Blue Cross Blue Shield Blue Care Network of Michigan

Nonprofit corporations and independent licensees of the Blue Cross and Blue Shield Association

Changes to medical necessity criteria for prior authorizations for medical benefit drugs

For Blue Cross commercial and BCN commercial

Revised Oct. 17, 2025

The medical necessity criteria for medical benefit drugs that require prior authorization are based on current medical information and the recommendations of the Blue Cross Blue Shield of Michigan Pharmacy and Therapeutics Committee, which includes physicians, pharmacists and other experts. During periodic reviews of medical necessity criteria, the committee may recommend changes that result in updates to medical policies.

When we update a medical policy for a drug, we'll add a row for the drug at the top of the following table. The row will outline the changes to the medical necessity criteria, the date on which the changes were approved by the Pharmacy and Therapeutics Committee and the date on which the changes will go into effect.

You can view complete medical necessity criteria in our medical policies. To do this, go to **bcbsm.com/providers**, click *Resources* and then click *Search Medical Policies* to open the Medical Policy Router Search page. Enter the name of the drug in the *Policy/Topic Keyword* field and press *Enter*.

Medical policies that include the changes listed below will be posted to our Medical Policy Router on the effective date.

Drug	Changes to medical necessity criteria	Published date	Effective date
Duopa™ (carbidopa and levodopa) Onapgo™ (apomorphine hydrochloride) Vyalev™ (foscarbidopa/foslevodopa)	A. Criteria a. FDA approved indications b. FDA approved age c. Member must be established on and responsive to a levodopa-containing treatment regimen d. Current treatment regimen must include at least one of the following in addition to levodopa-based therapy: 1. Dopamine agonist 2. Catechol-o-methyltransferase (COMT) inhibitor 3. Monoaminoxidase-B (MAO-B) inhibitor 4. Amantadine e. Motor fluctuations are inadequately controlled by current treatment regimen, with member experiencing an average of at least 2.5 hours of "off" time per day	10/17/2025	12/1/2025

Drug	Changes to medical necessity criteria	Published date	Effective date
	f. Trial and failure, contraindication, or intolerance to the preferred drugs as listed in BCBSM/BCN's prior authorization and step therapy documents B. Quantity Limitations, Authorization Period and Renewal Criteria a. Quantity Limits: Align with FDA recommended dosing b. Authorization Period: One year at a time c. Renewal Criteria: Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit, such as disease stability or improvement.		
Cimzia® (certolizumab pegol)	The member will self-administer Cimzia unless clinically unable to do so	10/09/2025	11/24/2025
Cosentyx® (secukinumab)	The member will self-administer Cosentyx unless clinically unable to do so	10/09/2025	11/24/2025
Entyvio® (vedolizumab)	The member will self-administer Entyvio unless clinically unable to do so	10/09/2025	11/24/2025
Omvoh™ (mirikizumab-mrkz)	The member will self-administer Omvoh unless clinically unable to do so	10/09/2025	11/24/2025
Orencia® (abatacept)	The member will self-administer Orencia unless clinically unable to do so	10/09/2025	11/24/2025
Simponi Aria® (golimumab)	The member will self-administer Simponi unless clinically unable to do so	10/09/2025	11/24/2025
Ultomiris® (ravulizumab)	Trial and failure, contraindication, OR intolerance to preferred eculizumab product: Bkemv for shared diagnosis	10/09/2025	11/24/2025

Changes to medical necessity criteria for prior authorizations for medical benefit drugs

For Blue Cross commercial and BCN commercial

Revised Oct. 17, 2025

Drug	Changes to medical necessity criteria	Published date	Effective date
Vyvgart® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)	The member will self-administer Vyvgart Hytrulo unless clinically unable to do so	10/09/2025	11/24/2025
Zevaskyn™ (prademagene zamikeracel)	• Total wound area must be >200 cm^2 • Not to be used in combination on the same wound with other gene therapies for the treatment of RDEB, including prior treatment with Zevaskyn	10/09/2025	11/24/2025
Bkemv™ (eculizumab-aeeb)	For myasthenia gravis indication: trial and failure, contraindication, OR intolerance to Rystiggo® AND Vyvgart® or Vyvgart Hytrulo	9/1/2025	10/16/2025
Epysqli® (eculizumab-aagh)	For myasthenia gravis indication: trial and failure, contraindication, OR intolerance to Rystiggo AND Vyvgart or Vyvgart Hytrulo	9/1/2025	10/16/2025

Changes to medical necessity criteria for prior authorizations for medical benefit drugs

For Blue Cross commercial and BCN commercial

Revised Oct. 17, 2025

Drug	Changes to medical necessity criteria	Published date	Effective date
Omvoh® (mirikizumab-mrkz)	For ulcerative colitis: • Preferred products: preferred adalimumab biosimilar (Pharmacy benefit) AND Simponi® (pharmacy benefit) AND preferred ustekinumab SC (pharmacy benefit) AND Skyrizi® (pharmacy benefit), AND Tremfya (pharmacy benefit) AND either Xeljanz/XR (Pharmacy benefit) or Rinvoq® (pharmacy benefit) • Nonpreferred products: Zeposia® (pharmacy benefit) and Entyvio® SC (pharmacy benefit) For Crohn's disease: • Preferred products: preferred adalimumab biosimilar (pharmacy benefit), Rinvoq (pharmacy benefit), Skyrizi (pharmacy benefit), Tremfya (pharmacy benefit) AND preferred ustekinumab SC (pharmacy benefit) • Nonpreferred products: Cimzia (pharmacy benefit) and Entyvio SC (pharmacy benefit)	9/1/2025	10/16/2025
Cinryze® (c1 esterase inhibitor, human)	Trial and failure, contraindication, OR intolerance to Haegarda, AND Orladeyo, AND Takhzyro (age appropriate), AND Andembry (age appropriate)	8/7/2025	9/22/2025
Gamifant® (emapalumab-lzsg)	**Sections A and B will be replaced with the following:** A. Criteria: a. FDA approved indication b. FDA approved age c. Diagnosis of primary (familial) hemophagocytic lymphohistiocytosis (HLH) i. Must meet one of the following:	8/7/2025	9/22/2025

Drug	Changes to medical necessity criteria	Published date	Effective date
	a) Biallelic pathogenic gene mutation in either the PRF1, UNC13D, STX11, or STXBP2 genes with signs and symptoms of HLH b) Absent or low perforin expression or defective or impaired cytotoxic lymphocyte exocytosis with signs and symptoms of HLH c) Must meet 5 out of the following criteria: 1. Fever greater than or equal to 38.5ºC 2. Splenomegaly 3. Cytopenias affecting greater than or equal to 2 of 3 lineages in the peripheral blood 1) Hemoglobin less than 90 g/L (in infants less than 4 weeks of age, hemoglobin less than 100 g/L) 2) Platelets less than 100 x 109/L 3) Neutrophils less than 1.0 x 109/L 4. Hypertriglyceridemia and/or hypofibrinogenemia: 1) Fasting triglycerides greater than or equal to 3.0 mmol/L 2) Fibrinogen less than or equal to 1.5 g/L 5. Hemophagocytosis in the bone marrow, spleen, or lymph nodes 6. Ferritin greater than or equal to 500 µg/L 2 of 7 7. Soluble CD25 greater than or equal 2,400 U/mL		

Drug	Changes to medical necessity criteria	Published date	Effective date
	ii. Must be used in combination with dexamethasone iii. Refractory, recurrent, or progressive disease or intolerance with conventional HLH therapy with dexamethasone and etoposide defined as: a) Having not responded or not achieved a satisfactory response to conventional therapy OR b) Having not maintained a satisfactory response to conventional therapy OR c) Intolerance to conventional therapy d. Diagnosis HLH/macrophage activation syndrome (MAS) i. Must have ferritin greater than 684 ng/mL and any 2 of the following: a) Platelet count less than or equal to 181 x 109/L b) Aspartate aminotransferase (AST) greater than 48 U/L c) Triglycerides greater than 156 mg/dL d) Fibrinogen less than or equal to 360 mg/dL ii. Must be diagnosed with systemic juvenile idiopathic arthritis or adult onset Still's disease iii. Must have had an inadequate response to high-dose intravenous glucocorticoids defined as greater than or equal to 2 mg/kg/day of prednisone equivalent in two divided doses or at least 60 mg/day in patients weighing 30 kg or more, including but not limited to, pulses up to 30 mg/kg/day for at least 3 consecutive days		

Drug	Changes to medical necessity criteria	Published date	Effective date
	e. Trial and failure, contraindication, or intolerance to the preferred drugs as listed in BCBSM/BCN's utilization management medical drug list B. Quantity Limitations, Authorization Period and Renewal Criteria a. Quantity Limits: Align with FDA recommended dosing b. Authorization Period: One year at a time c. Renewal Criteria: Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit		
Herceptin Hylecta™ (trastuzumab and hyaluronidase-oysk)	Trial and failure, intolerance or a contraindication to the preferred products as listed in the Oncology Value Management program prior authorization list.	8/7/2025	12/1/2025
Vyepti® (eptinezumab-jjmr)	Trial and failure, contraindication, OR intolerance to Aimovig AND Emgality	8/7/2025	9/22/2025
Alhemo® (concizumab-mtci)	Hemophilia A and Hemophilia B: For those with inhibitors less than 5 BU/mL, a trial and failure of additional higher doses of factor is required.	6/5/2025	7/21/2025
Hemophilia products	For all hemophilia products, the member will be required to self-administer unless clinically unable to do so	6/5/2025	7/21/2025
Imfinzi™ (durvalumab) Libtayo® (cemiplimab-rwlc) Tecentriq® (atezolizumab) Tecentriq Hybreza™ (atezolizumab and hyaluronidase-tqjs)	• For use in non-small cell lung cancer: Treatment until unacceptable toxicity or disease progression for up to a total of 24 months of therapy • Trial and failure, intolerance or a contraindication to the preferred products as listed in the Oncology Value Management program prior authorization list	6/5/2025	7/21/2025

Changes to medical necessity criteria for prior authorizations for medical benefit drugs

For Blue Cross commercial and BCN commercial

Revised Oct. 17, 2025

Drug	Changes to medical necessity criteria	Published date	Effective date
Onivyde® (liposomal irinotecan)	Trial and failure, intolerance or a contraindication to the preferred products as listed in the Oncology Value Management program prior authorization list	6/5/2025	7/21/2025
Tremfya® (guselkumab)	Subcutaneous formulation ONLY: The member will self-administer Tremfya unless clinically unable to do so.	6/5/2025	7/21/2025
Actemra® (tocilizumab) Avtozma® (tocilizumab-anoh) Tofidence™ (tocilizumab-bavi) Tyenne™ (tocilizumab-aazg)	The member will self-administer tocilizumab unless clinically unable to do so.	4/10/2025	5/27/2025
Cinryze™ (c1 esterase inhibitor, human)	Trial and failure, contraindication **or** intolerance to Haegarda® **and** Orladeyo® **and** Takhzyro®, as appropriate for the member's age.	4/10/2025	5/27/2025
Drugs managed under the Medical Benefit Oncology Drug Class Policy	No prior failure based on efficacy of a drug with the same mechanism of action unless retrial with the same mechanism of action is recommended by guidelines or supported by a randomized, controlled clinical trial.	4/10/2025	5/27/2025

Changes to medical necessity criteria for prior authorizations for medical benefit drugs

For Blue Cross commercial and BCN commercial

Revised Oct. 17, 2025

Drug	Changes to medical necessity criteria	Published date	Effective date
Evenity® (romosozumab-aqqg)	• Diagnosis of osteoporosis with a T-score of less than or equal to -2.5, history of a fragility fracture or high FRAX® (fracture risk assessment tool) fracture probability, which is defined as a 10-year major osteoporotic fracture risk greater than or equal to 20% or hip fracture risk greater than or equal to 3% • If the member has very high-risk osteoporosis: Trial and failure (such as reduction of T-score or fracture) of zoledronate **or** a preferred denosumab product if zoledronate is contraindicated To be considered very high risk, the member must meet **one** of the following criteria: 1. Recent fracture (for example, within the past 12 months) 2. Fractures while on approved osteoporosis therapy 3. Multiple fractures 4. Fractures while on drugs causing skeletal harm (for example, long-term glucocorticoids) 5. Very low T-score (for example, less than -3.0) 6. High risk for falls or history of injurious falls 7. Very high fracture probability by FRAX (for example, major osteoporosis fracture greater than 30%, hip fracture greater than 4.5%) or other validated fracture risk algorithm • If a member is high risk: Trial and failure (such as reduction of T-score or fracture) of oral or IV bisphosphonates **and** preferred denosumab product unless contraindicated	4/10/2025	5/27/2025

Changes to medical necessity criteria for prior authorizations for medical benefit drugs

For Blue Cross commercial and BCN commercial

Revised Oct. 17, 2025

Drug	Changes to medical necessity criteria	Published date	Effective date
Keytruda® (pembrolizumab)	Trial and failure, intolerance or a contraindication to the preferred products as listed in the Oncology Value Management program prior authorization list.	4/10/2025	5/27/2025
Opdivo® (nivolumab)	• For use in non-small cell lung cancer: Treatment until unacceptable toxicity or disease progression for up to a total of 24 months of therapy • Trial and failure, intolerance or a contraindication to the preferred products as listed in the Oncology Value Management program prior authorization list.	4/10/2025	5/27/2025
Zinplava™ (bezlotoxumab)	Can't be used in combination with fecal microbiota products, such as Rebyota® or Vowst™.	4/10/2025	5/27/2025
Rebyota® (fecal microbiota, livejslm)	Can't be used in combination with Zinplava™ or Vowst™. Note: This was also announced in a Feb. 13, 2025, provider alert.	2/13/2025	3/31/2025
Ryoncil® (remestemcel-Lrknd)	• The member must have tried and failed, or have a contraindication or intolerance to, Jakafi® (ruxolitinib) when age appropriate per FDA labeling. • The provider must attest to providing clinical outcome information within the appropriate provider portal as requested by Blue Cross or BCN. Note: This was also announced in a Feb. 13, 2025, provider alert.	2/13/2025	3/31/2025