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Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

P&T Date: 06/11/2026

Tremfya® (guselkumab)

HCPCS: J1628

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

- A. Coverage of the requested drug is provided when all the following are met:
 - a. FDA approved age
 - b. FDA approved weight
 - c. Diagnosis of psoriasis (PsO)
 - i. Trial and failure, contraindication, or intolerance to one topical corticosteroid
 - d. Diagnosis of ulcerative colitis (UC)
 - e. Diagnosis of Crohn's disease (CD)
 - f. Diagnosis of psoriatic arthritis (PsA)
 - g. Not to be used in combination with other biologics or targeted disease-modifying anti-rheumatic drugs (DMARDs) for the same indication
 - h. The member will self-administer Tremfya unless clinically unable to do so.
 - i. Trial and failure of the preferred products as listed in the 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

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at <http://www.cms.hhs.gov/>. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Tremfya (guselkumab) is an interleukin-23 inhibitor (IL-23i) with the following indications:
 - Adults and pediatric patients 6 years of age and older who also weigh at least 40 kg with moderate-to-severe plaque psoriasis who are candidates for systemic therapy of phototherapy
 - Adults and pediatric patients 6 years of age and older who also weigh at least 40 kg with active psoriatic arthritis
 - Adults with moderately to severely active ulcerative colitis
 - Adults with moderately to severely active Crohn's disease (CD)
- Tremfya is available as a subcutaneous (SC) injection and an intravenous (IV) infusion. The IV formulation is only indicated for the induction phases of ulcerative colitis and CD, whereas the SC formulation is indicated for plaque psoriasis, psoriatic arthritis, and both the induction and maintenance phases of ulcerative colitis and CD.
- Per the prescribing information, Tremfya may be administered alone or in combination with traditional DMARDs (e.g., methotrexate) for psoriatic arthritis. There is no robust clinical evidence supporting the safety and efficacy of Tremfya used in combination with other biologic agents or targeted DMARDs (e.g., Janus kinase (JAK) inhibitors).
- Clinical reasons a patient may be unable to self-administer Tremfya include:
 - Patient or caregivers are unable to perform subcutaneous injections with proper technique
 - Member requires monthly medical support from the physician
- Psoriasis
 - Psoriasis is a chronic, painful and life-altering immune-mediated disease which predominantly manifests with skin and joint involvement. Patients also experience significant cardiovascular and psychological comorbidities. Approximately 2% of U.S. adults are affected by psoriasis (men and women equally), and it can occur at any age. Approximately 90% of psoriasis-affected patients have plaque psoriasis, which is characterized by well-defined round or oval plaques that vary in size and often coalesce. The severity of psoriasis is defined as: mild = less than 3% of body affected; moderate = 3-10% of body affected; and severe being more than 10% of the body affected.
 - Per the 2020 Joint American Academy of Dermatology (AAD)- National Psoriasis Foundation (NPF) guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures: topical corticosteroids provide a high efficacy and good safety option for patients with localized disease. They are generally recommended as first-line therapy. Choice of steroid potency may depend on severity, location, patient preference, and patient age, while the duration of treatment may vary with steroid potency, location and severity of disease often ranging from 2-12 weeks. Therapeutic regimens may include 2-4 weeks with a topical steroid applied twice daily, followed by a maintenance regimen where topical steroids are alternated with a steroid-sparing topical agent. Treatment with topical steroids for over 12 weeks is recommended under careful supervision by a physician.
 - Per the 2019 Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with phototherapy, phototherapy serves as a reasonable and effective treatment option for patients requiring more than topical medications and/or those wishing to avoid systemic medications or simply seeking an

adjunct to a failing regimen. Guidelines also state that the majority of patients with mild-to-moderate disease have adequate disease control with topical therapies and phototherapy alone.

- Per the 2020 Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with systemic nonbiologic therapies, many oral medications, including methotrexate, cyclosporine, and acitretin, have been used for decades to treat psoriasis, each with its own benefits and risks. Most work by targeting the immune system, whereas others, such as acitretin, work predominantly by decreasing keratinocyte hyperproliferation, thus restoring the normal epidermal differentiation. Both methotrexate and cyclosporine are category A guideline recommendations for the treatment of moderate to severe psoriasis in adults and for severe, recalcitrant psoriasis, respectively. Studies examining the use of methotrexate and cyclosporine in psoriasis showed the primary efficacy endpoints met within 12-16 weeks. Acitretin is a category B guideline recommendation as monotherapy for plaque psoriasis, with full treatment response expected within 3-6 months.
- Per the 2019 Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics, biologic agents, as monotherapy or combined with other topical or systemic medications, have a high benefit-to-risk ratio. Tumor necrosis factor-alpha inhibitors (TNFi) have a category "A" recommendation as a monotherapy treatment option for adult patients with moderate-to-severe plaque psoriasis. TNFi biosimilars approved by the FDA should be considered similar to the reference branded version of the drug and therefore interchangeable. IL-12/23i, IL-23i, and IL-17i products have a category "A" recommendation as a monotherapy treatment option for use in adult patients with moderate-to-severe plaque psoriasis.

- Psoriatic Arthritis

- PsA is a chronic inflammatory disease affecting the joints that is associated with psoriasis. PsA occurs in up to 30% of patients with psoriasis, most commonly appearing between the ages of 30 and 50. PsA causes pain, stiffness, and swelling in and around the joints. If not properly treated, progressive joint damage may occur.
- The 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis recommends a TNFi or oral small molecule (OSM; e.g., methotrexate, sulfasalazine, cyclosporine, leflunomide) in treatment-naïve patients with active PsA over an IL-17i or IL-12/23i.
 - In treatment-naïve patients, OSMs may be used over TNFi agents in patients without severe PsA and without severe psoriasis, those who prefer an oral drug instead of parenteral therapy, or those with contraindications to TNFi treatment (i.e. Congestive heart failure, previous serious infections, recurrent infections, demyelinating disease).
 - IL-17i or IL-12/23i therapies may be used in lieu of TNFi agents in treatment-naïve patients with severe psoriasis or contraindications to TNFi and may be used instead of OSMs in patients with severe psoriasis or severe PsA. IL-17i biologics are recommended over an IL-12/23i.
- For patients who have initiated OSM therapy, the guidelines recommend switching to a TNFi, IL-17i, or IL-12/23i if PsA continues to be active despite treatment with OSM. Switching to a TNFi is recommended over an IL-17i, IL-12/23i, abatacept (Orencia®), or tofacitinib (Xeljanz®/XR). Switching to an IL-17i is recommended over an IL-12/23i, abatacept or tofacitinib. Switching to an IL-23i is recommended over abatacept or tofacitinib. Alternatives to the recommended agents may be considered based on disease severity, contraindications to recommended therapy, preference of route of administration, and frequency of administration.

- Ulcerative colitis

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- Ulcerative colitis (UC) is a chronic disease affecting the large intestine with an ongoing rising incidence worldwide and more recent updated estimates in the United States. Using pooled data from both commercial and public insurance (physician-coded diagnoses), the incidence of UC was estimated to be 6.3 per 100,000 person-years (95% confidence interval [CI], 6.1–6.6) and in adults, higher than that estimated for CD using the same methodology. The age-standardized, sex-standardized, and insurance-standardized prevalence per 100,000 population is estimated to be 305 (95% CI, 302–308), with a 2020 census-extrapolated US prevalence of 1.253 million people living with UC. UC is characterized by chronic inflammation of the large intestine that is frequently associated with involvement of the rectum but often extends proximally to involve additional areas of the colon. Despite advances in understanding environmental associations and risks, the causes of UC remain complex and unknown. UC causes significant morbidity but fortunately has a low incidence of mortality. Patients with active disease are more likely to have comorbid psychological conditions of anxiety and depression and are more likely to have impaired social interactions or career progression. Longstanding UC is also associated with a defined risk of dysplasia and colorectal cancer (CRC) which is believed to be primarily related to more extensive bowel involvement and longstanding mucosal inflammatory activity.
- The 2024 AGA living clinical practice guideline on pharmacological management of moderate-to-severe UC suggests early use of advanced therapies with or without immunomodulator therapy, rather than gradual step-up after failure of 5-aminosalicylic acid (5-ASAs) in adult outpatients with moderate-to-severe UC. They comment that patients, particularly those with less severe disease who place higher value on the safety of 5-ASA therapy and lower value on the efficacy of immunosuppressive therapies, may reasonably choose gradual step therapy with 5-ASA therapy.
- The 2025 ACG clinical guideline update: ulcerative colitis in adults have many recommendations for the remission in moderately to severely active UC including oral budesonide MMX, oral systemic corticosteroids, S1P receptor modulators (ozanimod and etrasimod), ustekinumab, guselkumab, mirikizumab, risankizumab, vedolizumab, infliximab (in combination with a thiopurine), adalimumab or golimumab, tofacitinib, and upadacitinib, while recommending against monotherapy with thiopurines or methotrexate. These guidelines also have strategies for the induction of remission in moderately to severely active UC and include that 5-ASA therapy could be used as monotherapy, nonsystemic corticosteroids such as budesonide MMX can be considered before the use of systemic therapy, systemic corticosteroids can be considered in severely active UC, and that corticosteroids may be avoided entirely when other effective induction strategies are planned.
- The 2025 ACG guideline has many recommendations for maintenance of remission in patients with previously moderately to severely active UC and includes recommending against systemic corticosteroids, methotrexate, or adding 5-ASA to anti-TNF therapy. In those who are in remission due to corticosteroid induction, thiopurines are recommended over corticosteroids. The 2025 ACG guideline recommends continuing ozanimod, etrasimod, ustekinumab, guselkumab, mirikizumab, risankizumab, vedolizumab, adalimumab, golimumab, infliximab, tofacitinib, and upadacitinib after induction with said medication.

- Crohn's disease

- Crohn's disease (CD) is an idiopathic inflammatory disorder of unknown etiology with genetic, immunologic, and environmental influences. The incidence of CD has steadily increased over the past several decades. The diagnosis and treatment of patients with CD continues to evolve. The chronic intestinal inflammation that occurs in CD can over time lead to the development of intestinal complications such as strictures, fistulas, and abscesses. These complications can lead to inhibition of intestinal function or to surgery that itself can result in some morbidity and loss of intestinal function.

- The 2025 American College of Gastroenterology (ACG) guidelines management recommendations for patients with CD are based on disease location, severity, presence of disease-associated complications including extraintestinal manifestations, and factors affecting future prognosis. Therapeutic approaches are individualized with the composite goal of achieving clinical and endoscopic remission without significant adverse effects of treatment. CD treatment should be considered as a sequential continuum to treat acute disease or induce clinical remission and then to maintain response/remission with overall improvements in quality of life.
- Medical treatment of CD is usually categorized into induction and maintenance therapy. Regimens are generally chosen according to the patient's risk profile and disease severity with a goal to achieve clinical and biomarker response within 12 weeks of treatment initiation followed by durable steroid-free control of disease activity including both clinical and endoscopic remission. It is important to acknowledge; however, that CD clinical trials have only recently incorporated objective outcomes such as endoscopic improvement as a coprimary outcome. Another therapeutic goal is to prevent disease complications, such as strictures and fistulae. While medical therapy may be successful in some patients with fistulizing disease, including perianal disease, there is less evidence for medication efficacy in stricturing CD given the known fibrotic component of chronic strictures. Medical therapy used to treat CD primarily include supportive care including dietary-based strategies, corticosteroids and advanced therapies including anti-TNF agents, anti-integrins, anti-ILs, and JAK inhibitors.
- A recent open-label randomized controlled trial (PROFILE—Predicting Outcomes for Crohn's Disease Using a Molecular Biomarker) evaluated 2 separate approaches to the management of newly diagnosed CD, early combined immunosuppression with infliximab plus immunomodulator or accelerated step-up therapy where conventional management with corticosteroids was followed by immunomodulator, then followed by infliximab use. The primary endpoint was sustained steroid-free and surgery-free remission at week 48. Those in the early combined group were significantly more likely to achieve steroid-free and surgery-free remission (79% vs 15%). This study demonstrates the benefit of early intervention with advanced therapy as compared to a serial approach first requiring the use of conventional therapy. The guidelines suggest against requiring failure of conventional therapy before initiation of advanced therapy for the management of CD.
- The 2025 ACG guidelines do recommend oral corticosteroids for short-term induction of remission in patients with moderately to severely active CD, as conventional corticosteroid treatment, such as prednisone and methylprednisolone given orally or intravenously for more severe disease, is effective in alleviating signs and symptoms of a flare. The use of corticosteroids should not exceed 3 continuous months without attempting to introduce corticosteroid-sparing agents (such as biologic therapy or immunomodulators). Despite their effectiveness in reducing signs and symptoms of active CD, nearly 1 in 4 patients will have prolonged exposure to corticosteroids (i.e., greater than 6 months), particularly earlier in their disease course with approximately 15% of patients becoming steroid-dependent with an inability to taper without subsequent recrudescence of symptoms.
- The 2025 ACG guidelines recommend against azathioprine and 6-mercaptopurine for induction of remission in moderately to severely active CD, but they can be used for maintenance of remission in patients who had induction of remission with corticosteroids at proper doses (azathioprine at doses of 1.5–2.5 mg/kg/d and 6-mercaptopurine at doses of 0.75–1.5 mg/kg/d). Methotrexate (up to 25 mg once weekly via intramuscular or subcutaneous injection) can also be used for maintenance of remission in patients with moderately to severely active CD who had induction of remission with corticosteroids.
- The 2025 ACG guidelines recommend anti-TNF agents (intravenous infliximab, subcutaneous adalimumab, subcutaneous certolizumab pegol) for induction and maintenance of remission for moderately to severely active CD. They also recommend combination therapy of intravenous infliximab with immunomodulators

(thiopurines) as compared with treatment with either immunomodulators alone or intravenous infliximab alone in patients with CD who are naive to those agents. Biosimilar infliximab, adalimumab, and ustekinumab are effective treatments for patients with moderate-to-severe CD and can be used for de novo induction and maintenance therapy. There are data to support the safety and efficacy of transitioning or switching to biosimilar infliximab or adalimumab for with patients CD in stable disease maintenance.

- Intravenous and subcutaneous vedolizumab, ustekinumab, risankizumab, mirikizumab, and guselkumab are all recommended for induction and maintenance of remission for patients with moderately to severely CD, whereas JAK inhibitors are recommended in these patients who have previously been exposed to anti-TNF agents.
- The 2025 American Gastroenterological Association (AGA) guidelines mirror the ACG guidelines and suggest, in adult outpatients with moderate to severely active CD, upfront use of advanced therapy compared with step-up therapy with initial use of corticosteroids and/or immunomodulator monotherapy.
- The 2025 AGA guidelines recommend using infliximab, adalimumab, ustekinumab, risankizumab, guselkumab, mirikizumab, or upadacitinib over no treatment, and suggest using certolizumab pegol and vedolizumab over no treatment.
- The 2025 AGA guidelines suggest using a higher efficacy rather than lower efficacy medication in advanced therapy-naïve patients (Higher efficacy medications: infliximab, adalimumab, vedolizumab, ustekinumab, risankizumab, mirikizumab, guselkumab; Lower efficacy medications: certolizumab pegol, upadacitinib). In patients with prior exposure to one or more advanced therapies, particularly TNF antagonists, the 2025 AGA guidelines suggest using higher efficacy, or intermediate efficacy medication rather than a lower efficacy medication. (Higher efficacy medications: adalimumab, risankizumab, guselkumab, upadacitinib; Intermediate efficacy medications: ustekinumab, mirikizumab; lower efficacy medications: certolizumab pegol, vedolizumab).

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Policy History												
#	Date	Change Description										
1.6	Effective Date: 07/01/2026 P&T Date: 06/11/2026	Updated to remove conventional therapy requirement for Crohn's disease and ulcerative colitis due to updated guidelines. Updated guideline sections in the background to correspond with removal of conventional therapy requirement.										
1.5	Effective Date: 12/04/2025	Added FDA approved weight criterion based on expanded indications for psoriatic arthritis and psoriasis to now include pediatrics 6 years and older weighing at least 40 kg										
1.4	P&T Date: 10/09/2025 Effective Date: 01/01/2026	Updated wording to remove "subcutaneously only" with regard to self-administration to align with other policies in this class.										
1.3	Effective Date: 06/05/2025	Updated to require subcutaneous products to be self-administered unless clinically unable to do so										
1.2	Effective Date: 04/10/2025	Updated to include the new Crohn's disease indication										
1.1	Effective Date: 10/03/2024	Updated to include new IV formulation. Included criteria for ulcerative colitis – new indication associated with the new IV formulation. Added "for the same indication" to the not to be used in combination with other biologics or targeted DMARDs criteria										
1.0	Effective Date: 09/26/2024	UM medical management system update for BCBS and BCN <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	No	BCNA	No
Line of Business	PA Required in Medical Management System (Yes/No)											
BCBS	Yes											
BCN	Yes											
MAPPO	No											
BCNA	No											

* The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or <http://dailymed.nlm.nih.gov/dailymed/index.cfm>.

Blue Cross Blue Shield/Blue Care Network of Michigan

Medication Authorization Request Form



This form is to be used by participating physicians to obtain coverage for **drugs covered under the medical benefit**. For commercial members only, please complete this form and submit via fax to 1-877-325-5979. If you have any questions regarding this process, please contact BCBSM Provider Relations and Servicing or the Medical Drug Helpdesk at 1-800-437-3803 for assistance.

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PATIENT INFORMATION	PHYSICIAN INFORMATION
Name	Name
ID Number	Specialty
D.O.B. ☐ Male ☐ Female	Address
Diagnosis	City /State/Zip
Drug Name	Phone/Fax: P: () - F: () -
Dose and Quantity	NPI
Directions	Contact Person
Date of Service(s)	Contact Person Phone / Ext.

STEP 1: DISEASE STATE INFORMATION

- Is this request for: ☐ Initiation ☐ Continuation Date patient started therapy: _____
- Administered by patient or a medical professional? ☐ patient (self) ☐ health care professional (physician, nurse, etc.)
- Site of administration? ☐ Provider office/Home infusion ☐ Other: _____
☐ Hospital outpatient facility (go to #4) Reason for Hospital Outpatient administration: _____
☐ Hospital inpatient facility for Car-T therapy only (for example: Kymriah, Yescarta, or Tecartus) (go to #5)
- Please specify location of administration if hospital outpatient infusion: _____
- Please specify location of administration if hospital inpatient infusion: _____
- Please provide the NPI number for the place of administration: _____
- Initiation AND Continuation of therapy:**
 - What is the patient's diagnosis? _____
 - What other medication has the patient received for their condition? Please list _____
 - Please describe the response to previous therapies: _____
 - Will the patient be receiving any other treatment for the listed condition while on this medication? Please list: _____
 - Please list any labs values important for diagnosing or monitoring this patient's condition: _____
- Continuation of therapy:**
 - Has the patient progressed while on this medication? ☐ yes ☐ no
 - How has the patient's condition changed while on this medication?

☐ Improved: Please describe: _____
 ☐ Stable: please describe: _____
 ☐ Worsened; Please describe: _____
 ☐ Other; Please describe: _____

Chart notes are required for the processing of all requests. Please add any other supporting medical information necessary for our review (required)

Coverage will not be provided if the prescribing physician's signature and date are not reflected on this document.

☐ Request for expedited review: I certify that applying the standard review time frame may seriously jeopardize the life or health of the member or the member's ability to regain maximum function

Physician's Name	Physician Signature	Date
Step 2: Checklist	☐ Form Completely Filled Out ☐ Provide chart notes	☐ Attach test results
Step 3: Submit	By Fax: BCBSM Specialty Pharmacy Mailbox 1-877-325-5979	By Mail: BCBSM Specialty Pharmacy Program P.O. Box 312320, Detroit, MI 48231-2320

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7/26/2018, 9/18/2018; 1/31/2020; 3/17/2020; 8/9/2021