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

PATIENT SUPPORT AND PRIOR AUTHORIZATION (PA) RESOURCE GUIDE

Steps to help adult patients start on Omvoh for the treatment of moderately to severely active ulcerative colitis (UC)

INDICATION

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

SELECT IMPORTANT SAFETY INFORMATION

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

Please see additional Important Safety Information on page 8 and click for Prescribing Information and Medication Guide for Omvoh. Please see Instructions for Use included with the device.

PROVIDE A COMPLETE AND ACCURATE PA

COVERAGE DYNAMICS MAY VARY BY FORMULATION AND PLAN

Omvoh dosing begins with IV induction and then transitions to SC maintenance. It is important to remember that while plans generally cover IV infusions under the medical benefit and SC injections under the pharmacy benefit, **patient may have differences in coverage requirements for each specific benefit.**

See the Roadmap for How Omvoh Together Can Help Facilitate the Patient Experience

This brochure is designed to provide you and your office staff with an easy-to-follow guide to completing PA requests for Omvoh.

IV=intravenous; PA=prior authorization; SC=subcutaneous

[a]PA criteria are set by the applicable plan. Lilly makes no claim as to safety or efficacy of the use of a product in any manner inconsistent with a product's label.

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 individual plans for specific information on their coverage policies.

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HELP YOUR PATIENTS GET ACCESS

RELEVANT INFORMATION TO BE INCLUDED IN THE PA REQUEST FORMS FOR OMVOH IV AND SC

Please note, you may need to submit individual PA requests for each formulation.

It is important to check coverage requirements for each individual plan to ensure all requirements and documentation are satisfied.

MEDICAL INFORMATION	**Medication Name**	Omvoh (mirikizumab-mrkz)
	Indication	Treatment of moderately to severely active UC in adults
	Dosing	Omvoh 300 mg IV every 4 weeks for 3 doses, then Omvoh 2 × 100 mg prefilled pens (200 mg) SC every 4 weeks Omvoh is available as a 300 mg IV single-dose vial and as 100 mg SC single-patient-use prefilled pens Please see **Prescribing Information** for additional information
	Continuation of Therapy	If the patient has already received Omvoh, request continuation of therapy and document treatment history
CLINICAL INFORMATION	**Diagnosis**	Moderately to severely active UC
	ICD-10 Codes	Physicians should select appropriate disease-specific code(s) based on the individual patient's diagnosis Please refer to the **Ordering, Billing, and Coding Guide** for more information on coding
	Prior Medications	List all the therapies the patient has tried and failed for treatment of UC
	Pre-Initiation Lab Testing	Negative TB test, bilirubin, LFTs, and immunization records may be required as part of the PA criteria

ACCESS INSIGHT
Omvoh Together can conduct a benefits investigation to inform you of any administration requirements.

ICD-10=International Statistical Classification of Diseases, Tenth Revision; LFT=liver function test; TB=tuberculosis

SELECT IMPORTANT SAFETY INFORMATION

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.

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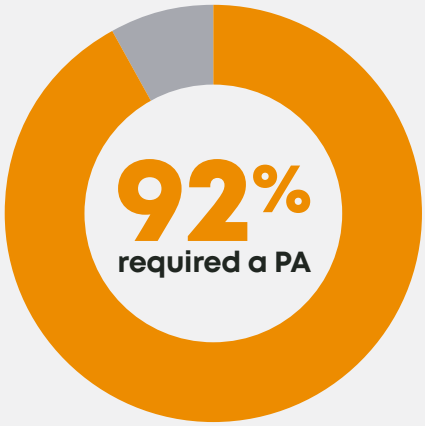
PROVIDE A COMPLETE AND ACCURATE PA

Many health and pharmacy benefit plans will require a PA before they cover Omvoh. It is important that your PA request be completed accurately to facilitate your patient's access to their medication.

Separate PAs may be required for IV and SC formulations. To help your patients get timely access to Omvoh, please be sure to submit the PA request to the appropriate insurers.

COVERAGE AND RESTRICTIONS MAY VARY ACROSS PLANS

As of November 2022, among all covered advanced therapies for UC on commercial plans[a]:



Payer coverage and reimbursement for Omvoh may be influenced by several factors, including:

- Patient insurance benefits
- Omvoh acquisition requirements (eg, buy-and-bill, specialty pharmacy)
- Site of service of Omvoh administration

Source: Managed Markets Insight & Technology (MMIT), LLC as of 11/2022 and is subject to change without notice. Please contact the plan or state for the most current information.

[a]For all known plans. Includes biologics and tofacitinib. Approximately 4% of plans are unknown. Approximately 16% of therapies across all known commercial plans are not covered.

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SELECT IMPORTANT SAFETY INFORMATION

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.

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OMVOH TOGETHER PA APPEALS SUPPORT

CLICK THE BUTTONS BELOW TO ACCESS OMVOH TOGETHER COVERAGE RESOURCES

Medical Necessity Letter

Coverage Authorization Appeal Letter

Omvoh Together is a customer support program designed to help patients start treatment and feel supported along the way. Field Reimbursement Managers (FRMs) are your conduit to Omvoh Together and work with healthcare providers (HCPs) on navigating patient access and exploring savings options

OMVOH TOGETHER ASSISTS PATIENTS WITH:

Access support

- Managing both medical and pharmacy benefits investigation and providing next steps navigating the insurance process
- Identifying payer requirements for in-network infusion site and in-network specialty pharmacies
- Determining out-of-pocket costs if benefits investigation is requested
- Initiating the Savings Program[a] for eligible, commercially insured patients

Ongoing support

- Confirming continued eligibility for the Savings Program[a]
- Suggesting useful resources that may help patients understand their condition
- Offering injection training and sharps disposal container

Omvoh Together will work with your patients to help navigate access and evaluate potential savings

[a]**Governmental beneficiaries excluded, terms and conditions apply.**

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OMVOH TOGETHER OVERVIEW

FIELD REIMBURSEMENT SUPPORT

The FRM is an experienced access professional who can help navigate the complex access and reimbursement environment to help eligible patients get access to Omvoh. FRMs are:

Knowledgeable

Understand Omvoh Together support, access challenges, and support and savings options for commercially insured patients

Helps address access challenges

Connected

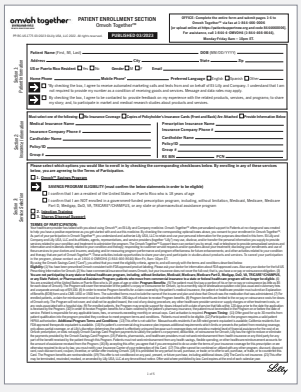
Integrated with the Omvoh Together call center

Committed

Provide information to support patient access to Omvoh

THREE OPTIONS FOR ENROLLING IN OMVOH TOGETHER

Options for enrollment



1 HCP office initiated

- DOWNLOAD the Omvoh Together Enrollment Form at Omvoh.com/hcp/enrollment
- FAX to 1-844-466-0006
- UPLOAD a digital copy online at Patientsupportnow.org and use code 8444660006
- Visit the secure Omvoh Together Provider Portal at Patientsupport.lilly.com to complete and submit an enrollment form

2 Patient initiated

Savings and support online at Omvoh.com/savings-support

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OMVOH SAVINGS PROGRAM

PRESCRIBE OMVOH KNOWING THAT SAVINGS MAY BE AVAILABLE FOR YOUR PATIENTS

The Omvoh Savings Program can help with monthly out-of-pocket costs for eligible, commercially insured patients

$5
per treatment[a]

If your patients have **commercial insurance that covers Omvoh**, they may be eligible to pay as little as $5 per treatment.

$0
per treatment[a]

If your patients have **commercial insurance that does not cover Omvoh**, they may be eligible to pay as little as $0 per treatment.

Treatment is defined as one infusion or one 28-day supply of injections.
[a]Governmental beneficiaries excluded; terms and conditions apply.

TERMS AND CONDITIONS:

Subject to Lilly USA, LLC's ("Lilly's") right to terminate, rescind, revoke, or amend the Omvoh (mirikizumab-mrkz) Savings Card Program's ("Program" or "Card") eligibility criteria, and terms and conditions, the Program expires and savings end on 06/30/2027 or for up to 30 months whichever comes first. **Program savings are not available to patients without commercial drug insurance or whose claims for Omvoh are eligible to be reimbursed, in whole or in part, by any state, federal, or government funded healthcare program, including, without limitation, Medicaid, Medicare, Medicare Part D, Medigap, DoD, VA, TRICARE®/CHAMPUS, or any prescription drug assistance program.**

Program savings for Omvoh infusion Card savings are subject to monthly and annual maximum savings, outlined below. You must have commercial insurance that covers Omvoh and a prescription consistent with FDA-approved product labeling to pay as little as $5 for each infusion up to a maximum of 3 infusions. For enrolled patients with coverage for Omvoh, the Program may provide support for infusions with a date of service that falls within 120 days prior to the date the enrollment form is received by the Program. To receive Program savings for the $5 Program, your healthcare provider must submit a claim for coverage to your medical insurance provider. You must have commercial insurance without coverage for Omvoh and a prescription consistent with FDA-approved product labeling to pay as little as $0 for each infusion up to a maximum of 3 infusions and be enrolled in the Program on or before the date of service. To receive Program savings for the $0 Program, your healthcare provider must submit a prior authorization (PA) request for Omvoh to your insurance provider before initiating treatment with Omvoh and provide the results of the PA demonstrating your insurance provider has denied coverage. Subject to Lilly USA, LLC's ("Lilly") right to terminate, rescind, revoke, or amend Card eligibility criteria and/or Card terms and conditions which may occur at Lilly's sole discretion, without notice, and for any reason, savings may continue until 06/30/2027 or for up to 30 months whichever comes first, provided you continue to meet the Program's terms and conditions and you first utilize the Program benefits no later than 12/31/2024.

Program savings for Omvoh injections Card savings are subject to a monthly and annual maximum savings, outlined below. You must have commercial insurance that covers Omvoh and a prescription consistent with FDA-approved product labeling to pay as little as $5 per fill. You must have commercial insurance without coverage for Omvoh and a prescription consistent with FDA-approved product labeling to pay as little as $0 for each 28-day supply of Omvoh. To receive Program savings for the $0 Program, your healthcare provider must submit a prior authorization (PA) request for Omvoh to your insurance provider prior to your 1st fill, an appeal prior to your 5th fill, and a PA prior to your 13th fill and provide the results of each demonstrating your insurance provider has denied coverage.

MONTHLY AND ANNUAL MAXIMUM SAVINGS: For patients with commercial insurance with coverage for Omvoh: Program savings for claims covered under the medical and/or pharmacy portion of your medical insurance for Omvoh are limited up to 3 infusions over total lifetime of the Program and up to 14 injection fills per calendar year, subject to a combined (injection and infusion) maximum monthly savings of wholesale acquisition cost plus usual and customary fees and separate maximum annual savings of $9,450 for each calendar year. Monthly and annual maximums are set at Lilly's absolute discretion and may be changed by Lilly with or without notice. For patients with commercial insurance without coverage for Omvoh: Program savings for claims not covered under the medical and/or pharmacy portion of your medical insurance are limited up to 3 infusions over total lifetime of the Program and up to 14 injection fills for each calendar year, subject to a combined (injection and infusion) maximum monthly savings and a separate annual maximum savings. Monthly and annual maximums are set at Lilly's absolute discretion and may be changed by Lilly with or without notice.

ADDITIONAL TERMS AND CONDITIONS: You are responsible for any applicable taxes, fees, and any amount that exceeds the monthly or annual maximum savings. Participation in the Program requires a valid patient HIPAA authorization. Card activation is required. This Program may be terminated, rescinded, revoked, or amended by Lilly USA, LLC at any time without notice and for any reason. Subject to additional terms and conditions. Eligibility criteria and terms and conditions for the Omvoh Savings Card may change from time to time at Lilly's sole discretion and for any reason; the most current version can be found at https://www.omvoh.com/savings-support. Program benefits void where prohibited by law.

DoD=U.S. Department of Defense; HIPAA=Health Insurance Portability and Accountability Act; VA=U.S. Department of Veterans Affairs

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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

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Infections

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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.

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

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Reference: Omvoh (mirikizumab-mrkz). Prescribing Information. Lilly USA, LLC.

Lilly