SENTARA COMMUNITY PLAN
(MEDICAID)

MEDICAL 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 1-844-305-2331**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

Drug Requested: Tremfya® IV (guselkumab) for UC and CD (J1628) (Medical)

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

Member Name: _____

Member Sentara #: _____ **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 Name/Form/Strength: _____

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

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

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

- ❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

IV induction (loading dose) for treatment of ulcerative colitis and crohn's disease can only be billed under the **MEDICAL BENEFIT**. NDC: 57894-0650-01/02; J1628; 200 mg/20 mL= 200 billable units

Adult Dosing:

- ❑ Induction IV: NDC: 57894-0650-01/02 – Tremfya IV 200 mg/20 mL vial – J1628
  - 200 mg administered by intravenous infusion over at least 1 hour at Week 0, Week 4, and Week 8

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.

(Continued on next page)

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 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
- ❑ Member is ≥18 years
- ❑ Trial and failure to ONE conventional agent (i.e., 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, sulfasalazine) used in the treatment of UC after at least a 3-month duration of therapy
- ❑ Member is not receiving guselkumbab in combination with another biologic agent for UC or non-biologic immunomodulator (e.g., upadacitinib)
- ❑ Member has tried and failed **BOTH**:

❑ adalimumab-adbm (Boehringer Ingelheim) **OR** Hadlima® (adalimumab-bwwd)	❑ Pyzchiva® syringe/vial (Requires trial and failure of a preferred TNF-alpha inhibitor)

❑ **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
- ❑ Member is ≥ 18 years
- ❑ Trial and failure to of a compliant regimen of oral corticosteroids (unless contraindicated) or intravenous corticosteroids
- ❑ Member is not receiving guselkumab in combination with another biologic agent for CD or non-biologic immunomodulator (e.g., upadacitinib)
- ❑ Member has tried and failed **BOTH**:

❑ adalimumab-adbm (Boehringer Ingelheim) **OR** Hadlima® (adalimumab-bwwd)	❑ Pyzchiva® syringe/vial (Requires trial and failure of a preferred TNF-alpha inhibitor)

(Continued on next page)

❑ **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
- ❑ 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 8

Medication being provided by Specialty Pharmacy - PropriumRx

For urgent reviews: Practitioner should call Sentara Health Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****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
REVISED/UPDATED/REFORMATTED: ~~12/13/2024; 6/20/2025;~~ **12/15/2025**