VELODIZUMAB (ENTYVIO™) MEDICAL POLICY [1]

POLICY NUMBER:

EFFECTIVE DATE: [MM/DD/YYYY] **LAST UPDATED:** [MM/DD/YYYY]

DEVELOPED BY: [Employee Name] **APPROVED BY:** [Employee Name]

POLICY:

Velodizumab is an integrin receptor antagonist indicated for adults for the treatment of moderately to severely active ulcerative colitis and moderately to severely active Crohn's disease. This facility is committed to providing high-quality care, promoting patient safety, and supporting staff adherence to best practices. This policy, in conjunction with relevant departmental policies, establishes a standardized process for the safe administration of velodizumab.

SCOPE:

This policy applies to all personnel at [facility] who are responsible for the preparation and/or administration of parenteral medications.

RESPONSIBILITIES:

It is the responsibility of [insert title of the responsible party] to ensure that all personnel responsible for the preparation and administration of parenteral medications complete the required education and training according to [insert facility policy on staff training and education].

It is the responsibility of every person responsible for the preparation and administration of parenteral medication to adhere to the contents of this policy and remain current with facility training.

ACRONYMS:

FDA Food and Drug Administration
JCV John Cunningham virus
PML Progressive Multifocal Leukoencephalopathy
TB Tuberculosis
USP United States Pharmacopeia
VAD vascular access device

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[1] The National Infusion Center Association (NICA) develops templates to be used as a reference to support, not replace, the use of professional judgment in the development of organization-specific policies. NICA templates are for informational purposes only and may not reflect all relevant regulations and requirements from applicable oversight agencies including but not limited to state/local health departments, departments of professional licensure, FDA, or other regulatory authorities. NICA assumes no responsibility for any damages or adverse effect(s) resulting from or related to the readers' interpretation or application of this information. For complete medication information, refer to www.entyvio.com

CRITERIA AND INDICATIONS FOR USE:

- Velodizumab is indicated for the treatment of moderate-to-severely active ulcerative colitis and Crohn's disease.
- Approved diagnoses[2]:

- K51.00 Ulcerative (chronic) pancolitis w/o complications
- K51.20 Ulcerative (chronic) proctitis w/o complications
- K51.30 Ulcerative (chronic) rectosigmoiditis w/o complications
- K51.50 Left-sided colitis w/o complications
- K51.80 Other ulcerative colitis w/o complications
- K51.90 Ulcerative colitis, unspecified, w/o complications
- K50.00 Crohn's disease of small intestine w/o complications
- K 50.10 Crohn's disease of large intestine without complications
- K50.80 Crohn's disease of both small and large intestine without complications
- K50.90 Crohn's disease, unspecified, without complication

PROCEDURE:

1) Review Referral:
   a) Confirm the order for velodizumab is complete and signed by a licensed independent practitioner with active prescriptive authority.
   b) All referrals must be accompanied by documentation supporting medical necessity, including but not limited to:
      i) medical records confirming diagnosis including:
         Results and date of colonoscopy
      ii) [Tuberculosis screening according to local practice]
   c) If the referral is incomplete [insert facility protocol, e.g., "notify referring provider to request outstanding clinical documentation"]
   d) Confirm receipt of referral with the referring provider [per facility policy]
   e) Contact patient/care partner to:
      i) Confirm receipt of referral.
      ii) Inform the patient/care partner of the next steps and what to expect.
      iii) Obtain additional information required for referral (e.g., demographic and insurance information).
   f) Begin the insurance verification and authorization process.
   g) Upon treatment approval, contact the patient/care partner to schedule the velodizumab infusion. When scheduling, discuss the following with the patient: [e.g.:
      i) bring a current list of prescriptions and over-the-counter medications (including vitamins and supplements);
      ii) make a list of questions for the infusion team;
      iii) patient preparation information; and
      iv) facility-specific arrival instructions.
2) Prior to treatment:
   a) Confirm the patient's identity using two unique patient identifiers.
   b) Review the medical record to confirm the dose/treatment number.

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[2] The ICD-10 diagnosis codes above may be reasonably related to a diagnosis within the product's approved label. It is not all inclusive, and other codes may be appropriate. NICA does not guarantee payment of any claim. Coding, coverage, and reimbursement may vary significantly by payer, plan, patient, and setting of care. It is the sole responsibility of the provider to select the proper code and ensure the accuracy of all claims used in seeking reimbursement.

c) Provide velodizumab education with the patient/care partner [insert facility patient education policy, e.g., "Provide and review written medication information (e.g., FDA approved patient medication guide) prior to initial treatment at a minimum, and offer written information prior to each subsequent treatment."]. Document education in the patient's medical record.

d) Verify that current informed consent is on file. Alternatively, obtain informed consent prior to treatment.

e) Confirm that the medical record contains complete and current clinical documentation prior to every treatment, including:

i) colonoscopy report, and

ii) negative TB screening [per local practice or policy]

f) Obtain a full set of vital signs [insert facility-specific protocol e.g., "to include blood pressure, pulse, temperature, respiratory rate, and oxygen saturation."]

g) Hold the infusion and notify the prescriber if:

i) vital signs are abnormal,

ii) fever or signs/symptoms of illness or active infection,

iii) planned/recent surgical procedure,

iv) signs or symptoms of progressive multifocal leukoencephalopathy (PML); mood or neurological changes

- PML is a rare and often fatal opportunistic infection affecting the central nervous system. PML is caused by the John Cunningham virus (JCV) and typically only occurs in patients who are immunocompromised. Patients being treated with velodizumab should be monitored for any new onset, or worsening, of neurological signs and symptoms such as progressive weakness on one side of the body or clumsiness of limbs, disturbance of vision, and changes in thinking, memory, and orientation leading to confusion and personality changes.

v) recent live vaccinations, or

vi) signs of liver injury such as new onset abdominal pain, fatigue, dark urine, or jaundice

- There have been reports of elevations of transaminase and/or bilirubin in patients who have been treated with velodizumab. This elevated transaminase and bilirubin can be an important predictor of severe liver injury that may lead to death or require a liver transplant in some patients. Monitor patients for signs of liver injury prior to every infusion and educate the patient on symptoms to monitor at home.

h) Review the order.

i) Prior to preparing velodizumab, obtain vascular access [e.g., "per Vascular Access Device Placement policy"].

j) Gather supplies:

i) Gloves
ii) Alcohol prep pads
iii) Empty syringe
iv) 21-to-25 gauge needle
v) 1 vial of 300 mg velodizumab
vi) 1 vial of sterile water for injection (alternatively may use 0.9% sodium chloride for injection or lactated ringers)
vii) One infusion bag with 0.9% sodium chloride injection, USP, or lactated ringers

k) Prepare designated medication preparation area [e.g., "refer to Parenteral Medication Preparation policy," or "disinfect area…" etc.].

3) Medication preparation:

a) Select velodizumab vial required for the ordered dose
b) Velodizumab is supplied as sterile lyophilized cake that must be reconstituted.
c) Using aseptic technique:
    i) Remove the flip-off cap from the vial of velodizumab and wipe with an alcohol swab.
    ii) Reconstitute the vial of velodizumab with 4.8 mL of sterile water for injection (alternatively may use 0.9% sodium chloride injection or lactated ringers to reconstitute).
    iii) Insert the syringe needle into the vial through the center of the stopper and direct the stream of diluent to the wall of the vial to avoid excessive foaming.
    iv) Gently swirl the vial for at least 15 seconds to dissolve the lyophilized powder. Do not shake or invert vigorously.
    v) Allow the solution to sit for up to 20 minutes at room temperature to allow for reconstitution and for any foam to settle; the vial can be swirled and inspected for dissolution during this time.
    vi) If not fully dissolved after 20 minutes, allow another 10 minutes for dissolution. Do not use the vial if not dissolved within 30 minutes.
    vii) Visually inspect for particulate matter and discoloration. The solution should be clear or opalescent, colorless to light brownish yellow, and free of visible particulates. Do not administer any solution that shows uncharacteristic color or contains particulates.
        a. If particulate matter or discoloration is noted, do not use. Remove from inventory and complete the following:
            i. [insert facility protocol e.g., "refer to Adverse Event policy"]
            ii. Report to [identify responsible party e.g., "nurse manager"].
    viii) Once dissolved, gently invert the vial three times.
    ix) Reconstituted solution yields velodizumab 300 mg/5 mL.
    x) Use an alcohol swab to disinfect the injection port of the IV diluent bag.
    xi) Using aseptic technique, withdraw 5 mL (300 mg) of reconstituted solution using a syringe with a 21- to-25 gauge needle.
    xii) Add the 5 mL of reconstituted velodizumab solution to the diluent bag containing 250 mL of 0.9% sodium chloride or lactated ringers and gently mix the infusion bag.
    viii) Infuse diluted velodizumab immediately. If not able to infuse immediately, may be stored at 2°C to 8°C (36°F to 46°F) for up to 4 hours, after which point it must be discarded.

4) Administration:
    a) Prime the administration set with the prepared velodizumab.
    b) Assess the patency of the vascular access device (VAD) by [insert facility protocol, e.g., "confirming blood return and flushing with 0.9% Sodium Chloride per Vascular Access policy"].
    c) Disinfect the needleless connector and attach the administration set and prepared velodizumab to VAD.
    d) ["Set flow rate" or "program infusion pump"] to infuse the entire volume of diluted velodizumab over 30 minutes.
    e) Continually monitor the patient's treatment tolerance throughout the infusion, assessing for any signs or symptoms of an infusion-related reaction. If an infusion-related reaction is suspected, immediately stop the infusion and [insert facility-specific protocol e.g., "initiate Hypersensitivity Reaction Management Protocol"].
    f) After the infusion is complete, flush the VAD with a total of 30 mL 0.9% sodium chloride.
    g) Obtain a full set of vital signs at the completion of the infusion.

5) Discharge:
   a) If vital signs are within normal limits and patient is otherwise stable, remove VAD [e.g., "according to facility policy"], document the patient's treatment tolerance and VAD site assessment.
   b) Review discharge instructions with the patient/care partner:
      i) Expected side effects.
      ii) Symptoms to report and to whom they should be reported.
      iii) Adverse reactions, whether confirmed or suspected, should be reported to the FDA at (800) FDA-1088 or www.fda.gov/medwatch.
      iv) Remind the patient/care partner to complete blood work and diagnostic imaging (e.g., colonoscopy), as applicable.

Medication Policy Protocol: This medication policy will be reviewed and updated if necessary [insert facility protocol e.g., "at least annually, or more frequently as necessary."]

REFERENCES

1. Takeda Pharmaceuticals, Inc. Prescribing Information. 2022.
2. National Infusion Center Association. Standards of Excellence for Ambulatory Infusion Centers (1st ed.). Madison, WI: Omnipress. 2023.