omvoh together™
(mirikizumab-mrkz)
300 mg/15 mL infusion | 100 mg/mL injection

The following information is presented for informational purposes only and is not intended to provide reimbursement or legal advice. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. While we have made an effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it. Providers are encouraged to contact third-party payers for specific information on their coverage policies. For more information, please call Omvoh Together at 1-844-4-OMVOH4 (1-844-466-8644).

Letter of Medical Necessity Guide

The purpose of a **Letter of Medical Necessity (LMN)** is to explain the prescribing healthcare provider's (HCP's) rationale and clinical decision-making when choosing a treatment.[a] Many health plans require that an LMN accompany submissions of Appeal, Formulary Exception Request, and Tiering Exception Request Letters.

This resource, **Composing a Letter of Medical Necessity**, provides information on the process of drafting an LMN. A sample letter is attached to this document and includes information that plans often require. Note that some plans have specific forms that must be utilized to document an LMN. Follow the patient's plan requirements when requesting Omvoh; otherwise, treatment initiation may be delayed.

COMMON CLINICAL EVIDENCE REQUIRED FOR COVERAGE AUTHORIZATION REQUESTS AND LMNs INCLUDE:

- Patient's condition (diagnosis), ICD-10 code, and severity of disease for which Omvoh is being/will be used
- Information about the current treatment(s) being used for the patient's condition and how the patient is doing clinically while taking the current treatment(s)
- Previous therapies used, dates used, and reasons for discontinuation
- Clinical rationale for why other treatments are not appropriate, if applicable
- Clinically relevant and patient-specific information that makes Omvoh an appropriate therapy for the patient

Omvoh Together will work with you to help navigate patient access.

For more information, please visit Omvoh.com/hcp/support-for-your-patients or call Omvoh Together at 1-844-4-OMVOH4 (1-844-466-8644).

ICD-10=International Statistical Classification of Diseases, Tenth Revision

[a]For Medicare beneficiaries, specific requirements need to be met for the HCP to be considered a legal representative of the patient in an appeal. For additional information, please **click here**.

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This template can be used by HCPs for explaining medical necessity.

Sample Letter of Medical Necessity for Omvoh With Instructions

<Physician's letterhead>

<Date>
<Health plan's name>
ATTN: **<Department>**
<Medical director's name>
<Health plan's address>
<City, State ZIP>

<Patient's name>
<Date of birth>
<Case ID number>
<Dates of service>

Include the patient's full name, date of birth, plan ID number, and case ID number (if applicable).

Re: Letter of Medical Necessity for Omvoh™ (mirikizumab-mrkz)

To Whom it May Concern:

I am writing to request coverage for <intravenous (IV)/subcutaneous (SC)> Omvoh under the <pharmacy benefit/medical benefit>, which I have prescribed for <patient's name>. My patient <is new to therapy/has been treated with IV Omvoh, and we are now requesting transition to SC Omvoh>. This letter provides pertinent medical history regarding my patient and their treatment, as well as my clinical rationale for prescribing Omvoh.

Select which situation applies to this patient based on their current/past treatments.

Medical History

Provide information that is applicable to the primary diagnosis/diagnoses.

<Please include overview of disease course of the patient, including history and severity of disease, any symptoms, and hospitalizations. If there have been changes in disease activity or patient assessment of condition, include that information as well>.

Provide a copy of the patient's medical records that include the following information: patient's history (including prior treatments), ICD-10 code, present-day condition and symptoms, as well as any allergies and existing comorbidities.

Previous Treatments

<History of previous therapies, including start/stop dates>
<Reasons for discontinuation of previous therapies, including documentation of inadequate response and/or intolerable adverse events>

Document prior treatments and how long each treatment lasted, as well as the rationale for discontinuing those treatments.

Clinical Rationale

<Clinical rationale for why your patient will benefit from Omvoh over preferred agents for the treatment (use this for plans that have formulary exclusions or step therapy). Include information on why other agents are not an appropriate option>.

<Placeholder for tiering exception (Medicare)>
<Explain why lower-tiered formulary drugs would not be as medically appropriate as Omvoh. If the patient is currently being treated with Omvoh, explain the benefits that the patient has experienced since starting Omvoh and the expected outcomes if Omvoh was to be discontinued>.

Please note, the patient will not be taking Omvoh in combination with another biologic therapy or JAK (Janus kinase) inhibitor.

Based on my professional experience, treatment with Omvoh is appropriate, medically necessary, and supported by their individual medical history. <Additionally, upon completion of induction therapy with IV and an adequate therapeutic response, I will be transitioning my patient to SC maintenance therapy with Omvoh. Please consider approving the request for Omvoh SC therapy as well.> Attached are relevant laboratory test results and medical records to support my rationale. If you have any additional questions, please contact me at <physician's phone number> or via email at <physician's email>. Thank you for your time and consideration.

Do not include this information if the letter is for the SC formulation of Omvoh, or if the pharmacy and medical benefits are administered by different companies.

Sincerely,
<Physician's signature and specialty, if applicable>

Enclosed: <Medical records, clinical notes, medication history, relevant laboratory reports that support the need for Omvoh, and other supporting information>

Attach any clinical documentation that supports your recommendation.

View an example on pages 5 and 6 for use on your office letterhead.

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INDICATION

Omvoh is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS - Omvoh is contraindicated in patients with a history of serious hypersensitivity reaction to mirikizumab-mrkz or any of the excipients.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Serious hypersensitivity reactions, including anaphylaxis during intravenous infusion, have been reported with Omvoh administration. Infusion-related hypersensitivity reactions, including mucocutaneous erythema and pruritus, were reported during induction. If a severe hypersensitivity reaction occurs, discontinue Omvoh immediately and initiate appropriate treatment.

Infections

Omvoh may increase the risk of infection. Do not initiate treatment with Omvoh in patients with a clinically important active infection until the infection resolves or is adequately treated. In patients with a chronic infection or a history of recurrent infection, consider the risks and benefits prior to prescribing Omvoh. Instruct patients to seek medical advice if signs or symptoms of clinically important acute or chronic infection occur. If a serious infection develops or an infection is not responding to standard therapy, monitor the patient closely and do not administer Omvoh until the infection resolves.

Tuberculosis

Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with Omvoh. Do not administer Omvoh to patients with active TB infection. Initiate treatment of latent TB prior to administering Omvoh. Consider anti-TB therapy prior to initiation of Omvoh in patients with a history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Monitor patients for signs and symptoms of active TB during and after Omvoh treatment. In clinical trials, subjects were excluded if they had evidence of active TB, a history of active TB, or were diagnosed with latent TB at screening.

Hepatotoxicity

Drug-induced liver injury in conjunction with pruritus was reported in a clinical trial patient following a longer than recommended induction regimen. Omvoh was discontinued. Liver test abnormalities eventually returned to baseline. Evaluate liver enzymes and bilirubin at baseline and for at least 24 weeks of treatment. Monitor thereafter according to routine patient management. Consider other treatment options in patients with evidence of liver cirrhosis. Prompt investigation of the cause of liver enzyme elevation is recommended to identify potential cases of drug-induced liver injury. Interrupt treatment if drug-induced liver injury is suspected, until this diagnosis is excluded. Instruct patients to seek immediate medical attention if they experience symptoms suggestive of hepatic dysfunction.

Please see additional Important Safety Information on the next page and click for Prescribing Information and Medication Guide for Omvoh. Please see Instructions for Use included with the device.

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IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

Immunizations

Avoid use of live vaccines in patients treated with Omvoh. Medications that interact with the immune system may increase the risk of infection following administration of live vaccines. Prior to initiating therapy, complete all age-appropriate vaccinations according to current immunization guidelines. No data are available on the response to live or non-live vaccines in patients treated with Omvoh.

ADVERSE REACTIONS

Most common adverse reactions (≥2%) associated with Omvoh treatment are upper respiratory tract infections and arthralgia during induction, and upper respiratory tract infections, injection site reactions, arthralgia, rash, headache, and herpes viral infection during maintenance.

MR HCP ISI UC APP

Please click for Prescribing Information and Medication Guide for Omvoh.
Please see Instructions for Use included with the device.

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<Date>
<Health plan's name>
ATTN: <Department>
<Medical director's name>
<Health plan's address>
<City, State ZIP>

<Patient's name>
<Date of birth>
<Case ID number>
<Dates of service>

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Sincerely,
<Physician's signature and specialty, if applicable>

Enclosed: <Medical records, clinical notes, medication history, relevant laboratory reports that support the need for Omvoh, and other supporting information>