Blue Cross Blue Shield Blue Care Network of Michigan

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Effective Date: 10/03/2024

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. Not to be used in combination with other biologics or targeted disease-modifying anti-rheumatic drugs (DMARDs) for the same indication
   c. 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) indicated for use in adults with moderately to severely active ulcerative colitis.

- 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 treatment. 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.

References:

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<table>
<tr><th colspan="3">Policy History</th></tr>
<tr><th>#</th><th>Date</th><th>Change Description</th></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.*