Vedolizumab

Adjudication Guideline

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Approved by:	Responsible:	Related Adjudication Guidelines:
Daman	Pharmaceutical Standards & Governance	N/A

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1. Abstract

1.1 For Members

Vedolizumab is used to treat adults over the age of 18 with moderate to severe Crohn's Disease, Ulcerative Colitis and Pouchitis.

1.2 For Medical Professionals

Vedolizumab is a recombinant humanized IgG1 monoclonal antibody directed against the human lymphocyte α4β7 integrin, a key mediator of gastrointestinal inflammation. It is used in the treatment of moderate to severe active ulcerative colitis and Crohn's disease for patients who have had an inadequate response with lost response to or were intolerant to inhibitors of tumour necrosis factor-alpha (TNF-alpha) or other conventional therapies.

2. Scope

The scope of this adjudication rule is to highlight the medical indications, and coverage details for Vedolizumab as per the policy terms and conditions of each health insurance plan administered by Daman.

3. Adjudication Policy

3.1 Eligibility / Coverage Criteria

Vedolizumab is an integrin receptor antagonist indicated for:

1. **Adult Ulcerative Colitis (UC):** with moderately to severely active UC who have had an inadequate response with lost response to, or were intolerant to a tumour necrosis factor (TNF) blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids:
   - Inducing and maintaining clinical response
   - Inducing and maintaining clinical remission
   - Improving endoscopic appearance of the mucosa
   - Achieving corticosteroid-free remission.

2. **Adult Crohn's Disease (CD):** with moderately to severely active CD who have had an inadequate response with lost response to or were intolerant to a TNF blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids:
   - Achieving clinical response
   - Achieving clinical remission
   - Achieving corticosteroid-free remission

3. **Moderately to severely active chronic pouchitis:** is indicated for the treatment of adult patients with moderately to severely active chronic Pouchitis, who have undergone proctocolectomy and ileal pouch anal anastomosis for ulcerative colitis and have had an inadequate response with or lost response to antibiotic therapy. Treatment with vedolizumab should be initiated in parallel with standard of care antibiotic (e.g., four-week of ciprofloxacin).

Discontinuation of treatment should be considered if no evidence of therapeutic benefit is observed by 14 weeks of treatment with vedolizumab.

Medical criteria for initial approval for Crohn's disease

1. Diagnosis of moderately to severely active Crohn's disease (CD); and
2. One of the following:
   - History of failure, contraindication, or intolerance to at least one of the following conventional therapies: – Tumour necrosis factor (TNF) blocker [e.g., Adalimumab, Certolizumab – Immunomodulator (e.g., azathioprine, 6-mercaptopurine)
   - Corticosteroid: dependent (e.g., unable to successfully taper corticosteroids without a return of the symptoms of CD)

Medical criteria for continuation of therapy for Crohn's disease

1. The member must have met all initial authorization criteria; and
2. Documentation of positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:
   - Abdominal pain or tenderness; or
   - Diarrhea; or
   - Body weight; or
   - Abdominal mass; or
   - Hematocrit; or
   - Endoscopic appearance of the mucosa; or
   - Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)

Medical criteria for initial approval for Ulcerative colitis

1. For members who have previously received a biologic or targeted drug or
2. For the treatment of active UC for members who had an inadequate response, intolerance, or contraindication to at least one conventional therapy option or
3. For members who have been hospitalized for acute, severe UC (e.g., continuous bleeding, severe toxic symptoms, including fever and anorexia)

Medical criteria for continuation of therapy for Ulcerative colitis

1. For all members who are using the requested medication for active ulcerative colitis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

- Stool frequency; or
- Rectal bleeding; or
- Urgency of defecation; or
- C-reactive protein (CRP); or
- Fecal calprotectin (FC); or • Endoscopic appearance of the mucosa; or
- Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score) Clinical response: reduction in complete Mayo score of ≥3 points

and ≥30% from baseline with an accompanying decrease in rectal bleeding sub-score of ≥1 point or absolute rectal bleeding sub-score of ≤1 point.

Assessment Prior to Initiating
Prior to initiating treatment with Vedolizumab, all patients should be up to date with all immunizations according to current immunization guidelines.

Dosage and Administration

- Administer Vedolizumab as an intravenous infusion over 30 minutes. Do not administer as an intravenous push or bolus
- The recommended dosage of Vedolizumab in adults with ulcerative colitis or Crohn's disease is 300 mg administered by intravenous infusion at zero, two and six weeks and then every eight weeks thereafter.
- Discontinue therapy in patients who show no evidence of therapeutic benefit by Week 14.
- The recommended dose regimen of subcutaneous vedolizumab as a maintenance treatment, following at least 2 intravenous infusions, is 108 mg administered by subcutaneous injection once every 2 weeks. The first subcutaneous dose should be administered in place of the next scheduled intravenous dose and every 2 weeks thereafter.
- For moderately to severely active chronic pouchitis, the recommended dose regimen of intravenous Vedolizumab is 300 mg administered at Weeks 0, 2, and 6, then every 8 weeks thereafter, initiated in parallel with standard-of-care antibiotic therapy (e.g., a four-week course of ciprofloxacin), with discontinuation considered if no therapeutic benefit is observed by Week 14.

DRUG INTERACTIONS

- Because of the potential for increased risk of PML and other infections, avoid the concomitant use of Vedolizumab with natalizumab or TNF blockers.
- Live vaccines may be administered concurrently with ENTYVIO only if the benefits outweigh the risks.

3.2 Requirements for Coverage

- Failure to submit, upon request or when requesting a clinical history, indication the need for testing will result in rejection of claim.
- Kindly code the ICD-10 and the CPT codes to the highest level of specificity
- Eligible clinician specialities

3.3 Non-Coverage

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- Indications not approved by the relevant regulatory authority
- Age less than 18 years

3.4 Payment and Coding Rules

- Kindly apply DOH payment rules and regulations and relevant coding manuals for ICD, Drugs.

4. Denial Codes

Regulator denial codes with description are elaborated for reference. These are specialized codes directed by regulator, that explains the reason of rejection of the service by DAMAN to the providers.

Code	Code Description
CODE-010	Activity/diagnosis inconsistent with clinician's speciality
MNEC-003	Service is not clinically indicated based on good clinical practice
MNEC-004	Service is not clinically indicated based on good clinical practice, without additional supporting diagnosis/activities
MNEC-005	Service/supply may be appropriate, but too frequent
CLAI-012	Submission not compliant with contractual agreement between provider & payer
PRCE-002	Payment is included in the allowance for another service
CODE-013	Invalid principal diagnosis (for example E-codes)

5. Appendices

5.1 References

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5.2 Revision History

Date	Version No.	Change(s)
27/12/2022	V1.0	Creation of Adjudication Guideline-External Instruction Template.
04/11/2024	V2.0	No changes / updated in the new format
26/10/2025	V3.0	Addition of dosing and administration details for the pouchitis indication, along with updated references.

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