# 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: Omvoh™ SQ & IV** (mirikizumab-mrkz)

**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 Name/Form/Strength:** _____

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

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

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

**ATTENTION:** Omvoh IV induction (loading dose) for treatment of Crohn's Disease & Ulcerative Colitis can only be billed under the **MEDICAL BENEFIT**. NDC: 00002-7575-01; J2267

## Adult Dosing Ulcerative Colitis:

- ❑ **Induction IV: NDC: 00002-7575-01 – Omvoh (J2267) IV 300 mg/15 mL vial; 1 vial = 300 billable units**
  - 300 mg administered by intravenous infusion over at least 30 minutes at Week 0, Week 4, and Week 8
- ❑ **Maintenance SubQ:**
  - 200 mg administered by subcutaneous injection (given as two consecutive injections of 100 mg each) at Week 12, and every 4 weeks thereafter
    - **NDC: 00002-8011-27 – Omvoh 100 mg/mL prefilled pen**
    - **NDC: 00002-8870-27 – Omvoh 100 mg/mL prefilled syringe**

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## Adult Dosing Crohn's Disease:

- ❑ **Induction IV: NDC: 00002-7575-01 – Omvoh (J2267) IV 300 mg/15 mL vial; 3 vials = 900 billable units**
  - 900 mg administered by intravenous infusion over at least 90 minutes at Week 0, Week 4, and Week 8
- ❑ **Maintenance SubQ:**
  - 300 mg administered by subcutaneous injection (given as two consecutive injections of 100 mg and 200 mg in any order) at Week 12, and every 4 weeks thereafter
    - **NDC: 0002-7717-11 – Omvoh 200 mg/2 mL + 100 mg/mL prefilled pen**
    - **NDC: 0002-7722-11 – Omvoh 200 mg/2 mL + 100 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: Ulcerative Colitis**

❑ **Maintenance Dose – 200 mg administered by subcutaneous injection (given as two consecutive injections of 100 mg each) at Week 12, and every 4 weeks thereafter**

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

- ❑ Member has a diagnosis of **Ulcerative Colitis**
- ❑ Medication has been prescribed by a **Gastroenterologist**
- ❑ Member meets **ONE** of the following:
  - ❑ Member has tried and failed budesonide or high dose steroids (40-60 mg prednisone)
  - ❑ Member has tried and failed at least **ONE** of the following **DMARD** therapies for at least **three (3) months**
    - ❑ 5-aminosalicylates (balsalazide, olsalazine, sulfasalazine)
    - ❑ oral mesalamine (Apriso, Asacol/HD, Delzicol, Lialda, Pentasa)

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- ❑ Member meets **ONE** of the following:
  - ❑ Member tried and failed, has a contraindication, or intolerance to **TWO** of the following **PREFERRED** biologics:

| | | |
|---|---|---|
| ❑ Preferred adalimumab product | ❑ Rinvoq® | ❑ Simponi® |
| ❑ Skyrizi® SC (on-body injector) | ❑ Stelara® | ❑ Tremfya® |
| ❑ Xeljanz®/XR® | ❑ Zymfentra™ | |

***NOTE: COMM/FAMIS preferreds = Humira/Cyltezo/Yuflyma -** Humira NDC's starting with 83457 are not approved, NDC's starting with 00074 (MFG: Abbvie) are preferred; **SG/IP/HIX preferreds = Simlandi or adalimumab-adbm**

  - ❑ Member has been established on Omvoh™ for at least 90 days **AND** prescription claims history indicates **at least a 90-day supply of Omvoh was dispensed within the past 130 days (verified by chart notes or pharmacy paid claims)**

## ❑ Diagnosis: Crohn's Disease

## ❑ Maintenance Dose – 300 mg administered by subcutaneous injection (given as two consecutive injections of 100 mg and 200 mg in any order) at Week 12, and every 4 weeks thereafter

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

- ❑ Member has a diagnosis of **Crohn's Disease**
- ❑ Medication has been prescribed by a **Gastroenterologist**
- ❑ Member meets **ONE** of the following:
  - ❑ Member has tried and failed budesonide or high dose steroids (40-60 mg prednisone)
  - ❑ Member has tried and failed at least **ONE** of the following **DMARD** therapies for at least **three (3) months**
    - ❑ 5-aminosalicylates (balsalazide, olsalazine, sulfasalazine)
    - ❑ oral mesalamine (Apriso, Asacol/HD, Delzicol, Lialda, Pentasa)
- ❑ Member meets **ONE** of the following:
  - ❑ Member tried and failed, has a contraindication, or intolerance to **TWO** of the following **PREFERRED** biologics:

| | | |
|---|---|---|
| ❑ Preferred adalimumab product | ❑ Cimzia® | ❑ Skyrizi® SC (on-body injector) |
| ❑ Stelara® | ❑ Rinvoq® | ❑ Zymfentra™ |

***NOTE: COMM/FAMIS preferreds = Humira/Cyltezo/Yuflyma -** Humira NDC's starting with 83457 are not approved, NDC's starting with 00074 (MFG: Abbvie) are preferred; **SG/IP/HIX preferreds = Simlandi or adalimumab-adbm**

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- ❑ Member has been established on Omvoh™ for at least 90 days **AND** prescription claims history indicates **at least a 90-day supply of Omvoh was dispensed within the past 130 days (verified by chart notes or pharmacy paid claims)**

| ❑ **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 900 mg administered by intravenous infusion over at least 30 minutes at Week 0, Week 4, and Week 8

| **Medication being provided by Specialty Pharmacy – Proprium Rx** |
|---|

***Not all drugs may be covered under every Plan***

***If a drug is non-formulary on a Plan, documentation of medical necessity will be required.***

****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.***