Transcript Details

This is a transcript of an educational program. Details about the program and additional media formats for the program are accessible by visiting: https://reachmd.com/programs/medical-industry-feature/bowel-urgency-in-ulcerative-colitis/54425/

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Bowel Urgency as a Key Symptom in Ulcerative Colitis

Narrator:
INDICATIONS
Omvoh is an interleukin-23 antagonist indicated for adults with moderately to severely active ulcerative colitis, or UC, or moderately to severely active Crohn's disease, or CD.

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

This is not the complete Important Safety Information for Omvoh. Please see additional Important Safety Information at the end of this video.

Dr. Navabi:
For many patients with moderate to severe ulcerative colitis, or UC, bowel urgency is often hard to talk about, and they keep it to themselves. It is time we bring bowel urgency into the UC conversation.

Hi there, I'm Dr. Ehsan Navabi. I'm a board-certified gastroenterologist practicing in Southern California. I'm also director of the Inflammatory Bowel Disease Center for United Medical Doctors.

Christie Morrison:
And I'm Christie Morrison, nurse practitioner at Texas Digestive Disease Consultants and Oshi Health in San Antonio, Texas.

We're excited to share some of our experiences from patients in our clinics and discuss about a measure of bowel urgency severity that has helped us review this with them.

Dr. Navabi:
We will then dive into Omvoh's clinical trial data and how Omvoh can help your patients with their bowel urgency.

Bowel urgency is a symptom that many of my patients experience. But it can be hard for the patient to talk about this symptom.

How would you define bowel urgency, and how often do patients come to you experiencing this symptom?

Christie Morrison:
Bowel urgency is defined as the sudden or immediate need to have a bowel movement, and it is one of the most disruptive symptoms for patients with ulcerative colitis.[4]

Dr. Navabi:
Bowel urgency is something that patients have to think about throughout their day. Sometimes, it has led to some of my patients missing work or making other adjustments in their day.

Christie Morrison:
In the US, 47% of patients with moderate to severe UC reported wearing a diaper or other protection due to bowel urgency concerns. That's despite receiving advanced therapies.

This is similar to what I have been experiencing in my practice, if not more. Most of my patients know where the closest bathrooms are along their commutes. I often hear from them about the impacts of bowel urgency in their personal lives.

In your practice, how do you talk to your patients about bowel urgency and the impact that it has on their lives? And why is it so critical

to have these conversations?

Dr. Navabi:
There may have been measures of disease that we may not have discussed before. I ask my patients about what limits their daily life, especially related to difficulties finding bathrooms. Or these could include any concerns that limit activities. Being able to hang out with friends or even going to work. This is what we call bowel urgency, and I ask them to talk more about if they have had such issues.

Christie Morrison:
Dr. Navabi, can you explain how bowel urgency was measured in the Omvoh clinical trials?

Dr. Navabi:
Omvoh is the only approved biologic to study bowel urgency using the Urgency Numeric Rating Scale, or UNRS, a novel measure of bowel urgency developed by Lilly per FDA guidance.

The UNRS is a validated and reliable 11-point scale that allows patients to report the severity of urgency to have a bowel movement from 0 to 10, with 0 having no urgency and 10 having the worst possible urgency.

Christie Morrison:
The efficacy and safety of Omvoh were studied in adult patients with moderately to severely active UC in the Phase 3 LUCENT trials, which included patients who had been bio-exposed and some who were bio-naive.

Dr. Navabi:
Before diving into bowel urgency data, let's quickly review some key results from LUCENT trials.

The primary endpoints were clinical remission at Week 12 in LUCENT-1 and at Week 40 in LUCENT-2, or Week 52 of Omvoh treatment.

At Week 12, 65% of patients taking Omvoh achieved clinical response, and 24% achieved clinical remission.

Among those patients who achieved clinical response with Omvoh at Week 12, 51% achieved clinical remission at Week 52 compared to 27% of patients on placebo.

When assessing bowel urgency, we see that a greater proportion of Omvoh patients achieved improvement compared to placebo at Week 12. And bowel urgency improvement was defined as achieving a weekly average UNRS of 0 to 1.

Among patients who achieved clinical response with Omvoh at Week 12, 39% of patients achieved a UNRS score of 0 to 1 compared to 23% of patients on placebo at Week 52.

At Week 52, 61% of patients achieved at least a 3-point reduction in the UNRS compared to 41% of patients on placebo.

Christie Morrison:
Additionally, UNRS score reductions were maintained throughout LUCENT-2, with patients taking Omvoh achieving an average reduction of 3.91 at Week 52.

Dr. Navabi:
How did patients do in the long-term LUCENT-3 study?

Christie Morrison:
In those patients who achieved clinical remission with Omvoh at Week 52, 69% of patients also achieved bowel urgency improvement at 4 years as measured by observed data.

Dr. Navabi:
After reviewing these data, what does it mean to you and your patients to know that there is a validated tool available, like the UNRS, to assess the severity of bowel urgency?

Christie Morrison:
Bowel urgency is more than a "Yes" or "No." For many of my patients, it's a very personal and often embarrassing symptom to discuss.

That's why it's so important, as healthcare providers, to offer patients a space where they feel comfortable to discuss this and the right tools can help them communicate how urgency is truly affecting them, when the typical way they would use this may cause them embarrassment.

Dr. Navabi:

As providers, it is important to open that conversation up to help the patient achieve their treatment goals.

The UNRS tool provides me with a measure of how my patients are progressing between visits.

Christie Morrison:
When it comes to the safety profile, the most common adverse reactions that patients experienced included upper respiratory tract infections, arthralgia, injection site reactions, rash, headache, and herpes viral infections.

Additionally, no new safety signals were identified during 4 years of UC treatment with Omvoh.

After today's thoughtful discussion, bowel urgency will definitely remain a priority topic when I am engaging with my patients with moderate to severe UC.

Dr. Navabi:
Thank you so much for joining us. To watch additional videos on Omvoh, visit omvoh.lilly.com/hcp for more information.

Please continue watching for additional safety information.

Narrator:
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 subject 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 druginduced 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 associated with Omvoh (≥2% of subjects and at a higher frequency than placebo) in ulcerative colitis treatment are upper respiratory tract infections and arthralgia during the induction study (UC-1), and upper respiratory tract infections, injection site reactions, arthralgia, rash, headache, and herpes viral infection during the maintenance study (UC-2).

Most common adverse reactions associated with Omvoh in the Crohn's disease study (CD-1) (≥5% of subjects and at a higher

frequency than placebo) are upper respiratory tract infections, injection site reactions, headache, arthralgia, and elevated liver tests.

Omvoh injection is available as a 300 mg/15 mL solution in a single-dose vial for intravenous infusion, and as a 100 mg/mL solution or a 200 mg/2 mL solution in a single dose prefilled pen or prefilled syringe for subcutaneous injection. Refer to the Prescribing Information for dosing information.

MR HCP ISI CD APP

This is not the complete Important Safety Information for Omvoh. Please see the beginning of this video for additional Important Safety Information and see links to Prescribing Information and Medication Guide on this website (or below this video).

References:

1. Omvoh (mirikizumab-mrkz). Prescribing information. Lilly USA, LLC.
2. Dubinsky MC, Irving PM, Panaccione R, et al. Incorporating patient experience into drug development for ulcerative colitis: development of the Urgency Numeric Rating Scale, a patient-reported outcome measure to assess bowel urgency in adults. J Patient Rep Outcomes. 2022;6(1):31. doi:10.1186/s41687-022-00439-w
3. Dubinsky M, Vadhariya A, Su S, et al. The Urgency Numeric Rating Scale: psychometric evaluation in adults with Crohn's disease. Adv Ther. 2025;42(2)(Incl suppl mat):1044-1060. doi:10.1007/s12325-024-03081-8
4. Dubinsky M, Bleakman AP, Panaccione R, et al. Bowel urgency in ulcerative colitis: current perspectives and future directions. Am J Gastroenterol. 2023;118(11):1940-1953. doi:10.14309/ajg.0000000000002404
5. Travis S, Bleakman AP, Dubinsky MC, et al. The Communicating Needs and Features of IBD Experiences (CONFIDE) study: US and European patient and health care professional perceptions of the experience and impact of symptoms of moderate-to-severe ulcerative colitis. Inflamm Bowel Dis. 2024;30(6):939-949. doi:10.1093/ibd/izad142
6. Dubinsky MC, Shan M, Delbecque L, et al. Psychometric evaluation of the Urgency NRS as a new patient-reported outcome measure for patients with ulcerative colitis. J Patient Rep Outcomes. 2022;6(1):114. doi:10.1186/s41687-022-00522-2
7. Sands BE, D'Haens G, Clemow DB, et al. Mirikizumab four-year sustained and durable efficacy and safety in ulcerative colitis: Final findings from the LUCENT-3 open-label extension study. Inflamm Bowel Dis. Published online March 2, 2026. doi:10.1093/ibd/izag007
8. Data on file. DOF-MR-US-0011. Lilly USA, LLC.
9. Data on file. DOF-MR-US-0059. Lilly USA, LLC.
10. Data on file. DOF-MR-US-0053. Lilly USA, LLC.
11. Data on file. DOF-MR-US-0101. Lilly USA, LLC.
12. D'Haens G, Dubinsky M, Kobayashi T, et al. Mirikizumab as induction and maintenance therapy for ulcerative colitis. N Engl J Med. 2023;388(26):2444-2455. doi:10.1056/NEJMoa2207940
13. Data on file. DOF-MR-US-0104. Lilly USA, LLC.