BlueCross BlueShield Federal Employee Program

ENTYVIO
(vedolizumab)

Pre - PA Allowance

None

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Moderate to severely active Ulcerative Colitis (UC)
2. Moderate to severely active Crohn's Disease (CD)

AND ALL of the following:

a. Inadequate treatment response, intolerance, or contraindication to at least **ONE** conventional therapy option (see Appendix 1)
b. Inadequate treatment response, intolerance, or contraindication to a biologic DMARD or targeted synthetic DMARD (see Appendix 2) if adjudicated through the pharmacy benefit
c. Patient's condition will be re-evaluated at week 14 to confirm if therapy with Entyvio may continue
d. Prescriber will initiate dosing via IV infusion on weeks 0 and 2
e. Prescriber will be dosing the patient within the FDA labeled maintenance dose of the following:
    i. IV infusion: 300 mg every 8 weeks
    ii. Subcutaneous administration: 108 mg every 2 weeks
f. Patient **MUST** have tried the preferred product(s) (see Appendix 3), if adjudicated through the pharmacy benefit, unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
g. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 2)

Prior - Approval Limits

Quantity

Diagnosis	Dosage Form	Strength	Quantity
Crohn's disease (CD)	IV	300 mg IV vial	9 IV vials per 365 days **OR**

Crohn's disease (CD)	IV then switch to SC	300 mg IV vial 108 mg SC pen/syringe	2 IV vials + 6 SC pens/syringes per 84 days **OR**
Ulcerative colitis (UC)	IV	300 mg IV vial	9 IV vials per 365 days **OR**
Ulcerative colitis (UC)	IV then switch to SC	300 mg IV vial 108 mg SC pen/syringe	2 IV vials + 6 SC pens/syringes per 84 days

Duration 12 months

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Ulcerative Colitis (UC)
2. Crohn's Disease (CD)

AND ALL of the following:

a. Prescriber will be dosing the patient within the FDA labeled maintenance dose of the following:
   i. IV infusion: 300 mg every 8 weeks
   ii. Subcutaneous administration: 108 mg every 2 weeks
b. Patient **MUST** have tried the preferred product(s) (see Appendix 3), if adjudicated through the pharmacy benefit, unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)
c. **NOT** to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 2)

Prior - Approval *Renewal* Limits

Quantity

Diagnosis	Dosage Form	Strength	Quantity
Crohn's disease (CD)	IV	300 mg IV vial	1 IV vial per 56 days
Crohn's disease (CD)	SC	108 mg SC pen/syringe	6 SC pens/syringes per 84

			days
Ulcerative colitis (UC)	IV	300 mg IV vial	1 IV vial per 56 days
Ulcerative colitis (UC)	SC	108 mg SC pen/syringe	6 SC pens/syringes per 84 days

Duration 18 months

APPENDIX 1 – List of Conventional Therapies

Conventional Therapy Options for CD
1. Mild to moderate disease – induction of remission: a. Oral budesonide, oral mesalamine b. Alternatives: metronidazole, ciprofloxacin
2. Mild to moderate disease – maintenance of remission: a. Azathioprine, mercaptopurine b. Alternatives: oral budesonide, methotrexate intramuscularly (IM)
3. Moderate to severe disease – induction of remission: a. Prednisone, methylprednisolone intravenously (IV) b. Alternatives: methotrexate IM
4. Moderate to severe disease – maintenance of remission: a. Azathioprine, mercaptopurine b. Alternative: methotrexate IM
5. Perianal and fistulizing disease – induction of remission c. Metronidazole ± ciprofloxacin
6. Perianal and fistulizing disease – maintenance of remission d. Azathioprine, mercaptopurine e. Alternative: methotrexate IM

Conventional Therapy Options for UC
1. Mild to moderate disease – induction of remission: a. Oral mesalamine (e.g., Asacol, Lialda, Pentasa), balsalazide, olsalazine b. Rectal mesalamine (e.g., Canasa, Rowasa) c. Rectal hydrocortisone (e.g., Colocort, Cortifoam) d. Alternatives: prednisone, azathioprine, mercaptopurine, sulfasalazine
2. Mild to moderate disease – maintenance of remission: a. Oral mesalamine, balsalazide, olsalazine, rectal mesalamine b. Alternatives: azathioprine, mercaptopurine, sulfasalazine
3. Severe disease – induction of remission: a. Prednisone, hydrocortisone IV, methylprednisolone IV b. Alternatives: cyclosporine IV, tacrolimus, sulfasalazine
4. Severe disease – maintenance of remission: a. Azathioprine, mercaptopurine b. Alternative: sulfasalazine

5. Pouchitis:
    a. Metronidazole, ciprofloxacin
    b. Alternative: rectal mesalamine

Appendix 2 – List of DMARDs

Biological disease-modifying drugs (DMARDs)

Generic Name	Brand Name
abatacept	Orencia
adalimumab	Humira
anakinra	Kineret
bimekizumab-bkzx	Bimzelx
brodalumab	Siliq
certolizumab	Cimzia
etanercept	Enbrel
golimumab	Simponi/Simponi Aria
guselkumab	Tremfya
infliximab	Remicade
ixekizumab	Taltz
risankizumab-rzaa	Skyrizi
rituximab	Rituxan
sarilumab	Kevzara
secukinumab	Cosentyx
spesolimab-sbzo	Spevigo
tildrakizumab-asmn	Ilumya
tocilizumab	Actemra
ustekinumab	Stelara
vedolizumab	Entyvio

Targeted synthetic disease-modifying drugs (DMARDs)

Generic Name	Brand Name
apremilast	Otezla
baricitinib	Olumiant
deucravacitinib	Sotyktu
tofacitinib	Xeljanz/XR
upadactinib	Rinvoq

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Appendix 3 - List of Preferred Products

Diagnosis	Standard Option/Basic Option Preferred Products	Blue Focus Preferred Products
Crohn's disease (CD)	*must try **TWO** preferred products: Humira** Rinvoq Skyrizi Stelara (SC) Tremfya	Humira
Ulcerative colitis (UC)	*must try **TWO** preferred products: Humira** Rinvoq Skyrizi Stelara (SC) Tremfya	Humira

**Including all preferred biosimilars (see reference product criteria)