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

ORDERING, CODING, AND BILLING GUIDE

For Omvoh infusion and injection

INDICATION

Omvoh is an interleukin-23 antagonist indicated for the treatment of moderately to severely active ulcerative colitis in adults.

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.

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

Omvoh.com/hcp/support-for-your-patients
1-844-4-OMVOH4 (1-844-466-8644)
Monday through Friday
8 AM to 10 PM ET

Please see additional Important Safety Information on pages 11-12 and click for Prescribing Information and Medication Guide for Omvoh. Please see Instructions for Use included with the device.

GUIDANCE FOR USE

This guide is intended to be an educational reference, providing general information regarding the ordering, coding, and billing of Omvoh. This guide is offered for informational purposes only and is not intended to provide reimbursement or legal advice. Each healthcare provider (HCP) or healthcare entity is responsible for determining the appropriate codes, coverage, and payment for individual patients. Lilly does not guarantee third-party coverage or payment or reimbursement for denied claims.

HCPs should always verify coverage prior to initiating therapy and determine the appropriate codes on a case-by-case basis. Insurance coverage, coding, claims filing, and reimbursement vary by setting of care as well as by payer type.

This guide is up-to-date as of 12/13/2023. Although Lilly has made every effort to be current as of the publication of this guide, the information is subject to change. Similarly, all International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM), Current Procedural Terminology (CPT), and Healthcare Common Procedure Coding System (HCPCS) codes are supplied for informational purposes only. This information does not represent any statement, promise, or guarantee by Lilly about coverage, levels of reimbursement, payment, availability, or charge. Additional information may exist, and actual coverage and reimbursement decisions are made by individual payers. Providers should contact the applicable third-party payers for specific information on coding and billing requirements.

OMVOH PRODUCT INFORMATION

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

Omvoh is an interleukin-23 antagonist indicated for the treatment of moderately to severely active ulcerative colitis in adults.[1]

DOSING AND ADMINISTRATION

Intravenous (IV) infusions with Omvoh are administered every 4 weeks for 3 doses before transitioning to maintenance dosing at Week 12.[1]

Subcutaneous (SC) injections every 4 weeks for maintenance are available in a prefilled pen.[1]

STORAGE AND HANDLING[1]

- Store refrigerated at 2°C to 8°C (36°F to 46°F)
- Do not freeze. Do not use Omvoh if it has been frozen
- Do not shake
- Keep Omvoh in the original carton to protect from light until the time of use
- Omvoh is sterile and preservative-free. Discard any unused portion
- If needed, the prefilled pen may be stored at room temperature up to 30°C (86°F) for up to 2 weeks in the original carton to protect from light. Once Omvoh has been stored at room temperature, do not return to the refrigerator. If these conditions are exceeded, Omvoh must be discarded
- The vial and prefilled pen are not made with dry natural rubber latex

INDUCTION VIA IV INFUSION

300 mg IV[a] at Weeks 0, 4, and 8

Week 0 | Week 4 | Week 8

MAINTENANCE VIA SC INJECTION

200 mg SC via 2 x 100 mg consecutive injections every 4 weeks starting at Week 12

Week 12 and every 4 weeks thereafter

[a]Over at least 30 minutes.[1]
Omvoh is intended for use under the guidance and supervision of a healthcare professional. Patients may self-inject after training in proper technique.[1]

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.

OMVOH SPECIALTY INFORMATION AND RELEVANT DIAGNOSIS CODES

OMVOH PARTICIPATING SPECIALTY DISTRIBUTORS[1]

Omvoh for IV use is available for ordering by Lilly Authorized Specialty Distributors of Record. A full list of distributors can be accessed at Trade.lilly.com/assets/pdf/authorizeddistributorsofrecords.pdf

OMVOH SPECIALTY PHARMACIES

Omvoh for SC use is available for ordering by any specialty pharmacy, and any hospital-owned pharmacy can stock and dispense Omvoh, if it is covered.

For questions about storage and transportation, call the Lilly Answers Center at **1-800-LillyRx (1-800-545-5979)**.

OMVOH NDCs				
Package	**Strength**	**10-Digit NDC**	**Size**	**11-Digit NDC[a]**
OMVOH VIAL	20 mg/mL (300 mg/15 mL)	0002-7575-01	Carton of 1	00002-7575-01
OMVOH PREFILLED PEN	100 mg/mL	0002-8011-27	Carton of 2	00002-8011-27

INTERNATIONAL CLASSIFICATION OF DISEASES, 10TH REVISION, CLINICAL MODIFICATION (ICD-10-CM)

ICD-10-CM codes are used to identify a patient's diagnosis. At least 1 ICD-10-CM diagnosis code must be included in all hospital and physician office claims to describe the patient's diagnosis. The ICD-10-CM diagnosis codes listed are provided only as examples of potentially relevant codes relating to ulcerative colitis. Providers should consult a current ICD-10-CM manual and select the most appropriate diagnosis code(s) to accurately describe a patient's condition. All diagnosis codes should be supported with adequate documentation.

DIGITS 1-3[2]	
Code	**Description**
K51	Ulcerative colitis

DIGIT 4[2]	
Code	**Description**
0	Ulcerative (chronic) pancolitis
3	Ulcerative (chronic) rectosigmoiditis
5	Left sided colitis
8	Other ulcerative colitis
9	Ulcerative colitis, unspecified

DIGITS 5-6[2]	
Code	**Description**
0	Without complications
1	With complications
11	With rectal bleeding
18	With other complication
19	With unspecified complications

Example: K51.311 = Ulcerative colitis, ulcerative (chronic) rectosigmoiditis with rectal bleeding

FDA=U.S. Food and Drug Administration; GTN=Global Tracking Number; HIPAA=Health Insurance Portability and Accountability Act; NDC=National Drug Code; UPC=Universal Product Code

[a]Note that the product's NDC has been "zero-filled" to ensure creation of an 11-digit code that meets HIPAA standards.

RELEVANT BILLING CODES

PAYER REQUIREMENTS FOR CODING OF MEDICINES MAY VARY, INCLUDING WHICH MISCELLANEOUS CODE TO USE. PLEASE CHECK WITH THE PAYER TO CONFIRM BILLING REQUIREMENTS.

CPT CODES[3]		
Code	**Description**	**Additional information**
96365	IV infusion, for therapy, prophylaxis, or diagnostic (specify substance or drug); initial, up to 1 hour	
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); SC or intramuscular	• Not used for administration of vaccines • Use for non-antineoplastic hormonal therapy injections • Do not use for anti-neoplastic non-hormonal or hormonal injections • Do not use for allergen immunotherapy

HCPCS CODES[4]	
Code	**Description**
J3490	Unclassified drugs
J3590	Unclassified biologics
C9399	Unclassified drugs or biologicals
Level II Modifier	**Description**
JZ	Zero drug wastage

A product-specific HCPCS code is not available at this time. Lilly will provide updates when an HCPCS code is assigned to Omvoh. Payer requirements for coding of medicines may vary, including which miscellaneous code to use. Please check with the payer to confirm billing requirements.

Payers may require specific drug-identifying information on claims with a miscellaneous code, such as:

- Drug name (brand and generic)
- NDC in the 11-digit format
- Dose and strength
- Method of administration
- Units billed
- Invoice

HCPs should consult the current CPT manual and always select the code that accurately describes the administration service performed for the patient and contact the payer for additional coding information required.

Omvoh may be billed under pharmacy or medical benefit, and patients may have separate entities that provide pharmacy and medical benefits. It is the responsibility of the provider to appropriately bill the patient for services rendered medical benefit or refer patient to utilization of pharmacy benefit.

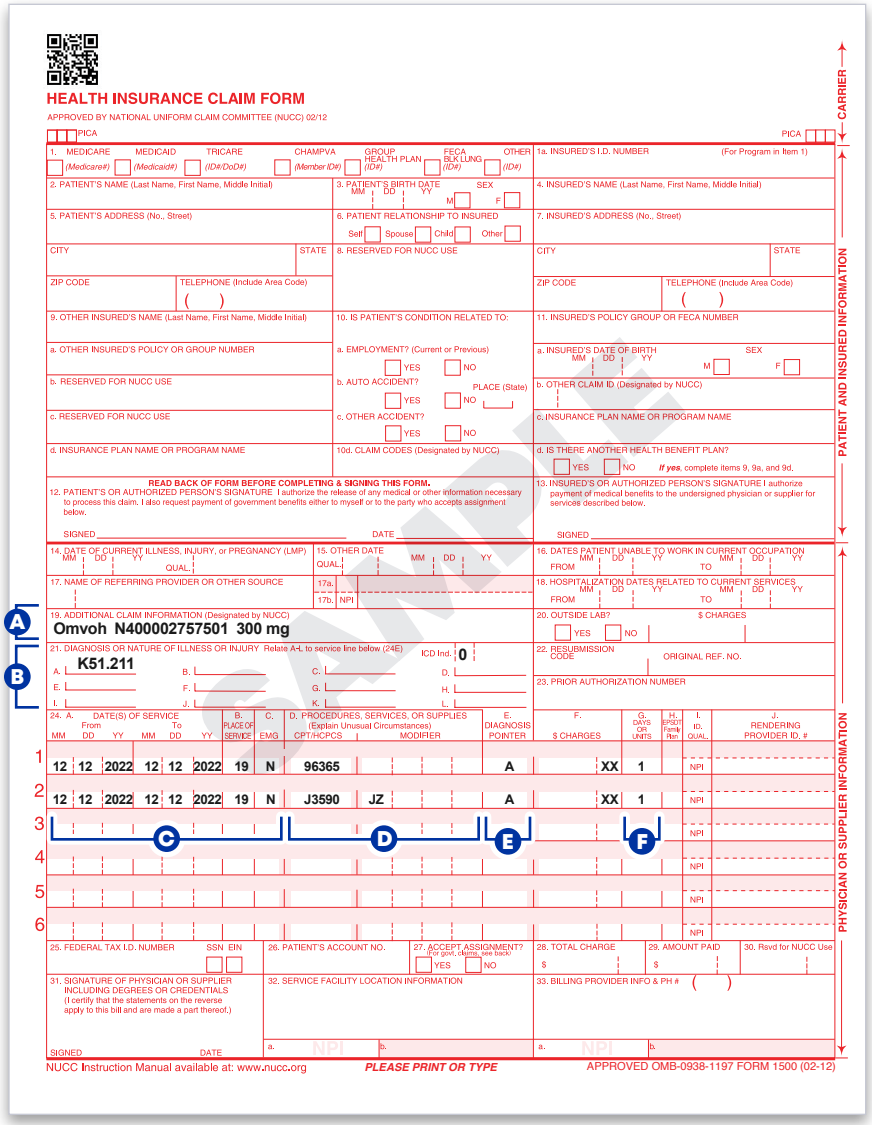
Typically, SC injections of Omvoh are billed under pharmacy benefit, and infusions of Omvoh are billed under medical benefit. Case-by-case situations may warrant different billing practices, and providers are responsible for accurate billing and documentation for services rendered.

Click **here** for the HCP Buy and Bill Portal.

Please contact Omvoh Together™ at **1-844-4-OMVOH4** (**1-844-466-8644**) for assistance with billing and related information.

SAMPLE FORMS[5]

HCP OFFICE CLAIM FORM (CMS-1500)



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE (Medicare#) MEDICAID (Medicaid#) TRICARE (ID#/DoD#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA BLK LUNG (ID#) OTHER (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

3. PATIENT'S BIRTH DATE MM DD YY SEX M F

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED Self Spouse Child Other

7. INSURED'S ADDRESS (No., Street)

CITY STATE

8. RESERVED FOR NUCC USE

CITY STATE

ZIP CODE TELEPHONE (Include Area Code) ( )

ZIP CODE TELEPHONE (Include Area Code) ( )

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? YES NO PLACE (State)

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO *If yes*, complete items 9, 9a, and 9d.

READ BACK OF FORM BEFORE COMPLETING & SIGNING THIS FORM.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

SIGNED DATE

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED

14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

15. OTHER DATE QUAL. MM DD YY

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

17a.

17b. NPI

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO

A 19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)
Omvoh N400002757501 300 mg

20. OUTSIDE LAB? YES NO $ CHARGES

B 21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind. 0
A. K51.211 B. C. D. E. F. G. H. I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1 12 12 2022	12 12 2022	19	N	96365		A		XX 1			NPI
2 12 12 2022	12 12 2022	19	N	J3590	JZ	A		XX 1			NPI
3											NPI
4											NPI
5											NPI
6											NPI

C D E F

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES NO

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)
SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION
a. NPI b.

33. BILLING PROVIDER INFO & PH # ( )
a. NPI b.

NUCC Instruction Manual available at: www.nucc.org **PLEASE PRINT OR TYPE** APPROVED OMB-0938-1197 FORM 1500 (02-12)

CARRIER — PATIENT AND INSURED INFORMATION — PHYSICIAN OR SUPPLIER INFORMATION

SAMPLE

A Box 19: Additional Claim Information

Box 19 of the CMS-1500 claim form (or its electronic equivalent) is frequently utilized to obtain information regarding the use of drugs. The information will vary, but may include some or all of these items:

- Drug name
- NDC
- Date of treatment
- Total dose administered
- Route of administration

Please refer to the payer's most current instructions regarding the use of this field.

B Box 21: Diagnosis or Nature of Illness or Injury

Enter the appropriate diagnosis code in lines A-L to identify the patient's diagnosis/condition and the applicable ICD indicator to identify which ICD code version is being reported. Use the highest level of specificity. See page 4 for a list of diagnostic codes. The applicable ICD-10 indicator is 0 because the diagnosis in A is an ICD-10-CM diagnosis code.

C Box 24A and 24B: Date(s) and Place of Service

Enter the date of service and the appropriate place of service code. When required by payers to provide the NDC, enter the code.

D Box 24D: Procedures, Services, or Supplies

Enter the appropriate HCPCS codes and modifier(s) for Omvoh. Enter the appropriate CPT code for the administration service.

CPT

- **96365:** IV infusion, for therapy, prophylaxis, or diagnostic (specify substance or drug); initial, up to 1 hour
- **96372:** Therapeutic prophylactic, or diagnostic injection (specify substance or drug); SC or intramuscular

HCPCS

- **J3490:** Unclassified drugs, **J3590**: Unclassified biologics, **C9399**: Unclassified drugs or biologicals

HCPCS Level II Modifier

- JZ: Zero Drug Wastage

E Box 24E: Diagnosis Pointer

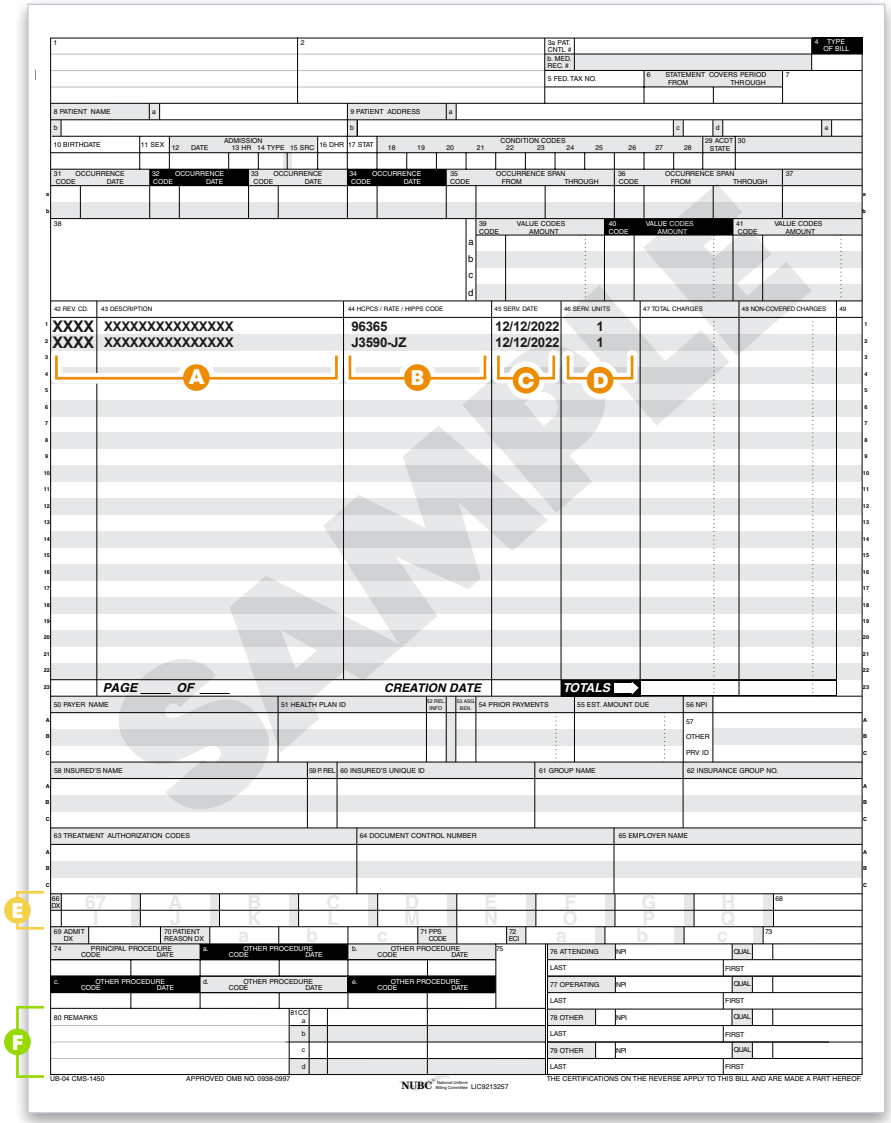
Enter the form provided reference letter from box 21 that corresponds to the diagnosis for which the product or procedure is being billed.

F Box 24G: Days or Units

Report billing units here. Based on standard Omvoh dosing, most payers will require a unit of "1" for an Omvoh administration billed under Unclassified HCPCS codes. Please confirm specific billing requirements with each individual payer.

SAMPLE FORMS[6]

OUTPATIENT HOSPITAL CLAIM FORM (CMS-1450 [UB-04])



A **Box 42 & 43: Revenue Codes and Description**
Enter the appropriate numeric revenue code in box 42 and the description in box 43 that correspond to the HCPCS or CPT codes outlined in box 44.

B **Box 44: Product and Procedure Coding**
Enter the HCPCS drug code and CPT code for the administration of Omvoh.

CPT
- **96365:** IV infusion, for therapy, prophylaxis, or diagnostic (specify substance or drug); initial, up to 1 hour
- **96372:** Therapeutic prophylactic, or diagnostic injection (specify substance or drug); SC or intramuscular

HCPCS
- **J3490:** Unclassified drugs, **J3590**: Unclassified biologics, and **C9399:** Unclassified drugs or biologicals

HCPCS Level II Modifier
- JZ: Zero Drug Wastage

C **Box 45: Service Date**
Enter the date of service.

D **Box 46: Service Units**
Report billing units here. Based on standard indicated dosing, units for Omvoh billed under Unclassified HCPCS codes, most forms require a unit of "1." Please confirm specific billing requirements with each individual payer.

E **Box 66: Diagnosis Codes**
Enter the appropriate ICD diagnosis code(s) that correspond(s) to the type and location of the disease with which the patient has been diagnosed. See page 4 for a list of diagnostic codes.

F **Box 80: Remarks**
To support the review and payment of the claim, include additional information as required by respective payers. This may include NDC, total dosage, and date Omvoh was administered.

CLAIM DELAYS AND DENIALS

Most health plans require a prior authorization request and supporting documentation to process and cover a claim for biologic treatments. A request allows the payer to review the reason for the requested treatment and determine its medical appropriateness.

Understanding the reasons why insurers may deny claims can help limit the number of denials. Common causes of delayed or denied claims may include:

Inaccurate or missing codes (e.g., HCPCS codes/ J-codes, CPT codes, ICD-10-CM codes)

Incorrect product information, such as incorrect product name

Missing or incorrect NDC, prior authorization number, National Provider Identifier

Incorrect patient identifier information (e.g., insurance identification number, date of birth)

Failure to follow payer-specific requirements

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Your Field Reimbursement Manager (FRM) is your dedicated point of contact for questions related to access and reimbursement. They are available to provide education and information to HCPs and staff to facilitate patient access to Omvoh.

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

Omvoh Together assists patients with:

Access support

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

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

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

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

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.

If you have a question about claim appeals, reimbursement issues, or insurance questions about Omvoh, contact us at **1-844-4-OMVOH4 (1-844-466-8644)**. Lilly does not guarantee third-party coverage or payment or reimbursement for denied claims.

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

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; VA=U.S. Department of Veterans Affairs

INDICATION

Omvoh is an interleukin-23 antagonist indicated for the treatment of moderately to severely active ulcerative colitis in adults.

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.

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.

References: 1. Omvoh (mirikizumab-mrkz). Prescribing Information. Lilly USA, LLC. **2.** CMS.gov. 2019 code tables and index. Centers for Medicare & Medicaid Services. https://www.cms.gov/medicare/coding/icd10/2019-icd-10-cm. Accessed August 22, 2022. **3.** Centers for Medicare & Medicaid Services. Billing and coding: complex drug administration coding. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=58544. Accessed March 8, 2023. **4.** Centers for Medicare & Medicaid Services. Billing and coding: hospital outpatient drugs and biologicals under the Outpatient Prospective Payment System (OPPS). https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=55913. Accessed March 8, 2023. **5.** Centers for Medicare & Medicaid Services. Health Insurance Claim Form (approved February 2012). https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf. Accessed August 22, 2022. **6.** Centers for Medicare & Medicaid Services. CMS-1450. https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/Downloads/CMS-1450.zip. Accessed August 22, 2022.