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 Appeal Guide

If coverage is denied by the patient's health plan, the payer may require an Appeal Letter.

This resource, **Letter of Appeal Guide**, provides information to healthcare providers (HCPs) when appealing a coverage denial from a patient's plan. A sample letter is attached to this document that features information many plans require to process a coverage authorization appeal. Follow the patient's plan requirements when requesting Omvoh; otherwise, treatment initiation may be delayed.

APPEAL CONSIDERATIONS TO SUPPORT COVERAGE

General Clinical Information

Below are 3 tips that may be helpful when appealing a coverage denial.

- Provide a copy of the patient's record with details on the patient's condition (diagnosis/diagnoses), ICD-10 code, and severity of disease for which Omvoh is being/will be used
- Provide 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)
- Document the previous therapies used, dates used, and reasons for discontinuation

Appeal-Specific Rationale

Clinical rationale should focus only on stated denial reason.

The following tips may help construct an appropriate appeal:

- Provide clinically relevant and patient-specific information that supports overturning denial
- If denial was due to the plan's preferred formulary agents not being used to treat this patient, provide the clinical rationale for why these agents are not appropriate for the patient
- Provide clinically relevant and patient-specific information that makes Omvoh an appropriate therapy for this 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).

Health Insurance Portability and Accountability Act of 1996 (HIPAA) Compliance

- Certain commercial insurers require additional release forms to be signed by the patient before an HCP can submit an appeal. Refer to the individual plan's website or representative for specific requirements
- 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**

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

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This template can be used by HCPs when appealing a coverage denial.

Sample Letter of Appeal 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: Appeal of Denial for Omvoh™ (mirikizumab-mrkz)

To Whom it May Concern:

I am writing to appeal your denial of coverage for <intravenous (IV)/subcutaneous (SC)> Omvoh under the <pharmacy benefit/medical benefit>, which I have prescribed for <patient's name>. The patient <is new to therapy/has been treated with IV Omvoh, and we are now requesting transition to SC Omvoh>. I understand you are denying coverage for <patient's name> because:

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

- <reason for the denial>
- <further reason(s) for the denial, if applicable>

Restate the reason for denial as close to verbatim as possible.

However, I believe the treatment with Omvoh is reasonable, appropriate, and medically necessary for my patient, based on my clinical experience, the patient's condition, and their medical history.

Clinical Information to Support Appeal

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

<Patient's name> is <a/an> <age> <male/female> who has been diagnosed with <condition> since <date of diagnosis>.

Please detail all past treatments

Identify drug name, strength, dosage form, and therapeutic outcome.

Past treatment(s)	Start/stop dates	Reason(s) for discontinuing

<Restate the denial reason and your clinical rationale for why the denial should be overturned and why Omvoh is appropriate and medically necessary for this patient.>

Excess information beyond the denial reason may influence the payer to deny coverage again.

Based on my professional experience, Omvoh is appropriate, medically necessary, and supported by their individual medical history. <Additionally, upon completion of induction therapy with IV, I will be transitioning my patient to SC maintenance therapy with Omvoh. Please consider approving the request for Omvoh SC therapy as well.> 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, denial letter, copies of original request, clinical notes, medication records, relevant laboratory reports that support the need for Omvoh, and other supporting information>

Attach any clinical documentation that supports overturning the decision to deny the request for coverage.

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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Sample Letter of Appeal for Omvoh™ (mirikizumab-mrkz)

<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>

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I am writing to appeal your denial of coverage for <intravenous (IV)/subcutaneous (SC)> Omvoh under the <pharmacy benefit/medical benefit>, which I have prescribed for <patient's name>. The patient <is new to therapy/has been treated with IV Omvoh, and we are now requesting transition to SC>. I understand you are denying coverage for <patient's name> because:

- <reason for the denial>
- <further reason(s) for the denial, if applicable>

However, I believe the treatment with Omvoh is reasonable, appropriate, and medically necessary for my patient, based on my clinical experience, the patient's condition, and their medical history.

Clinical Information to Support Appeal
<Patient's name> is <a/an> <age> <male/female> who has been diagnosed with <condition> since <date of diagnosis>.

Please detail all past treatments
<Past treatment(s)>
<Start/stop dates>
<Reason(s) for discontinuing>

<Restate the denial reason and your clinical rationale for why the denial should be overturned and why Omvoh is appropriate and medically necessary for this patient.>

Based on my professional experience, Omvoh is appropriate, medically necessary, and supported by their individual medical history. <Additionally, upon completion of induction therapy with IV, I will be transitioning my patient to SC maintenance therapy with Omvoh. Please consider approving the request for Omvoh SC therapy as well.> 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.

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

Enclosed: <Medical records, denial letter, copies of original request, clinical notes, medication records, relevant laboratory reports that support the need for Omvoh, and other supporting information>