screened for hepatitis B virus, hepatitis C virus, and HIV d. Member has been informed of anticipated benefits, risks and expectations with treatment including but not limited to the following i. Remission, post treatment occurrence of secondary malignancy, cytokine release syndrome, neurologic toxicity, and hypogammaglobulinemia 3. Treating and prescribing provider(s) attest to the following: a. Provider is a hematologist/oncologist experienced in treating with CAR-T therapy b. The hospital facility or associated clinic where the treatment will occur is specially certified per the drug manufacturer and in compliance with the YESCARTA and TECARTUS REMS program for the treatment (including immediate on-site access to tocilizumab) i. Treatment location for administration of requested medication is provided (inpatient, outpatient hospital). c. Member will be monitored at the certified healthcare facility daily for at least seven days for patients with MCL and at least 14 days for patients with ALL following infusion for signs and symptoms of Cytokine Release Syndrome (CRS) and neurologic events. 4. Member must not have any of the following:

HCPCS	Drug	Effective Date	Coverage Standards
			a. Active infection or inflammatory disorder b. History of a seizure disorder, cerebrovascular ischemia/hemorrhage, dementia, cerebellar disease, cerebral edema, posterior reversible encephalopathy syndrome, or any autoimmune disease with central nervous system (CNS) involvement c. History of prior allogeneic HSCT d. History of primary central nervous system lymphoma
J1303	**Ultomiris (ravulizumab-cwyz)**	**OP** **08/02/2023 - 12/31/9999** **IP** **01/01/2024 - 12/31/9999**	**Ultomiris** (ravulizumab-cwvz) may be approved if all the following criteria are met: 1. Member is diagnosed with either Paroxysmal Nocturnal Hemoglobinuria (PNH), Atypical Hemolytic Uremic Syndrome (aHUS), Generalized Myasthenia Gravis (gMG), or Neuromyelitis Optica Spectrum Disorder (NMOSD) AND 2. Member has been vaccinated for meningococcal disease according to current ACIP guidelines at least two weeks prior to medication initiation OR 3. Member is receiving 2 weeks of antibacterial drug prophylaxis if meningococcal vaccination cannot be administered at least 2 weeks prior to starting requested medication AND 4. Member does not have unresolved *Neisseria meningitidis* or any systemic infection 5. Prescriber is enrolled in the Ultomiris Risk Evaluation and Mitigation Strategy (REMS) program AND a. Medication is administered by or in consultation with a hematologist for PNH and by or in consultation with a hematologist or nephrologist for aHUS and by or in consultation with a neurologist for gMG and by or in consultation with a neurologist or ophthalmologist for NMOSD AND b. Member meets criteria listed below for specific diagnosis: i. <u>Paroxysmal nocturnal hemoglobinuria (PNH)</u> 1. Member is one month of age or older if prescribing the IV formulation OR is ≥ 18 years of age if prescribing the subcutaneous formulation AND 2. Diagnosis of PNH must be accompanied by detection of PNH clones by flow cytometry diagnostic testing AND 3. Baseline values are documented for the following: ❑ Serum lactate dehydrogenase (LDH) ❑ Hemoglobin levels ❑ Packed RBC transfusion requirement AND 4. Member has one of the following indications for therapy:

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			❑ Presence of a thrombotic event ❑ Presence of organ dysfunction secondary to chronic hemolysis ❑ Member is transfusion dependent ❑ Member has uncontrolled pain secondary to chronic hemolysis ii. Atypical hemolytic uremic syndrome (aHUS) 1. Member is one month of age or older if prescribing the IV formulation OR is ≥ 18 years of age if prescribing the subcutaneous formulation AND 2. Member does not have Shiga toxin E. coli related HUS (STEC-HUS) AND 3. Thrombotic Thrombocytopenic Purpura (TTP) has been ruled out by evaluating ADAMTS13 level or a trial of plasma exchange did not result in clinical improvement AND 4. Baseline values are documented for the following: ❑ Serum LDH ❑ Serum creatinine/eGFR ❑ Platelet count ❑ Dialysis requirement iii. Generalized myasthenia gravis 1. Member is 18 years of age or older AND 2. Member has a positive serologic test for anti-acetylcholine receptor (AchR) antibodies 3. Member has Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of Class II to IV disease; AND 4. Member has a MG-Activities of Daily Living (MG-ADL) total score of ≥6; AND 5. Member has trial and failure of treatment over at least 1 year with at least 2 immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate, etc.), or has failed at least 1 immunosuppressive therapy and required chronic plasmapheresis or plasma exchange (PE) or intravenous immunoglobulin (IVIG) iv. Neuromyelitis optica spectrum disorder (NMOSD): 1. Member is 18 years of age or older AND 2. Member has a positive test for anti-aquaporin-4 (AQP4) antibodies AND 3. Exclusion of alternative diagnoses have been evaluated AND 4. Member has one of the following clinical characteristics: □ Optic neuritis

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			□ Acute myelitis □ Area postrema syndrome (episode of otherwise unexplained hiccups or nausea and vomiting) □ Acute brainstem syndrome □ Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions □ Symptomatic cerebral syndrome with NMOSD-typical brain lesions Maximum dose: 3.6 g every 8 weeks (IV infusion) 490 mg once weekly (subcutaneous administration)
J0218	**Xenpozyme (olipudase alfa-rpcp)**	**OP** **08/10/2023 - 12/31/9999** **IP** **01/01/2024 - 12/31/9999**	**Xenpozyme** (olipudase alfa-rpcp) may be approved if all the following criteria are met: 1. Member has a documented diagnosis of acid sphingomyelinase deficiency (ASMD) with non-central nervous system (CNS) manifestations confirmed by a. Biallelic pathogenic variants in SMPD1 **AND** b. Residual acid sphingomyelinase enzyme activity is <10% of controls 2. Member has clinical manifestations of ASMD defined as ONE of the following a. Spleen volume of ≥6 MN for members ≥ 18 years of age or ≥5 MN for members <18 years of age **OR** b. Pulmonary function DLCO ≤ 70% of predicted normal 3. Member has the following baseline labs documented: a. LFTs (ALT, AST, and total bilirubin) b. Pulmonary function tests c. Lipid levels d. Platelet counts 4. Reauthorization requests may be approved if member has shown a documented clinical benefit with at least ONE of the following a. Reduced liver volume from baseline b. Reduced spleen volume from baseline c. Improved platelet count from baseline d. Improved DLCO score from baseline

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Q2041	**Yescarta (axicabtagene ciloleucel)**	**OP 08/11/2018 - 12/31/9999** **IP 01/01/2024 - 12/31/9999**	Chimeric Antigen Receptor (CAR) T-Cell treatment is a multi-step process including collection, infusion, and recovery. Treatment will only be approved once per member lifetime. Requests will be evaluated for medical necessity and reviewed on a case-by-case basis. **Yescarta** (axicabtagene ciloleucel) may be approved if all the following criteria are met: 1. Medical records and treating hematologist/oncologist provide testing to confirm member has one of the following diagnoses and prior treatment experience: a. Diagnosis for member age 18 years and older: i. Relapsed or refractory disease after two or more lines of systemic therapy 1. Diffuse large B-cell lymphoma (DLBCL), not otherwise specified 2. Primary mediastinal large B-cell lymphoma 3. High grade B-cell lymphoma 4. DLBCL arising from follicular lymphoma ii. Large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy b. Treatment regimens: i. The lymphoma has not responded to first line chemotherapy ii. The lymphoma has not responded to second or greater lines of chemotherapy, or iii. The lymphoma has relapsed within 12 months of an autologous hematopoietic stem cell transplant (HSCT) 2. Prior to treatment: a. Member will receive Lymphodepleting (LD) chemotherapy: i. Provide LD chemotherapy that member will receive including drug, dose, route frequency and duration prior to treatment with Yescarta. b. Member's parent or caretaker/guardian has been informed of anticipated benefits, risks and expectations with treatment including but not limited to the following i. Remission, post treatment occurrence of secondary malignancy, cytokine release syndrome, neurologic toxicity, and hypogammaglobulinemia c. Member has adequate liver, kidney, cardiac, and pulmonary function (must meet established criteria/measures) to receive full therapy. d. Member has been screened for hepatitis B virus, hepatitis C virus, and HIV 3. Treating and prescribing provider(s) attest to the following: a. Provider is a hematologist/oncologist experienced in treating with CAR-T therapy

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			b. The hospital facility or associated clinic where the treatment will occur is specially certified per the drug manufacturer and in compliance with the YESCARTA and TECARTUS REMS program for the treatment (including immediate on-site access to tocilizumab) i. Treatment location for administration of requested medication is provided (inpatient, outpatient hospital). c. Member has appropriate labs completed prior to Yescarta treatment for monitoring during and after treatment 4. Member must not have any of the following: a. History of primary central nervous system lymphoma b. Administration of live virus vaccination to member at least 6 weeks prior to therapy, during therapy, and until recovery of immune system post-CAR-T therapy c. Active infection or inflammatory disorder d. History of prior allogeneic HSCT
J3399	**Zolgensma (onasemnogene abeparvovec-xioi)**	**OP 07/01/2020 - 12/31/9999** **IP 01/01/2024 - 12/31/9999**	**Zolgensma** (onasemnogene abeparvovec-xioi) may be approved for members with a diagnosis of Spinal Muscular Atrophy (SMA) meeting all the following criteria: 1. Treatment is a single-dose, intravenous infusion, once per lifetime gene transfer 2. Medical records for prior treatment (if received) for SMA: a. Spinraza (nusinersen), risdiplam or other treatment: number of doses given (including if any were given as part of a clinical trial), administration date(s), and clinical outcomes [including Hammersmith Infant Neurological Examination Section 2 (HINE-2) or Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND) motor exam scales] b. Other supportive care including nutritional status (including GT/NG feeds), pulmonary status (including oxygen requirements/use, assistive devices), bulbar function, PT/OT/ST, etc. 3. Member has achieved full term gestational age prior to treatment (FDA approved labeling does not recommend treatment in patients before reaching full-term gestational age) AND 4. Member is equal to or younger than 24 months of age at time of Zolgensma administration a. Medical records and genetic testing confirm genotype: i. Member has bi-allelic mutations in SMN1 gene AND ii. Member has 2 or 3 copies for SMN2 gene AND 5. Treating and prescribing provider(s) attest to the following: a. Physician is neurologist or pediatrician experienced in treatment of SMA

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			b. Above physician attests the member will be assessed by at least one of the following exam scales at baseline and during all subsequent office visits, completed at least every 6 months AND will provide results to Health First Colorado via email (HCPF_pharmacypad@state.co.us) i. Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND) when member is 2-3 years old or younger ii. Hammersmith Functional Motor Scale Expanded (HFMSE) when member is 2-3 years old or older c. Pre-treatment: i. Treating provider to attest to obtain and assess liver function, platelet count, and troponin-I ii. Treating provider to attest that member will receive systemic corticosteroids equivalent to oral prednisolone 1mg/kg/day 1 day prior to infusion and continue for 30 days total treatment iii. Treating provider to attest that member's vaccination schedule does not conflict with receipt of corticosteroid regimen above (6.c.iii.) iv. Treating provider to attest that member's parent or guardian has been informed of anticipated benefits, risks and treatment expectations d. Post-treatment assessment of liver function, platelet count and troponin-I and monitoring up to at least 3 months post gene transfer 6. For members weighing greater than 13.5 kg, the treating provider must work with the manufacturer to obtain a kit providing the necessary dose in one kit. 7. Member must not have any of the following: a. Current viral infection or concomitant illness that creates unnecessary risk for gene transfer b. Presence of advanced SMA [e.g., permanent ventilation dependence (permanent defined as greater than 16 hours per day) or complete paralysis of limbs] c. Current or past medication use to treat myopathy, neuropathy or diabetes, including immunosuppressants (e.g., corticosteroids, cyclosporine, tacrolimus, methotrexate, cyclophosphamide, IVIG, rituximab) within last 3 months d. Pre-treatment abnormal laboratory values such as GGT > 3XULN; bilirubin ≥ 3.0 mg/dL; creatinine ≥ 1.8 mg/dL; Hgb < 8 or > 18 g/DI; WBC > 15,000 per cmm e. Pre-treatment Anti-AAV9 antibody titers >1:50 determined by an enzymelinked immunosorbent assay (ELISA) f. Treatment plan which includes treatment with Spinraza (nusinersin) post gene transfer

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J3393	**Zynteglo (betibeglogene autoemcel)**	**OP 07/01/2024 – 12/31/9999** **IP 07/01/2024 – 12/31/9999**	**Zynteglo** (betibeglogene autotemcel) may be approved if all the following criteria are met: 1. Member has a confirmed diagnosis of beta-thalassemia who require regular red blood cell (RBC) transfusions 2. Member is 4 years of age or older 3. Member is eligible for a hematopoietic stem cell transplant (HSCT) but is unable to find a matched related donor 4. Member has not received prior HSCT 5. Member does not take any prophylactic HIV antiretroviral medications or hydroxyurea for at least one month prior to mobilization 6. Member has a history of at least eight transfusions of packed red blood cells (pRBCs) per year in the prior two years 7. For members of childbearing potential: a. Member is not pregnant and prescriber acknowledges that pregnancy testing is recommended for members of reproductive potential prior to the start of mobilization, conditioning procedures, and medication administration AND b. Member has been counseled regarding the use of highly effective contraceptive methods from the start of mobilization through at least 6 months after medication administration c. Member has been counseled on the risk of infertility with myeloablative conditioning