Blue Cross Blue Shield Blue Care Network of Michigan

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P&T Date: 04/10/2025

Tremfya® IV (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. Diagnosis of ulcerative colitis (UC)
      i. Treatment with an adequate course of conventional therapy (such as steroids for 7 days, immunomodulators such as azathioprine for at least 2 months) has been ineffective or is contraindicated or not tolerated
   b. Diagnosis of Crohn's disease (CD)
      i. Treatment with an adequate course of conventional therapy (such as steroids for 7 days, immunomodulators such as azathioprine for at least 2 months) has been ineffective or is contraindicated or not tolerated
   c. Not to be used in combination with other biologics or targeted disease-modifying anti-rheumatic drugs (DMARDs) for the same indication
   d. 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 with moderate-to-severe plaque psoriasis who are candidates for systemic therapy of phototherapy
  - Adults 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. As of September 2024, the IV formulation is only indicated for the induction phase of ulcerative colitis and Crohn's disease. The SC formulation is indicated for plaque psoriasis, psoriatic arthritis, and the maintenance phase of ulcerative colitis treatment.
- 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).
- Ulcerative colitis
  - The 2019 ACG guidelines and the 2020 AGA guidelines for ulcerative colitis (UC) state therapeutic management in UC should be guided by the specific diagnosis, an assessment of disease activity, and disease prognosis. Treatment selection should be based not only on inflammatory activity but also on disease prognosis.
  - Remission can be induced using a variety of medications, including, oral 5-aminosalicylates (5-ASA), corticosteroids, or biologic agents. In patients with mild to moderately active disease, treatment with 5-ASA therapy has proven to be safe and efficacious for induction. Recommended dosing is 2 grams per day of oral 5-ASA or at least 1 gram per day of rectal 5-ASA with improvement usually seen within 4 weeks. A typical treatment course may be up to 8 weeks.
  - Oral steroids are recommended for induction for patients with severe disease or those who did not respond to 5-ASA therapy. The typical starting doses of oral prednisone are 40 – 60 mg per day, and clinical response is expected within 5 – 7 days of treatment. A typical treatment course with oral prednisone is 14 days. The duration of systemic corticosteroids should be as short as possible with early initiation of steroid-sparing therapy. The speed of the taper should be guided by clinical symptoms, cumulative steroid exposure, and onset of action of alternate therapies. Those unable to taper off of 10-20 mg of prednisone per day without relapsing are considered steroid dependent. Use systemic corticosteroids for maintenance of remission is not recommended.
  - Thiopurines, such as azathioprine and mercaptopurine, can be used to maintain remission. Guidelines recommend use of thiopurines over no medication or corticosteroids for maintenance therapy. Thiopurines are slow acting with maximum effectiveness of these agents being seen between 8 to 12 weeks from therapy initiation. They do not induce remission in moderately to severely active ulcerative colitis. Similarly, methotrexate is not an effective induction agent for induction or maintenance of remission.
  - In patients with moderate to severe disease, TNFi, Entyvio® (vedolizumab), and ustekinumab are recommended for the induction and maintenance of remission. For patients with moderate to severe disease in remission, guidelines do not recommend biologic monotherapy over thiopurine monotherapy.

Thiopurines can be used as adjunctive therapy for reducing immunogenicity against biologic therapy and are guideline recommended.

- Crohn's disease

  - The 2018 ACG guidelines establish therapeutic recommendations for patients with CD based upon disease location, disease severity, disease-associated complications, and future disease prognosis. Therapeutic approaches are individualized according to the symptomatic response and tolerance to medical intervention. Current therapeutic approaches should be considered a sequential continuum to treat acute disease or induce clinical remission and then to maintain response/remission. In general, clinical evidence of improvement should be evident within 2 – 4 weeks and the maximal improvement should occur within 12 – 16 weeks. Those with continued symptoms should be treated with an alternative therapy for mild to moderate disease, have their medication dose adjusted in order to attempt to optimize therapy, or advance to treatment for moderate to severe disease according to their clinical status.

  - Corticosteroids are used primarily for the treatment of flares of CD. Conventional corticosteroids are effective for reducing the signs and symptoms of active CD and induction of remission in patients with moderately to severely active CD. Oral corticosteroids are effective and can be used for short-term use in alleviating signs and symptoms of moderate to severely active disease. The ACG guidelines recommend prednisone equivalent doses ranging from 40 to 60 mg per day. These doses are typically maintained for 1 –2 weeks and tapered at 5 mg weekly until 20 mg and then 2.5 –5 mg weekly. Once begun, care should be taken to ensure that corticosteroids are successfully discontinued, and steroid-sparing agents should be used.

  - In patients with moderate-to-severe CD who remain symptomatic despite current or prior corticosteroid therapy, mercaptopurine, azathioprine, and intramuscular or subcutaneous methotrexate are effective steroid-sparing agents and guideline recommended. Maximum effectiveness of these agents can be seen between 8 to 12 weeks from therapy initiation. Methotrexate is also recommended in combination with steroids as effective for treatment of moderately active steroid-dependent/resistant CD. Cyclosporine, tacrolimus, and mycophenolate are not recommended for treatment of CD.

  - Biologics, such as TNFi are recommended to treat CD that is resistant to treatment with corticosteroids, thiopurines, or methotrexate. The ACG guidelines also recommend the use of biologics in combination with immunosuppressants to help decrease the formation of antibodies against the biologic therapy. There are no robust, published studies to support use of biologic agents in combination.

  - The 2021 AGA guidelines include similar recommendations for the management of moderate-to-severe CD compared to the recommendations cited in the 2018 ACG guidelines. Both guidelines recommend corticosteroids over no treatment for induction of remission. Additionally, both guidelines recommend thiopurines, such as azathioprine or 6-mercaptopurine, as steroid-sparing agents for maintenance of remission. The AGA guidelines also recommend the same biologic agents cited in the ACG guidelines for treatment of CD, with the exception of Tysabri® (natalizumab), which the ACG suggests against use of due to its associated risk of progressive multifocal leukoencephalopathy (PML).

  - Of note, the AGA guidelines conditionally recommend earlier introduction of biologic therapy prior to failure of corticosteroids; however, this recommendation is supported by a low level of clinical evidence. To date, no blinded randomized controlled trials (RCTs) have demonstrated the superiority of early introduction of biologic therapy compared to conventional induction therapy with corticosteroids followed by steroid-sparing therapy. The 2021 AGA guideline authors also acknowledge that earlier therapy with either combination immunomodulator plus biologic therapy or biologic monotherapy may result in over-treating some patients and potentially exposing them to treatment-related risks and costs with limited benefit.

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<tr><th colspan="3">Policy History</th></tr>
<tr><th>#</th><th>Date</th><th>Change Description</th></tr>
<tr><td>1.3</td><td>Effective Date: 04/10/2025</td><td>Updated to include the new Crohn’s disease indication</td></tr>
<tr><td>1.2</td><td>Effective Date: 12/02/2024</td><td>UM medical management system update for MAPPO and BCNA
<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>Yes</td></tr><tr><td>BCNA</td><td>Yes</td></tr></table></td></tr>
<tr><td>1.1</td><td>Effective Date: 10/03/2024</td><td>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</td></tr>
<tr><td>1.0</td><td>Effective Date: 09/26/2024</td><td>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></td></tr>
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** 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.*