

<p>SUBJECT: CLINICAL POLICIES – INJECTABLE MEDICATIONS_- OMVOH FOR THE TREATMENT OF INFLAMMATORY BOWEL DISEASE - MA</p> <p>POLICY NUMBER: HS-CP-MAI3I</p> <p>EFFECTIVE DATE: December 17,2025</p> <p>SERVICE/PRODUCT LINE: MEDICARE – MEDICAL</p>	<p>Product Line (check all that apply):</p> <p><input type="checkbox"/> All</p> <p><input type="checkbox"/> Group HMO</p> <p><input type="checkbox"/> Individual HMO</p> <p><input type="checkbox"/> PPO</p> <p><input type="checkbox"/> POS</p> <p><input checked="" type="checkbox"/> Medicare</p> <p><input type="checkbox"/> N/A</p>
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These guidelines are used in conjunction with the independent judgment of a qualified licensed physician and do not constitute the practice of medicine or medical advice. This Clinical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care and are solely responsible for the medical advice and treatment of members. This Clinical Policy is not intended to recommend treatment for members. Members should consult with their treating provider in connection with diagnosis and treatment decisions.

When coverage criteria are not fully established by Medicare including but not limited to National Coverage Decisions (NCD), Local Coverage Decisions (LCD), Medicare Manuals and National Coverage Articles, Sharp Health Plan develops Clinical Policies that serve as recommendations for medical necessity decisions. Sharp Health Plan utilizes evidence-based guidelines from nationally recognized professional organizations, peer reviewed medical and scientific literature and evidence-based consensus statements, which are all based on generally accepted standards of care.

I. BENEFIT STATEMENT: Any service reviewed and approved by this Sharp Health Plan Clinical Policy must be a covered benefit according to the member’s evidence of coverage (EOC). Since benefit plans vary in coverage and some plans may not provide coverage for certain services discussed in this clinical policy, decisions are subject to all terms and conditions of the applicable benefit plan. Benefit determinations should be based in all cases on the member’s contract benefits in effect at the time of service.

All reviewers must first identify member eligibility and all decisions of this clinical policy are subject to current state and/or federal law. This Clinical policy does not constitute plan authorization, nor is it an explanation of benefits. In the event of a conflict, a member’s benefit plan, EOC, always supersedes the information in the Clinical Policies.

II. REGULATORY: N/A

III. DESCRIPTION

This clinical policy should be utilized referencing the member’s specific Member Handbook to confirm the member’s coverage benefit(s). This policy defines the Sharp Health Plan (Plan) requirements for determination of medical necessity in order for mirikizumab (Omvoh) to be covered. This policy is to be used when there is no CMS criteria (NCD,LCD, NCA, Medicare Manual) for the drug in question.

This policy defines the Sharp Health Plan (Plan) criteria for coverage of medications with a parenteral (IM, SQ, IV, Intrathecal) route of administration. These are also referred to as a “medical benefit” medication. A separate policy governs medications administered through the pharmacy benefit (Sharp Health Plan Pharmacy

Procedure for Formulary and Pharmaceutical Management Procedures Development

IV. DEFINITIONS

- A. Qualified Individual is a Sharp Health Plan (Plan) member.
- B. Experimental and Investigational drugs and devices:
 - 1. Considered experimental if the FDA has not issued a specific indication or NDC number for the specific drug or device AND they are currently under investigation in a registered Clinical Trial.
 - 2. The Off-Label Use of an FDA approved prescription drug or device is not considered an experimental/investigational service if this off-label use is not currently being investigated in a registered Clinical Trial.
- C. Biosimilars: A biosimilar is a biologic that is highly similar to, and has no clinically meaningful differences from, another biologic that is already approved by the FDA (known as the original biologic or reference product). Biosimilars are made with the same types of natural sources as the original medication they were compared to; they are given the same way, have the same strength and dosage, and have the same potential side effects. A biosimilar provides the same treatment benefits as the original biologic.
- D. Injection: The introduction of a medicinal substance into the body; either subcutaneous, intramuscular, intravenous, intra-arterial or into other canals or cavities of the body. For purposes of this medical policy, a medication is provided either by a member (self-injectable) or by a medical provider. It is a "shot" or a dosage of medication given by way of a syringe and needle rather than over a period of time, though not to be given as part of a procedure.
- E. Infusion: The slow diagnostic, prophylactic, or therapeutic introduction of fluid or medicinal substance into a vein or tissue given over a period of time.

V. MEDICAL NECESSITY

- A. To be eligible for coverage under this policy, the member must be a Qualified Individual with active Plan membership.
- B. Additionally, the provision of physician samples does not guarantee coverage.
- C. Member is treated by a contracted network gastroenterologist.
- D. Adult Crohn's Disease Treatment Criteria
 - 1. Member is 18 years and older with moderate to severe Crohn's disease as indicated by one or more of the following:
 - a) Fever
 - b) Significant weight loss
 - c) Abdominal pain or tenderness
 - d) Intermittent nausea or vomiting
 - e) Significant anemia
 - f) Significant diarrhea or bloody diarrhea > 6 per day; and
 - 2. Member has failed to adequately respond to or is intolerant of one of the following, unless all are contraindicated or deemed by the treating physician to be inappropriate for the member's needs

due to severe disease:

- a) 6-mercaptopurine OR
 - b) Azathioprine OR
 - c) Methotrexate_OR
 - d) Corticosteroids; and
3. Member has one of the following:
- a) Documented negative TB test within 6 months of initiating therapy for persons who are naive to biologics, and repeat testing every 1-2 years for members with risk factors for TB who are continuing therapy with biologics; or
 - b) History of positive TB test and prior treatment for latent TB, with negative chest x-ray within 6 months of initiating therapy for persons who are naive to biologics; and
4. Dosing should align with the FDA-approved labeling; and
5. Member is not using two or more targeted immune modulators in combination for Crohn's disease; and
6. Authorization will be for no more than 12 months
7. Member meets **both** of the following:
- a) Member has tried two of the following drugs: adalimumab, certolizumab pegol (Cimzia), infliximab, and ustekinumab.
 - b) Member has tried vedolizumab (Entyvio).

E. Adult Ulcerative Colitis Treatment

1. Member is 18 years and older with severe ulcerative colitis as indicated by frequent loose bloody stools (≥ 6 per day) and one or more of the following:
 - a) Fever (temperature $\geq 37.5^{\circ}\text{C}$)
 - b) Tachycardia (HR ≥ 90 beats/minute)
 - c) Anemia (hemoglobin < 10.5 g/dL)
 - d) Elevated erythrocyte sedimentation rate (ESR) ≥ 30 mm/hour)
 - e) Elevated C-reactive protein (CRP); and
2. Member has failed to adequately respond to or is intolerant of one of the following, unless all are contraindicated or deemed by the treating physician to be inappropriate for the member's needs due to severe disease:
 - a) 5-aminosalicylic acid agents (e.g., balsalazide, mesalamine, sulfasalazine) OR
 - b) 6-mercaptopurine OR
 - c) Azathioprine OR
 - d) Corticosteroids; and

3. Member has one of the following:
 - a) Documented negative TB test within 6 months of initiating therapy for persons who are naive to biologics, and repeat testing every 1-2 years for members with risk factors for TB who are continuing therapy with biologics; or
 - b) History of positive TB test and prior treatment for latent TB, with negative chest x-ray within 6 months of initiating therapy for persons who are naive to biologics; and
4. Dosing should align with the FDA-approved labeling; and
5. Member is not using two or more targeted immune modulators in combination for ulcerative colitis; and
6. Authorization will be for no more than 12 months
7. Member meets **both** of the following:
 - a) Member has tried two of the following drugs: adalimumab, certolizumab pegol (Cimzia), infliximab, and ustekinumab.
 - b) Member has tried vedolizumab (Entyvio).

VI. NOT MEDICALLY NECESSARY

Any indication that does not meet the above Medical Necessary criteria.

VII. PROCEDURE/ATTACHMENTS

- A. All requests for medical injectable coverage will be reviewed by the delegated Plan Medical Group (PMG) or by the Plan, according to its regular and appropriate utilization management process, administered consistent with the Plan benefit.
- B. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this guideline. This Policy provides assistance in determining coverage under the member's benefit plan.
- C. The terms of a member's benefit plan summary defined in the evidence of coverage document may differ from the standard benefit plans upon which this guideline is based. In the event of a conflict, the member's specific benefit document supersedes these guidelines.
- D. The medical injectable will be subject to step therapy per SHP Clinical Policy I3- Injectable Medications.
- E. The Plan is not required to cover services or benefits that are not otherwise covered under the terms and conditions of the Plan contract.

VIII. CODES: N/A**IX. REFERENCES**

- A. ACG Clinical Guideline: Management of Crohn's Disease in Adults. Am J Gastroenterol. 2025 June;120(6):p 1225-1264.

- B. ACG Clinical Guideline Update: Ulcerative Colitis in Adults. Am J Gastroenterol. 2025 June;120(6):p 1187-1224.
- C. UpToDate, 2024. Al Hashash J and Regueiro M. Medical management of moderate to severe Crohn disease in adults. Retrieved online from: <https://www.uptodate.com/contents/medical-management-of-moderate-to-severe-crohn-disease-in-adults>.
- D. UpToDate, 2024. Cohen RD and Stein AC. Management of moderate to severe ulcerative colitis in adults. Retrieved online from: <https://www.uptodate.com/contents/management-of-moderate-to-severe-ulcerative-colitis-in-adults>.

X. REVISION HISTORY

Date	Modification (Original, Reviewed or Revised)
12/17/25	Original

Approved by: (Signature of VP /CMO) 	Approval date: 12/17/2025
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