PROVIDER NOTIFICATION OF POLICY CRITERIA CHANGE					
POLICY TITLE	**POLICY NUMBER**	**CRITERIA CHANGE**	**MATERIAL AMENDEMENT**	**EFFECTIVE DATE**	**LINK TO FULL POLICY**
Valoctocogene roxaparvovec-rvox (e.g., Roctavian)	2023050	Coverage criteria updated. Moved criterion regarding absence of active infection to policy guidelines. 1. Individual has severe or moderately severe hemophilia A as defined by residual Factor VIII activity levels less than or equal to 1 IU/dL (Ozelo, 2023); **AND** 2. Individual is 18 years of age or older (Roctavian, 2023); **AND** 3. Individual was assigned male at birth (Ozelo, 2023); **AND** 4. Individual has been treated with or exposed to Factor VIII concentrates or cryoprecipitate for a minimum of 150 exposure days (Roctavian, 2023); **AND** 5. Individual meets one of the following: a. Current or historical life-threatening hemorrhage; **OR** b. Repeated, serious spontaneous bleeding episodes; **AND** 6. Individual does not have a history of Factor VIII inhibitors or a positive screen result of greater than or equal to 0.6 Bethesda Units (BU) using the Nijmegen-Bethesda assay (Ozelo, 2023); **AND** 7. Individual does not have detectable pre-existing antibodies to the adeno-associated virus serotype 5 (AAV5) capsid (Roctavian, 2023); **AND** 8. Individual is HIV negative (Roctavian, 2023); **AND** 9. Individual has received a liver health assessment including enzyme testing and is absent of significant liver dysfunction or disease, defined as one or more of the following (Roctavian, 2023): a. Liver cirrhosis of any etiology; **OR** b. Active hepatitis B or C infection; **OR**	No	2/19/2025	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2023050

		c. Alanine transaminase (ALT) greater than or equal to 3 times the upper limit of normal; **OR** d. Bilirubin greater than or equal to 3 times the upper limit of normal; **OR** e. Alkaline phosphatase greater than or equal to 3 times the upper limit of normal; **OR** f. International normalized ratio (INR) greater than or equal to 1.4; **AND** 10. Individual should be able to receive corticosteroids and/or immunosuppression therapy (Roctavian, 2023); **AND** 11. Individual has no history of receiving gene therapy or under consideration for treatment with another gene therapy for hemophilia A (Roctavian, 2023); **AND** 12. Valoctocogene roxaparvovec-rvox (e.g., Roctavian) is being prescribed by or in consultation with a hematologist or a prescriber who specializes in hemophilia A and is being administered by or in consultation with a Hemophilia Treatment Center (HTC), and post-administration monitoring per the manufacturer recommendations is planned by or in consultation with an HTC. **POLICY GUIDELINES** Prescribing provider responsible to ensure individual does not have an active infection at scheduled infusion.			
Afamitresgene autoleucel (e.g., Tecelra)	2024078	Coverage criteria updated. Moved criterion regarding absence of active infection to policy guidelines. 1. Individual is 18 years of age or older; **AND** 2. Individual has a diagnosis of unresectable or Stage IV synovial sarcoma; **AND** 3. Individual has disease progression following 1 or more prior systemic chemotherapy with either doxorubicin or ifosfamide (D'Angelo, 2024); **AND**	No	2/19/2025	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2024078

		4. Individual is Human Leukocyte Antigen (HLA) -A*02:01P, -A*02:02P, 16 -A*02:03P, or -A*02:06P positive (D'Angelo, 2024); **AND** 5. Individual's tumor is MAGE-A4 antigen positive (D'Angelo, 2024); **AND** 6. Individual has had no prior treatment with tumor infiltrating lymphocytes (TIL) therapy; **AND** 7. Individual has an Eastern Cooperative Oncology Group Performance Status (ECOG) 0-1 (see policy guidelines) (D'Angelo, 2024); **AND** 8. Individual has no history of central nervous system (CNS) metastases or other CNS disorders; **AND** 9. Individual is not heterozygous or homozygous for HLA-A*02:05P; **AND** 10. Individual will be using Afamitresgene autoleucel (e.g., Tecelra) as a **one-time, single administration dose per lifetime**. **POLICY GUIDELINES** **ECOG Performance Status Scale** (ECOG, 2025) • Fully active, able to carry on all pre-disease performance without restriction • Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work • Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours • Capable of only limited self-care; confined to bed or chair more than 50% of waking hours • Completely disabled; cannot carry on any selfcare; totally confined to be or chair • Dead Prescribing provider responsible for ensuring individual does not have any active or serious infection.			

New-To-Market Medical Benefit Medication	2024079	New-To-Market Medical Benefit Drug List updated. **<u>Medication Name</u>** Aflibercept (e.g., Eydenzelt) Injection Apomorphine (e.g., Onapgo) infusion device Concizumab (e.g., Alhemo) injection Denileukin diftitox (e.g., Lymphir) injection Denosumab-qbde (e.g., Enoby) injection Fitusiran (e.g., Qfitlia) injection Gemcitabine (e.g., Inlexzo) intravesical system Marstacimab (e.g., Hympavzi) injection Onasemnogene abeparvovec (e.g., Itvisma) intrathecal injection Penpulimab-kcqx injection Pertuzumab-dpzb (e.g., Poherdy) injection Telisotuzumab vedotin-tllv (e.g., Emrelis) injection Ustekinumab-hmny (e.g., Starjemza) injection Zopapogene imadenovec-drba (e.g., Papzimeos) injection	No	2/19/2025	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2024079
Imetelstat (e.g., Rytelo)	2024080	Coverage criteria updated. 1. Individual is 18 years of age or older; **AND** 2. Individual has a diagnosis of low to intermediate risk myelodysplastic syndromes (MDS) (Rytelo, 2024; NCCN 2A); **AND** 3. Individual is transfusion-dependent (i.e., requiring 4 or more red blood cell units transfused over an 8-week period within the last 16 weeks) (Steensma, 2021); **AND**	Yes	3/19/2025	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2024080

		4. Individual is ineligible for or relapsed/refractory to erythropoiesis stimulating agent (ESA) and luspatercept treatment (see policy guidelines) (Steensma, 2021); **AND** 5. Individual will not be using Imetelstat (e.g., Rytelo) concurrently with another ESA; **AND** 6. Individual has an absolute neutrophil count of 1.5 x 1 billion/L or greater (Steensma, 2021); **AND** 7. Individual has platelets 75 x 1 billion/L or greater (Steensma, 2021); **AND** 8. Individual has an Eastern Cooperative Oncology Group (ECOG) (see policy guidelines) Performance Status score of 0 to 2 (Steensma, 2021); **AND** 9. Individual is not pregnant or breast feeding (Rytelo, 2024); **AND** 10. Imetelstat (e.g., Rytelo) will not be given with live or attenuated vaccines (Steensma, 2021).			
Belantamab mafodotin-blmf (e.g., Blenrep)	2020024	Coverage criteria updated. **INITIAL APPROVAL:** 1. Individual is 18 years of age and older (Blenrep, 2025); **AND** 2. Individual has a diagnosis of relapsed or refractory multiple myeloma (Blenrep, 2025); **AND** 3. Belantamab mafodotin-blmf (e.g., Blenrep) will be used in combination with bortezomib and dexamethasone (Blenrep, 2025); **AND** 4. Individual has received at least two prior lines of therapy, including a proteasome inhibitor (i.e., bortezomib or carfilzomib) and an immunomodulatory agent (i.e., thalidomide, lenalidomide, or pomalidomide) (Blenrep, 2025; NCCN 1); **AND** 5. Eastern Cooperative oncology Group (ECOG) performance status of 0 to 2. **<u>Off-label Indications</u>** **INITIAL APPROVAL:**	No	2/19/2025	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2020024

		1. Individual has a diagnosis of relapsed/refractory multiple myeloma (NCCN 2A); **AND** 2. Individual has received at least three prior lines of therapy for the treatment of multiple myeloma (NCCN 2A).			
Treatment of Hereditary Transthyretin-mediated Amyloidosis [Patisiran (e.g., Onpattro) and Vutrisiran (e.g., Amvuttra)]	2022042	New indication for Vutrisiran (e.g., Amvuttra) added. **<u>Cardiomyopathy of Wild-Type or Hereditary Transthyretin-Mediated Amyloidosis (ATTR-CM)</u>** 1. Individual is 18 years or older; **AND** 2. Documentation is provided that the diagnosis was confirmed by **ONE** of the following (i, ii, or iii): i. A technetium pyrophosphate scan (i.e., nuclear scintigraphy) showing grade 2 or 3 cardiac uptake AND cardiac uptake AND Systemic light chain amyloidosis is ruled out by showing the absence of monoclonal proteins by all of the following tests: a) serum kappa/lambda free light chain ratio, b) serum protein immunofixation, and c) urine protein immunofixation; **OR** ii. A tissue biopsy with confirmatory transthyretin (TTR) amyloid typing by mass spectrometry, immunoelectron microscopy, or immunohistochemistry; **OR** iii. Patient had genetic testing which, according to the prescriber, identified transthyretin (TTR) pathogenic variant; **AND** **Note:** Examples of TTR variants include Val122Ile variant and Thr60Ala variant. If the patient has wild-type amyloidosis, this is not a TTR pathogenic variant. 3. Diagnostic cardiac imaging has demonstrated cardiac involvement; **AND** **Note**: Examples of cardiac imaging include echocardiogram and cardiac magnetic imaging.	No	2/19/2025	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2022042

		Examples of cardiac involvement on imaging include increased thickness of the ventricular wall or interventricular septum. 4. Individual has New York Heart Association (NYHA) Functional Class I, II or III Heart Failure; **AND** 5. The medication is prescribed by or in consultation with a cardiologist or a physician who specializes in the treatment of amyloidosis; **AND** 6. Vutrisiran will not be used in combination with other medications indicated for the treatment of polyneuropathy of hereditary transthyretin-mediated amyloidosis or transthyretin-mediated amyloidosis-cardiomyopathy (e.g., acoramidis, eplontersen, inotersen, tafamidis products, or patisiran.			
Efgartigimod alfa and Hyaluronidase-qvfc (e.g., Vyvgart Hytrulo)	2024063	Policy transitioned to InterQual®.	No	2/19/2025	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2024063
Cipaglucosidase alfa-atga (e.g., Pombiliti)	2023051	Policy transitioned to InterQual®.	No	2/19/2025	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2023051
Avalglucosidase alfa-ngpt (e.g., Nexviazyme)	2021041	Policy transitioned to InterQual®.	No	2/19/2025	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2021041
Alglucosidase alfa (e.g., Lumizyme)	2020030	Policy transitioned to InterQual®.	No	2/19/2025	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2020030
Elapegademase-lvlr (e.g., Revcovi)	2024082	Policy transitioned to InterQual®.	No	2/19/2025	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2024082
Efgartigimod (e.g., Vyvgart)	2022001	Policy transitioned to InterQual®.	No	2/19/2025	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2022001