BlueCross BlueShield Federal Employee Program

ENTYVIO
(vedolizumab)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Entyvio (vedolizumab) is a humanized monoclonal antibody that specifically binds to the α4β7 integrin and blocks the interaction of α4β7 integrin with mucosal addressing cell adhesion molecule-1 (MAdCAM-1) and inhibits the migration of memory T-lymphocytes across the endothelium into inflamed gastrointestinal parenchymal tissue. The α4β7 integrin is expressed on the surface of a discrete subset of memory T-lymphocytes that preferentially migrate into the gastrointestinal tract. MAdCAM-1 is mainly expressed on gut endothelial cells and plays a critical role in the homing of T-lymphocytes to gut lymph tissue. The interaction of the α4β7 integrin with MAdCAM-1 has been implicated as an important contributor to the chronic inflammation that is a hallmark of ulcerative colitis and Crohn's disease (1).

Regulatory Status

FDA-approved indications: Entyvio is an integrin receptor antagonist indicated for adults in the treatment of: (1)

1. Moderately to severely active ulcerative colitis (UC)
2. Moderately to severely active Crohn's disease (CD)

Entyvio has warnings for infusion-related reactions and hypersensitivity reactions, infections, and progressive multifocal leukoencephalopathy (PML). Entyvio is not recommended in patients with active, severe infections until the infections are controlled. Patients who develop a severe infection while on treatment with Entyvio should have treatment withheld. Although unlikely, a risk of PML cannot be ruled out. Patients should be monitored for any new or worsening neurological signs or symptoms (1).

Entyvio should be administered intravenously by a healthcare provider on weeks 0 and 2 over approximately 30 minutes. On week 6, the patient may remain on intravenous therapy or switch to subcutaneous injection. Intravenous therapy may be given every eight weeks, while subcutaneous injection may be given every two weeks thereafter. Physicians will need to discontinue therapy in patients who show no evidence of therapeutic benefit by week 14 (1).

The safety and effectiveness of Entyvio in pediatric patients have not been established (1).

BlueCross BlueShield Federal Employee Program

ENTYVIO
(vedolizumab)

Summary

Entyvio (vedolizumab) is an integrin receptor antagonist indicated for adults in the treatment of moderate to severely active ulcerative colitis and moderate to severely active Crohn's disease. Entyvio has warnings for infusion-related reactions and hypersensitivity reactions, infections, and progressive multifocal leukoencephalopathy (PML). Therapy should be discontinued in patients who show no evidence of therapeutic benefit after the first 14 weeks of treatment. The safety and effectiveness of Entyvio in pediatric patients have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Entyvio while maintaining optimal therapeutic outcomes.

References

1. Entyvio [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; April 2024.