PROVIDER NOTIFICATION OF POLICY CRITERIA CHANGE					
POLICY TITLE	**POLICY NUMBER**	**CRITERIA CHANGE**	**MATERIAL AMENDEMENT**	**EFFECTIVE DATE**	**LINK TO FULL POLICY**
Esketamine (e.g., Spravato)	2019010	Effective January 14, 2026, this policy will be archived.	No	1/15/2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2019010
Pegcetacoplan (e.g., Empaveli)	2022041	Coverage criteria update. Added initial and continuation criteria for new labeled indications, C3G and IC-MPGN. **C3 GLOMERULOPATHY (C3G) OR PRIMARY IMMUNE-COMPLEX MEMBRANOPROLIFERATIVE GLOMERULONEPHRITIS (IC-MPGN)** **INITIAL APPROVAL:** 1. Individual is aged 12 years and older (Empaveli, 2025); **AND** 2. Individual weighs at least 30 kg or more (NCT05067127); **AND** 3. Individual has a diagnosis of one of the following: a. C3 glomerulopathy (C3G); **OR** b. Primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN) to reduce proteinuria; **AND** 4. Evidence of active renal disease or advance glomerulosclerosis/interstitial fibrosis as assessed by baseline renal biopsy per policy guidelines; **AND** 5. Individual has at least 1 g/day of proteinuria on a screening 24-hour urine collection and a urine protein-to-creatinine ratio (uPCR) of at least 1000 mg/g in at least 2 first-morning spot urine samples; **AND** 6. eGFR greater than or equal to 30 mL/min/1.73 square meters; **AND** 7. Individual is on stable regimen for C3G/IC-MPGN treatment, as described below: a. Angiotensin-converting enzyme (ACE) inhibitor/, angiotensin	No	1/15/2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2022041

		receptor blocker (ARB), and/or sodium-glucose cotransporter-2 inhibitor therapy that is stable and optimized for at least 12 weeks prior initiation of treatment; **AND** b. Stable doses of other medications that can affect proteinuria (e.g., steroids, mycophenolate mofetil, and/or other allowed immunosuppressants that the individual is receiving for treatment of C3G or IC-MPGN) for at least 8-12 weeks prior to the baseline renal biopsy; **AND** 8. If individual is on prednisone (or other systemic corticosteroid) for C3G or IC-MPGN treatment, the dosage is stable and no higher than 20 mg/day (or equivalent dosage of a corticosteroid other than prednisone) for at least 12 weeks prior; **AND** 9. Diagnosis of primary immune-complex membranoproliferative glomerulonephritis (ICMPGN) is **NOT** secondary to another condition (including but not limited to infection, malignancy, monoclonal gammopathy, a systemic autoimmune disease such as systemic lupus erythematosus, chronic antibody-mediated rejection, or a medication is excluded; **AND** 10. Individual **does not** have any of the following: a. Previous exposure to Pegcetacoplan (e.g., Empaveli); **OR** b. An absolute neutrophil count less than 1000 cells per microliter of blood. **CONTINUATION OF THERAPY:** 1. Documentation is provided that individual will be taking Pegcetacoplan (e.g., Empaveli) in combination with an angiotensin converting enzyme (ACE) inhibitor or angiotensin receptor blocker			

		(ARB) and/or sodium-glucose cotransporter-2 inhibitor therapy unless contraindicated or not tolerated; **AND** 2. Individual has experienced a clinical response as documented by significant reduction in proteinuria.			
Emapalumab-LZSG (e.g., Gamifant)	2019013	Coverage criteria updated. Criteria for HLH updated. Added labeled indication for HLH/MACROPHAGE ACTIVATION SYNDROME (MAS). Added continuation criteria for both labeled indications. **PRIMARY HEMOPHAGOCYTIC LYMPHOHISTIOCYTOSIS (HLH)** **INITIAL APPROVAL:** 1. Individual is newborn and older (Gamifant, 2025); **AND** 2. Individual has a diagnosis of Primary hemophagocytic lymphohistiocytosis (HLH) (Gamifant, 2025): a. Refractory disease (see policy guidelines); **OR** b. Recurrent disease (see policy guidelines); **OR** c. Progressive disease; **OR** d. Intolerance with conventional HLH therapy (etoposide & dexamethasone +/- methotrexate & hydrocortisone) or alemtuzumab (Gamifant, 2025; Locatelli, 2020); **AND** e. Documentation of **ONE** of the following: i. A gene mutation known to cause primary HLH**:** homozygosity or compound heterozygosity of verified HLH-associated mutations or of other immune regulatory genes AND clinical findings associated with HLH	No	1/15/2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2019013

		(Gamifant, 2025; Locatelli, 2020); **OR** ii. Presence of at least **Five** out of the following 8 clinical characteristics (Gamifant, 2025; Locatelli, 2020): 1. Fever greater than or equal to 38.5 C; **OR** 2. Splenomegaly; **OR** 3. Peripheral blood cytopenias affecting **two of the three** cell lineages: a. Hemoglobin (Hgb) less than 9 gram per deciliter of blood (for infants greater than 4 weeks, Hgb less than 10 gram per deciliter of blood); **OR** b. Platelet count of less than 100,000 per microliter of blood; **OR** c. Neutrophils less than 1,000 cells per microliter of blood; **OR** 4. **One** of the following:			

		a. Hypertriglyceridemia defined as fasting triglycerides greater than or equal to 265 milligrams per deciliter of blood mg/dL (greater than 3 millimoles per liter of blood); **OR** b. Hypofibrinogenemia defined as fibrinogen less than or equal to 150mg/dL; **OR** 5. Hemophagocytosis in bone marrow, spleen, or lymph nodes with no evidence of malignancy; **OR** 6. Low or absent natural killer cell activity; **OR** 7. Ferritin greater than or equal to 500 micrograms per liter of blood (a ferritin greater than 3,000 micrograms per liter of blood is more specific for HLH; a ferritin greater than 10,000 micrograms per			

		liter of blood is highly suggestive of HLH especially in children with no reason for iron overload) ; **OR** 8. Soluble CD25 greater than or equal to 2400 units per milliliter of blood; **AND** iii. Emapalumab-lzsg will be administered with dexamethasone (Gamifant, 2025; Locatelli, 2020); **AND** iv. The individual is a candidate for hematopoietic stem cell transplant (Locatelli, 2020; Trottestam, 2011; Jordan, 2011); **OR** v. Emapalumab is being used as part of the induction or maintenance phase of stem cell transplant, which is to be discontinued at the initiation of conditioning for stem cell transplant (Locatelli, 2020; Trottestam, 2011; Jordan, 2011). **CONTINUATION OF THERAPY:** 1. Individual continues to meet the initial approval criteria; **AND** 2. Individual has clinical response to treatment (improvement in initial clinical or laboratory parameters); **AND** 3. Documentation is provided that individual is experiencing residual active disease; **AND** 4. Documentation is provided that individual has not received a successful hematopoietic stem cell transplant; **AND** 5. Dose has been titrated to the minimum dose and frequency necessary to achieve satisfactory improvement as defined by FDA			

		labeling for Emapalumab-lzsg (e.g., Gamifant). **<u>HLH/MACROPHAGE ACTIVATION SYNDROME (MAS)</u>** **INITIAL APPROVAL:** 1. Individual is newborn and older (Gamifant, 2025); **AND** 2. Individual has a diagnosis of HLH/macrophage activation syndrome (MAS); **AND** 3. Individual has known or suspected Still's disease, [i.e., systemic Juvenile Idiopathic Arthritis (sJIA) or adult-onset Still's disease (AOSD)] (Gamifant, 2025); **AND** 4. Individual has had an inadequate response or intolerance to high-dose glucocorticoids; **OR** 5. Individual has recurrent MAS; **AND** 6. Documentation of the following (Gamifant, 2025): a. Ferritin greater than 684 micrograms per liter of blood; **AND** b. Two of the following: i. Platelet count is less than or equal to 181,000 cells per microliter of blood; **OR** ii. AST greater than 48 units per liter; **OR** iii. Triglycerides greater than 156 milligrams per deciliter of blood; **OR** iv. Fibrinogen less than or equal to 360 milligrams per deciliter of blood. **CONTINUATION OF THERAPY:** 1. Individual continues to meet the initial approval criteria; **AND** 2. Documentation is provided that individual has clinical response to treatment (improvement in initial clinical or laboratory parameters).			

Nogapendekin alfa inbakicept-pmln (e.g., Anktiva)	2024072	Criteria coverage updated. Continuation criteria regarding individual response to treatment moved to policy guidelines. **POLICY GUIDELINES** The prescribing oncologist is responsible for determining if: 1. Individual achieved a complete response at month 3 and maintenance therapy is indicated; **OR** 2. Individual did not achieve complete response at month 3 and reinduction therapy is indicated.	No	1/15/2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2024072
Tofersen (e.g., Qalsody)	2023032	Policy transitioned to InterQual®.	No	1/15/2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2023032
Alemtuzumab (e.g., Lemtrada)	2016015	Policy transitioned to InterQual®.	Yes	2/15/2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2016015
Apomorphine (e.g., Onapgo)	2025033	New policy developed. Indicated for the treatment of advanced primary Parkinson's disease.	No	1/15/2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2025033
Fecal microbiota, live-jslm (e.g., Rebyota)	2023028	Coverage criteria updated. Criteria updated to account for bezlotuxumab market discontinuation. **INITIAL APPROVAL:** 1. Individual is 18 years of age or older (Rebyota, 2022); **AND** 2. Individual has experienced at least 2 recurrent episodes of CDI (greater than or equal to 3 total CDI episodes) (Khanna, 2022) (Kelly, 2021); **AND** 3. Individual has CDI refractory to standard antibiotic therapy (i.e., fidaxomicin and vancomycin) (Rebyota, 2022); **AND** 4. Individual has been treated previously with FMT (Kelly, 2021); **AND**	No	1/15/2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2023028

		5. Individual has a positive stool test for C. difficile within 30 days of the prior authorization request (Khanna, 2022); **AND** 6. Individual will be using fecal microbiota, live-jslm (e.g., Rebyota) for prevention, not treatment, of CDI recurrence (Rebyota, 2022); **AND** 7. Fecal microbiota will not be used for the treatment of CDI.			
Site of Care or Site of Service Review	2018030	Coverage criteria updated. The site of care or site of service policy only applies to Plans who have a Medical Pharmacy Mandatory Site of Care requirement. This policy is for determination of whether the **non-preferred** site of care (e.g., site of service) meets **Primary Coverage** as defined in the member benefit certificate of coverage or be considered medically necessary for members of plans **without Primary Coverage Criteria** for the infusion and/or injection of the planned pharmacologic/biologic agent. An infused and/or injected pharmacologic/biologic agent should be administered in the least intensive, most cost-effective setting that is appropriate for the pharmacologic/biologic agent. Physician's office, standalone infusion center, or home infusion are the least intensive, most cost-effective settings and are the preferred sites of service for the pharmacologic/biologic agents subject to this policy. A hospital-based outpatient infusion department or hospital-based outpatient clinical level of care is non-preferred for the pharmacologic/biologic agents subject to this policy. Administration of pharmacologic/biologic agents subject to this policy at a hospital-based outpatient infusion department or hospital-based outpatient clinical level of care meets **Primary Coverage Criteria** when one of the following are met: 1. Individual is within first 90 days of therapy for the following:	Yes	2/15/2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2018030

		a. The initial course of infusion or injection of a medication b. Re-initiation of a medication after 6 months or longer following discontinuation of therapy; **OR** 2. Individual's primary residence is not within 30 miles of an in-network stand-alone infusion center and there is no in-network home infusion provider available to the individual; **OR** 3. Individual's clinical condition increases risk of complications for infusion or injections, including any of the following: a. History of a prior serious adverse event with the administered pharmacologic/biologic agent or similar agent; **OR** b. Deemed medically unstable as demonstrated in clinical records (e.g., subject to volume overload in the situation of large infusions); **OR** c. Continuing serious adverse events not mitigated by other interventions (e.g., premedication, altered infusion rate, etc.); **OR** d. Problems with vascular access requiring a more intensive level of care (e.g. children less than 13 years old). **For medications subject to this policy, see policy guidelines.** Sites of care (sites of service) include the following: in-patient hospital, out-patient hospital, hospital affiliated infusion center, in-patient skilled nursing facility, long-term acute care in-patient, physician/provider hospital-affiliated office, and emergency room (hospital affiliated or free standing); less intense, more cost-effective settings include approved ambulatory infusion centers, approved community provider offices, and home-based setting (including approved nursing home). Pharmacologic and biologic agents subject to this policy administered in an unapproved site-of-care			

		do not meet **Primary Coverage Criteria** and may be denied. For members of plans **without Primary Coverage Criteria**, pharmacologic and biologic agents subject to this policy administered in an unapproved site-of-care are considered not medically necessary. Services that are considered not medically necessary are considered exclusions in most member benefit certificates of coverage			
Injection, Clostridial Collagenase for Fibroproliferative Disorders	2010013	Coverage criteria updated. Initial approval criteria for Peyronie's disease updated. **INITIAL APPROVAL STANDARD REVIEW for up to 12 months:** 1. Individual has: a. A diagnosis of Peyronie's disease (Xiaflex, 2023); **AND** b. Disease is stable, quiescent, or unchanged for at least 3 months (See *stable disease under policy guidelines); **AND** 2. Individual is 18 years of age or older (Xiaflex, 2023); **AND** 3. An initial physical examination and an office-based intracavernous vasodilator injection test must be performed to document the degree of angulation, erectile function, and plaque characteristics. (AUA Guidelines for Peyronie's 2015); **AND** 4. Individual must have a penile curvature greater than or equal to 30 degrees (Xiaflex, 2023) and less than or equal to 90 degrees (AUA Guidelines for Peyronie's Disease, 2015); **AND** 5. Intact erectile function with or without Phosphodiesterase type 5 inhibitor (PDE5) pharmacotherapy must be documented before initial collagenase injection (AUA Guidelines for Peyronie's Disease, 2015); **AND**	Yes	2/15/2026	https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2010013

		6. Individual does not have the presence of an “hourglass” plaque deformity without curvature as the indication for collagenase injection (AUA Guidelines for Peyronie’s Disease, 2015); **AND** 7. Individual will not exceed a lifetime limit of two treatment courses (i.e., Up to 8 total treatment cycles or 16 injections) (Xiaflex, 2023); **AND** 8. Initial authorization will not exceed one treatment course (i.e., 4 treatment cycles or 8 injections) (Xiaflex, 2023); **AND** 9. Collagenase injection therapy must be performed by a urologist **or** an advanced practice registered nurse or physician assistant working in collaboration with a urologist.			