BlueCross BlueShield of North Carolina

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Corporate Medical Policy

Vedolizumab (Entyvio)

File Name:	vedolizumab_entyvio
Origination:	6/2014
Last CAP Review:	5/2019
Next CAP Review:	5/2020
Last Review:	5/2019

Description of Procedure or Service

Vedolizumab (Entyvio®) is an integrin receptor antagonist approved by the U.S. Food and Drug Administration (FDA) for the treatment of adults patients with moderately to severely active ulcerative colitis or Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to a tumor necrosis factor (TNF) blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids.

Integrin receptors are proteins expressed on the surface of certain cells and function as bridges for cell-cell interactions. Entyvio blocks the interaction of a specific integrin receptor (expressed on circulating inflammatory cells) with a specific protein (expressed on cells in the interior wall of blood vessels), and thereby blocks the migration of those circulating inflammatory cells across those blood vessels and into areas of inflammation in the gastrointestinal tract. The most common side effects in patients treated with Entyvio include headache, joint pain, nausea, and fever. The most serious risks associated with Entyvio include serious infections, hypersensitivity and infusion-related reactions, and hepatotoxicity.

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for Vedolizumab (Entyvio) for ulcerative colitis and Crohn's disease when it is determined to be medically necessary because the medical criteria and guidelines noted below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Vedolizumab (Entyvio) is covered

Entyvio (vedolizumab) may be medically necessary when the following criteria are met:

1. One of the following conditions is present:
    a. Adult patients (≥ 18 years of age) with moderately to severely active ulcerative colitis who have had an inadequate response with or were intolerant to conventional treatment such as corticosteroids or immunomodulators; **OR**

b. Adult patients (≥ 18 years of age) with moderately to severely active Crohn's Disease who have had an inadequate response with or were intolerant to conventional treatment such as corticosteroids or immunomodulators

When Vedolizumab (Entyvio) is not covered

Vedolizumab (Entyvio) is considered not medically necessary when criteria under "When Vedolizumab is covered" are not met.

Policy Guidelines

Vedolizumab (Entyvio) is administered by intravenous infusion.

For the treatment of **Ulcerative Colitis**, the recommended dosage is 300 mg given as a 30 minute intravenous infusion at zero, two and 6 weeks, then every 8 weeks thereafter.

For the treatment of **Crohn's Disease**, the recommended dosage is 300 mg given as a 30 minute intravenous infusion at zero, two and 6 weeks, then every 8 weeks thereafter.

Administration of Vedolizumab (Entyvio) - Site of Care Eligibility

1. Administration of Vedolizumab (Entyvio) may be given in an inpatient setting if the inpatient setting is medically necessary. An inpatient admission for the sole purpose of Vedolizumab (Entyvio) infusion is not medically necessary.
2. Vedolizumab (Entyvio) administration in a hospital outpatient setting is considered medically necessary if the following criteria are met:
    a. History of mild adverse events that have not been successfully managed through mild pre-medication (diphenhydramine, acetaminophen, steroids, fluids, etc.), OR
    b. Inability to physically and cognitively adhere to the treatment schedule and regimen complexity, OR
    c. First infusion, OR
    d. Less than 3 months since first Vedolizumab (Entyvio) infusion, OR
    e. First infusion after six months of no Vedolizumab (Entyvio) infusions, OR
    f. Requirement of a change in Vedolizumab (Entyvio) product.
3. Members who do not meet the criteria above are appropriate for Vedolizumab (Entyvio) administration in a home-based or physician office setting with or without supervision by a certified healthcare professional. Inpatient and hospital outpatient infusion, in the absence of the criteria in #1 or #2 above is considered not medically necessary.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: *J3380*

Prior to 1/1/16, there was no specific J code for Vedolizumab (Entyvio); however, providers could have billed with unlisted codes such as J3490 or J3590.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

U.S. Food and Drug Administration (FDA). Vedolizumab (Entyvio). Highlights of prescribing information. March 2014. Available at: https://www.entyviohcp.com/sign-up/

http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm398065.htm

Medical Director review 6/2014

Specialty Matched Consultant Advisory Panel review 6/2015

Medical Director review 7/2015

Specialty Matched Consultant Advisory Panel review 5/2016

Medical Director review 5/2016

Specialty Matched Consultant Advisory Panel review 5/2017

Medical Director review 5/2017

Specialty Matched Consultant Advisory Panel review 5/2018

U.S. Food and Drug Administration (FDA). Vedolizumab (Entyvio). Highlights of prescribing information. February 2018. Available at: https://general.takedapharm.com/ENTYVIOPI . Last accessed 7/2018.

Medical Director review 7/2018

Specialty Matched Consultant Advisory Panel review 5/2019

Policy Implementation/Update Information

7/1/14	New medical policy issued. Entyvio (vedolizumab) may be medically necessary when the following criteria are met: 1.One of the following conditions is present: a) Adult patients (≥ 18 years of age) with moderately to severely active ulcerative colitis who have had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids; **Or** b)Adult patients (≥ 18 years of age) with moderately to severely active Crohn's Disease who have had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids; **AND** 2.The patient has failed to respond adequately or is intolerant to Remicade® (infliximab).Medical director review 6/2014. (sk)
9/1/15	Billing/Coding section updated to include code: C9026. References updated. Specialty Matched Consultant Advisory Panel review 6/2015. Medical Director review 7/2015. (td)
12/30/15	Billing/Coding section updated to delete code C9026 and add code J3380 effective as of 1/1/16. (td)
7/1/16	Specialty Matched Consultant Advisory Panel review 5/25/2016. Medical Director review 5/2016. No changes to policy. (jd)
6/30/17	Specialty Matched Consultant Advisory Panel review 5/2017. Medical Director review 5/2017. (jd)

12/29/17 Policy Guidelines updated to include guidelines for "Site of Care Eligibility" related to infusion of Vedolizumab (Entyvio). Policy notification given 1/1/18, effective 4/1/18. (jd)

3/9/18 When Covered section revised; removed step therapy requirement, item #2 from the policy, "The patient has failed to respond adequately or is intolerant to Remicade® (infliximab)." Medical Director reviewed. (jd)

3/29/18 Under "When covered" removed "AND" from end of statement in section 1b to correct typographical error. Policy effective 4/1/18. (krc)

8/10/18 Updated "Description" section to include wording of FDA labeled indication. Updated "When Covered" section to include the following medical necessity statements: "a. Adult patients (≥ 18 years of age) with moderately to severely active ulcerative colitis who have had an inadequate response with or were intolerant to conventional treatment such as corticosteroids or immunomodulators; OR b. Adult patients (≥ 18 years of age) with moderately to severely active Crohn's disease who have had an inadequate response with or were intolerant to conventional treatment such as corticosteroids or immunomodulators." References added. Specialty Matched Consultant Advisory Panel review 5/23/2018. Medical Director review 7/2018. (krc)

5/28/19 Specialty Matched Consultant Advisory Panel review 5/15/2019. No change to policy intent. (krc)