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 Aug. 13, 2026

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. With the exception of any changes listed in this document, existing medical policy requirements will continue to apply.

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
Hemophilia products	Non-factor hemophilia products (for example, Alhemo®, Qfitlia™, Hympavzi®, Hemlibra®) must not be used in combination with other non-factor hemophilia products	08/13/2026	9/28/2026
Amvuttra™ (vutrisiran)	Trial and failure, contraindication, OR intolerance to Vyndamax®	6/11/2026	7/27/2026
Vyvgart® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)	Diagnosis of chronic idiopathic demyelinating polyneuropathy (CIDP): Trial and failure, contraindication, or intolerance to generic immunoglobulin therapy	6/11/2026	7/27/2026
Imaavy™	For MuSK positive myasthenia gravis: Trial and failure, contraindication, OR intolerance to Vyvgart/Vyvgart Hytrulo, Rystiggo and Uplizna	6/11/2026	7/27/2026
Rystiggo®	For MuSK positive myasthenia gravis: Trial and failure, contraindication, OR intolerance to Vyvgart/Vyvgart Hytrulo	6/11/2026	7/27/2026

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Uplizna® (inebilizumab-cdon)	For MuSK positive myasthenia gravis: Trial and failure, contraindication, OR intolerance to Vyvgart/Vyvgart Hytrulo	6/11/2026	7/27/2026
Spevigo® (spesolimab-sbvo)	For the treatment of GPP flares (intravenous formulation): i. Patient is experiencing a GPP flare of moderate-to-severe intensity defined by all of the following: 1. A Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) total score > 3 2. New or worsening pustules 3. GPPGA pustulation sub-score > 2 4. > 5% of body surface area (BSA) with erythema and the presence of pustules ii. Trial and failure, contraindication, or intolerance to one of the following systemic therapies: acitretin, cyclosporine, methotrexate, infliximab For the prevention of GPP flares (subcutaneous formulation): i. A GPPGA total score of 0 or 1 ii. A history of at least 2 past moderate-to-severe GPP flares with new or worsening pustulation iii. Member must have tried at least one of the following systemic therapies for the prevention of GPP flares and continued to experience GPP flares either during treatment, following dose reduction, or following/within one year of treatment discontinuation, unless contraindicated or not tolerated: acitretin, methotrexate, cyclosporine, infliximab. iv. Member must self-administer unless clinically unable to do so	6/11/2026	7/27/2026

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Drug	Changes to medical necessity criteria	Published date	Effective date
Tepezza™ (teprotumumab-trbw)	Must not be used in combination with or following any previous treatment with other insulin-like growth factor-1 receptor antagonist for the treatment of TED	6/11/2026	7/27/2026
Wainua® (eplontersen)	The member will self-administer Wainua unless clinically unable to do so	6/11/2026	7/27/2026
Abecma® (idecabtagene vicleucel)	• No prior treatment with allogeneic hematopoietic stem cell transplant • No prior treatment with autologous stem cell transplantation within 12 weeks prior to Abecma infusion	4/16/2026	6/1/2026
Amtagvi® (lifileucel)	The treatment must be prescribed by or in consultation with an oncologist.	4/16/2026	6/1/2026
Aucatzyl® (obecabtagene autoleucel)	The treatment must only be administered at certified bone marrow/stem cell transplant centers.	4/16/2026	6/1/2026
Carvykti® (ciltacabtagene autoleucel)	• No prior treatment with allogeneic hematopoietic stem cell transplant within the last six months • No prior treatment with autologous stem cell transplantation within the last 12 weeks • The treatment must only be administered at certified bone marrow/stem cell transplant centers	4/16/2026	6/1/2026
• Lutathera® (lutetium Lu 177 dotatate) • Pluvicto® (lutetium Lu 177 vipivotide tetraxetan)	Authorization period will align with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to six months at a time	4/16/2026	6/1/2026

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Omisirge® (omidubicel-onlv)	• The treatment must be prescribed by or in consultation with an oncologist • The treatment must only be administered at certified bone marrow/stem cell transplant centers	4/16/2026	6/1/2026
Tecelra® (afamitresgene autoleucel)	• The member must not have HLA-A*02:05 in either allele • The treatment must be prescribed by or in consultation with an oncologist • The treatment must only be administered at certified bone marrow/stem cell transplant centers	4/16/2026	6/1/2026

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Skyrizi® (risankizumab)*	**BCBSM/BCN members with Blue Cross or Blue Care Network's Custom, Clinical, or Preferred Drug List Formulary:** • Preferred adalimumab (pharmacy) AND preferred ustekinumab (pharmacy) products **BCBSM/BCN members with Blue Cross or Blue Care Network's Custom Select Formulary:** • Crohn's disease: o Preferred products: Preferred adalimumab biosimilar (pharmacy benefit), AND Tremfya (pharmacy benefit) AND preferred ustekinumab SC (pharmacy benefit) o Nonpreferred products: Cimzia (pharmacy or medical benefit) AND Entyvio SC (pharmacy benefit) • Ulcerative colitis: o Preferred products: preferred adalimumab biosimilar (pharmacy benefit) AND Simponi (pharmacy benefit) AND preferred ustekinumab SC (pharmacy benefit), AND Tremfya (pharmacy benefit) AND Xeljanz/XR® (pharmacy benefit) o Nonpreferred products: Zeposia (pharmacy benefit) AND Entyvio SC (pharmacy benefit)	03/17/2026	05/01/2026

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Drug	Changes to medical necessity criteria	Published date	Effective date
• Bildyos® • Boncresa™ • Bosaya™ • Conexxence® • denosumab-bbdz • denosumab-bmwo • denosumab-dssb • denosumab-bnht • Jubbonti® • Ospomyv™ • Osvyrti® • Prolia®	Trial and failure, contraindication, OR intolerance to Stoboclo® and Enoby™	02/23/2026	04/09/2026

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• Aukelso™ • Bilprevda® • Bomyntra® • denosumab-bbdz • denosumab-bmwo • denosumab-bnht • denosumab-dssb • Jubereq® • Oziltus™ • Wyost® • Xbryk™ • Xgeva®	Trial and failure, contraindication, OR intolerance to Osenvelt® and Xtrenbo™	02/23/2026	04/09/2026
Bkemv™	For myasthenia gravis with AchR positive: Trial and failure, contraindication, OR intolerance to Uplizna and Zilbrysq	02/12/2026	04/01/2026
Cosentyx®*	For psoriatic arthritis: • Trial and failure of four of the preferred products: Enbrel (pharmacy benefit), preferred adalimumab biosimilar (pharmacy benefit), Otezla (pharmacy benefit), Rinvoq (pharmacy benefit), preferred ustekinumab SC (pharmacy benefit), Tremfya (pharmacy benefit), Xeljanz/XR (pharmacy benefit), Simponi 50 SC (pharmacy benefit), Skyrizi (pharmacy benefit) AND • Nonpreferred products: Taltz AND Orencia	02/12/2026	04/01/2026

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Epysqli®	For myasthenia gravis with AchR positive: Trial and failure, contraindication, OR intolerance to Uplizna and Zilbrysq	02/12/2026	04/01/2026
Imaavy™	For myasthenia gravis with AchR and MuSK positive: Trial and failure, contraindication, OR intolerance to Rystiggo and Uplizna	02/12/2026	04/01/2026
Rystiggo®	For myasthenia gravis with AchR positive: Trial and failure, contraindication, OR intolerance to Vyvgart/Vyvgart Hytrulo	02/12/2026	04/01/2026
Soliris®	For myasthenia gravis with AchR positive: Trial and failure, contraindication, OR intolerance to Uplizna and Zilbrysq.	02/12/2026	04/01/2026
Ultomiris®	For myasthenia gravis with AchR positive: Trial and failure, contraindication, OR intolerance to Uplizna and Zilbrysq	02/12/2026	04/01/2026
Hereditary Angioedema Products (HAE)	Updated to remove genetic testing requirement for HAE diagnosis	12/04/2025	01/20/2026
Kebilidi™ (eladocagene exuparvovec-tneq)	A. Criteria: a. Coverage of the requested drug is considered investigational/experimental for all indications due to insufficient evidence of a clinical benefit i. BCBSM and BCN are awaiting the results of ongoing clinical trials to provide evidence of a clinical benefit	12/04/2025	01/20/2026
Lantidra™ (donislecel-jujn)	A. Criteria: a. Coverage of the requested drug is considered investigational/experimental for all indications due to insufficient evidence of a clinical benefit	12/04/2025	01/20/2026
Loqtorzi™ (toripalimab-tpzi)	Trial and failure, intolerance or a contraindication to the preferred products as listed in the Oncology Value Management program prior authorization list	12/04/2025	01/20/2026

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Skysona® (elivaldogene autotemcel)	A. Criteria: a. Coverage of the requested drug is considered investigational/experimental for all indications due to insufficient evidence of a clinical benefit i. BCBSM and BCN are awaiting the results of ongoing clinical trials to provide evidence of a clinical benefit	12/04/2025	01/20/2026
Entyvio® (vedolizumab)	Trial and failure, contraindication, OR intolerance to preferred adalimumab AND preferred ustekinumab products	11/17/2025	01/01/2026
Immune globulin replacement therapy medication	Preferred products for intravenous immunoglobulin infusion: • Gammagard • Octagam • Privigen • Gamunex-C Preferred products for subcutaneous immunoglobulin infusion: • Hizentra • Gammagard • Gamunex-C	11/17/2025	01/01/2026

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Skyrizi® (risankizumab)*	For Crohn's disease: • Preferred products: preferred adalimumab biosimilar (pharmacy benefit), Rinvoq (pharmacy benefit), Tremfya (pharmacy benefit) AND preferred ustekinumab SC (pharmacy benefit) For ulcerative colitis: • Preferred products: preferred adalimumab biosimilar (pharmacy benefit) AND Rinvoq (pharmacy benefit) AND Simponi (pharmacy benefit) AND preferred ustekinumab SC (pharmacy benefit) AND Tremfya (pharmacy benefit) AND Xeljanz/XR (pharmacy benefit)	11/17/2025	01/01/2026
Tremfya® IV (guselkumab)	Trial and failure, contraindication, OR intolerance to preferred adalimumab AND preferred ustekinumab products	11/17/2025	01/01/2026
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

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Ultomiris® (ravulizumab)	Trial and failure, contraindication, OR intolerance to preferred eculizumab product: Bkemv	10/09/2025	11/24/2025
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

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

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	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		

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	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

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• 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
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

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Drug	Changes to medical necessity criteria	Published date	Effective date
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

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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

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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

* Note: Formulary status is dependent on pharmacy benefits.