AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-305-671-0200**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Tremfya® SQ & IV (guselkumab) for CD & UC (Pharmacy)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy:** _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

ATTENTION: Tremfya IV induction (loading dose) for treatment of ulcerative colitis can only be billed under the **MEDICAL BENEFIT**. NDC: 57894-0650-02; J1628; 200 mg/20 mL= 200 billable units

Adult Dosing:

- ❑ **Induction IV: NDC: 57894-0650-02 – 200 mg/20 mL vial – J1628**
  - For Crohn's disease & ulcerative colitis: 200 mg administered by intravenous infusion over at least 1 hour at Week 0, Week 4, and Week 8
- ❑ **Induction SQ: NDC: 57894-0651-04 – Two 200 mg/2 mL single-dose prefilled pens in a carton**
  - For Crohn's disease & ulcerative colitis: 400 mg administered by subcutaneous injection at Week 0, Week 4, and Week 8

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- ❑ **Maintenance SubQ:**
  - 100 mg administered by subcutaneous injection at Week 16, and every 8 weeks thereafter, or 200 mg administered by subcutaneous injection at Week 12, and every 4 weeks thereafter. Use the lowest effective recommended dosage to maintain therapeutic response.
    - **NDC: 57894-0640-11 – 100 mg/mL One-Press patient-controlled injector**
    - **NDC: 57894-0640-01 – 100 mg/mL prefilled syringe**
    - **NDC: 57894-0640-06 – 100 mg/mL prefilled pen**
    - **NDC: 57894-0651-02 – 200 mg/mL prefilled pen**
    - **NDC: 57894-0651-22 – 200 mg/mL prefilled syringe**

NOTE: The Health Plan considers the use of concomitant therapy with more than one biologic immunomodulator (e.g., Dupixent, Entyvio, Humira, Rinvoq, Stelara) prescribed for the same or different indications to be experimental and investigational. Safety and efficacy of these combinations has **NOT** been established and will **NOT** be permitted.

❑ Will the member be discontinuing a previously prescribed biologic if approved for requested medication?

❑ Yes **OR** ❑ No

❑ If yes, please list the medication that will be discontinued and the medication that will be initiated upon approval along with the corresponding effective date.

Medication to be discontinued: _____ **Effective date:** _____

Medication to be initiated: _____ **Effective date:** _____

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

❑ **Diagnosis: Moderate-to-Severe Crohn's disease (CD)**

❑ **Maintenance Dose – 100 mg administered by subcutaneous injection at Week 16, and every 8 weeks thereafter, or 200 mg administered by subcutaneous injection at Week 12, and every 4 weeks thereafter. Use the lowest effective recommended dosage to maintain therapeutic response.**

Authorization Criteria: To be reviewed for approval under the pharmacy benefit

- ❑ Member has a diagnosis of moderate-to-severe **Crohn's disease**
- ❑ Prescribed by or in consultation with a **Gastroenterologist**

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- ❑ Member meets **ONE** of the following unless member has a contraindication or intolerance:
  - ❑ Member has tried and failed corticosteroids
  - ❑ Member has tried and failed at least one conventional systemic therapy (e.g., azathioprine, 6-mercaptopurine, or methotrexate)
  - ❑ Member has previously tried and failed another biologic medication other than the requested medication (e.g., adalimumab, Skyrizi, ustekinumab)
- ❑ According to the prescriber, the member will receive induction dosing with **ONE** of the following formulations within 3 months of initiating maintenance therapy with Tremfya subcutaneous
  - ❑ Tremfya intravenous infusion
  - ❑ Tremfya subcutaneous injection

❑ **Diagnosis: Moderate-to-Severe Ulcerative Colitis (UC)**

❑ **Maintenance Dose – 100 mg administered by subcutaneous injection at Week 16, and every 8 weeks thereafter, or 200 mg administered by subcutaneous injection at Week 12, and every 4 weeks thereafter. Use the lowest effective recommended dosage to maintain therapeutic response.**

Authorization Criteria: To be reviewed for approval under the pharmacy benefit

- ❑ Member has a diagnosis of moderate-to-severe **ulcerative colitis**
- ❑ Prescribed by or in consultation with a **Gastroenterologist**
- ❑ Member meets **ONE** of the following unless member has a contraindication or intolerance:
  - ❑ Member has tried and failed corticosteroids
  - ❑ Member has tried and failed at least **ONE** of the following **DMARD**:
    - ❑ 5-aminosalicylates (balsalazide, olsalazine, sulfasalazine)
    - ❑ oral mesalamine (Apriso, Asacol/HD, Delzicol, Lialda, Pentasa)
    - ❑ Other immunosuppressant drug: _____
  - ❑ Member has previously tried and failed another biologic medication other than the requested medication (e.g., adalimumab, Skyrizi, ustekinumab)
- ❑ According to the prescriber, the member will receive induction dosing with **ONE** of the following formulations within 3 months of initiating maintenance therapy with Tremfya subcutaneous
  - ❑ Tremfya intravenous infusion
  - ❑ Tremfya subcutaneous injection

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❑ **For Intravenous Induction Dose (If required) – One time approval for duration of 2 months, member to receive up to three (3) IV infusion doses**
Authorization Criteria: To be reviewed for one-time approval under the medical benefit

- ❑ Medication will be used as induction therapy
- ❑ Member must meet all maintenance dose authorization criteria above
- ❑ Medication being provided by:
  - ❑ **Location/site of drug administration:**_____
  - ❑ **NPI or DEA # of administering location**:_____
- ❑ Member to receive FDA approved loading dose of 200 mg administered by intravenous infusion over at least 1 hour at Week 0, Week 4, and Week 8

Medication being provided by a Specialty Pharmacy – Proprium Rx

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****

***Approved by Pharmacy and Therapeutics Committee**: ~~11/21/2024;~~ ~~5/22/2025;~~ ~~11/20/2025;~~ **3/26/2026**
REVISED/UPDATED/REFORMATTED: ~~12/11/2024, 6/30/2025; 10/31/2025, 12/8/2025;~~ **7/28/2026**