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: Entyvio® Pen (vedolizumab) **(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 Name/Form/Strength: _____

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

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

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

ATTENTION: Entyvio IV induction (loading dose) for treatment of Crohn's disease & ulcerative colitis can only be billed under the **MEDICAL BENEFIT**. NDC: 64764-0300-20; J3380

Quantity Limits: 2 pens per 28 days

Adult Dosing:

- ❑ **Induction IV: NDC: 64764-0300-20 – Entyvio IV 300 mg vial – J3380**
  - 300 mg infused intravenously over approximately 30 minutes at Week 0 and Week 2
- ❑ **Maintenance SubQ: NDC: 64764-0108-20/21 – Entyvio 108 mg/ 0.68 mL prefilled pen**
  - Following the first two Entyvio IV doses administered at Week 0 and Week 2 in UC, Entyvio may be switched to subcutaneous (SC) injection at Week 6
  - 108 mg administered by subcutaneous injection starting at Week 6, and then every 2 weeks thereafter
  - Entyvio may be switched from IV infusion to SC injection, for patients in clinical response or remission beyond Week 6. To switch patients to Entyvio SC injection, administer the first SC dose in place of the next scheduled IV infusion and every two weeks thereafter.
  - Discontinue Entyvio in patients who do not show evidence of therapeutic benefit by Week 14

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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.

❑ **Maintenance Dose – 108 mg administered by subcutaneous injection starting at Week 6, and then every 2 weeks thereafter**

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

- ❑ Member is 18 years of age or older
- ❑ Member has **ONE** of the following diagnoses:
  - ❑ Moderate-to-severe **Crohn's disease**
  - ❑ Moderate-to-severe **Ulcerative colitis**
- ❑ Prescribed by or in consultation with 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 **PREFERRED** biologics below **(verified by chart notes or pharmacy paid claims):**

❑ adalimumab product: Humira®, Cyltezo® or Hyrimoz®	❑ Rinvoq®	❑ Skyrizi® SC (on-body injector)
❑ Simponi®	❑ Stelara®	❑ Xeljanz®/XR®

***NOTE:** Humira NDC's starting with 83457 are not approved, NDC's starting with 00074 (MFG: Abbvie) are preferred; Hyrimoz NDC's starting with 83457 are not approved, NDC's starting with 61314 (MFG: Sandoz) are preferred

  - ❑ Member has been established on Entyvio® for at least 90 days **AND** claims history indicates **at least a 90-day supply of Entyvio 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 1 month, member to receive up to two (2) 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 300 mg administered by intravenous infusion over at least 30 minutes at Week 0 and Week 2

Medication being provided by 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:** ~~1/18/2024; 5/23/2024;~~ **7/26/2024**
REVISED/UPDATED/REFORMATTED: ~~2/26/2024; 5/17/2024; 6/5/2024;~~ **8/12/2024**