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-crohns-disease/54424/

ReachMD
www.reachmd.com
info@reachmd.com
(866) 423-7849

Bowel Urgency as a Key Symptom in Crohn's Disease

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.

CONTRAINDICTIONS
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. Nandi:
Bowel urgency is a disruptive symptom that we often talk about for patients with ulcerative colitis, but it's important to shine a light on how it impacts patients with Crohn's disease, too.[2,3] Hi, I'm Dr. Partha Nandi. I'm a clinical associate professor at Michigan State University and the Chief Medical Officer at Pinnacle GI Partners. I'm passionate about caring for patients with Crohn's disease.

Amy Stewart:
And I'm Amy Stewart, nurse practitioner at Capital Digestive Care in Washington, DC.

We're here today to discuss the importance of bowel urgency and the impact that it can have on patients with moderate to severe Crohn's disease.

Dr. Nandi:
We will also explore Omvoh's data on bowel urgency reduction through 3 years.

Patients with CD experience a variety of disruptive symptoms. And while fatigue is prevalent amongst many patients, bowel urgency is another symptom that many patients report, yet its impact is often underestimated in CD.

In the US in fact, 51% of patients with moderate to severe CD reported wearing a diaper or other protection due to bowel urgency concerns despite receiving advanced therapies.

As a gastroenterologist, I want to put a human face on that statistic. I recently cared for a young woman who had what should have been, really, a joyful event that was overshadowed by bowel urgency. And she planned her days around bathrooms, limited her activities, and wore protection out of caution and not choice. And that's the hidden cost of bowel urgency. It's not just a symptom. It impacts dignity at the moment that matters the most. And when over half of patients with moderate to severe Crohn's disease still feel forced to wear protection despite advanced therapies, it's clear to me that we must do better for our patients.

Amy Stewart:
I think historically bowel urgency is thought of less often as a symptom for patients with Crohn's disease — but it's one that we can't forget about. Urgency is difficult to manage for patients because of the unpredictability — and that unpredictability and not knowing when it may happen can be unsettling for them.

Dr. Nandi:
Amy, how do you define bowel urgency, and how often do your patients come to you experiencing this symptom?

Amy Stewart:
Bowel urgency can be defined as the sudden or immediate need to have a bowel movement.[1,5,6]

Some patients are not forthcoming about urgency unless they are specifically asked — as they can find it embarrassing. I include urgency as part of my IBD templated note that I ask patients about at every visit. I also ask about any "close calls" and fecal incontinence by saying "have you ever not made it? Or worried that you wouldn't make it?"

What about your practice, Dr. Nandi?

Dr. Nandi:
So Amy, bowel urgency is exactly as you described it. It's a sudden, often overwhelming need to have a bowel movement with little warning or control. And in my practice, Amy, it's one of the most common and distressing symptoms I hear about, especially from patients with moderate to severe Crohn's disease. And many of my patients experience it daily, some multiple times a day, and even patients on advanced therapy, well, they continue to report it. And here's what stands out to me — it's not just how frequent it is, right, but how much it impacts their lives, shaping where they go, how long they stay out, and whether they even feel safe leaving home at all.

Amy Stewart:
In your practice, Dr. Nandi, how do you clinically assess bowel urgency and its impact on a patient?

Dr. Nandi:
So in my practice, Amy, I assess bowel urgency by listening first and then by measuring it. So I ask patients how quickly they need to find a bathroom, how often urgency occurs, and whether it's led to accidents or lifestyle changes. I also use the Urgency Numeric Rating Scale, or UNRS, and that helps my patients quantify how severe their urgency feels in the past 24 hours.[6] And that score actually gives structure to what is often an emotional and underreported symptom. Understanding bowel urgency severity is critical. It's often the symptom that's most limiting to them. If we don't assess it intentionally, we miss a major driver of patient dissatisfaction.

Amy Stewart:
I completely agree. Urgency is more than just a yes or no. I ask patients, "How urgent? Are you able to finish a conversation or phone call? Are you jetting out of meetings at work? Are you able to take the metro if you live in DC, like me?" Helping them quantify can help us understand severity as well as track improvement over time.

Omvoh is the only approved biologic to measure bowel urgency severity using the validated and reliable scale known as the Urgency Numeric Rating Scale, or UNRS.

Developed by Lilly per FDA guidance as a novel measure of bowel urgency, the UNRS scale is an 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 being the worst possible urgency.

Dr. Nandi:
The efficacy and safety of Omvoh were evaluated in adult patients with moderately to severely active CD in the Phase 3 VIVID trials, which included patients who had been treated with a prior biologic as well as those who were bio-naive.

Amy Stewart:
Before we dive into the bowel urgency data, let's review some key results from the VIVID trials.

Patients taking Omvoh experienced clinically meaningful improvement in fatigue as early as Week 12.

Dr. Nandi:
The co-primary endpoints of VIVID-1 were the proportion of patients achieving clinical remission at Week 52 and endoscopic response at Week 52.

At Week 52, 53% of patients taking Omvoh achieved clinical remission compared to 36% taking placebo at baseline who then switched to Omvoh at Week 12 (placebo plus placebo/Omvoh) and 18% taking placebo only (placebo/placebo).

Forty-six percent of patients taking Omvoh achieved endoscopic response compared to 23% of patients taking placebo plus placebo/Omvoh and 9% of patients taking placebo/placebo.

Amy Stewart:
When evaluating the impact Omvoh had on bowel urgency, we can see that Omvoh has data on bowel urgency reduction through 3 years.

At Week 52, patients taking Omvoh demonstrated a 3.45 reduction in their UNRS scores from baseline compared to patients taking placebo, who achieved a 2.44 reduction from baseline.

At Week 152, Omvoh patients saw a 4.2 reduction in their UNRS scores.

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?

Dr. Nandi:
So Amy, the measurement of bowel urgency is more than just a "Yes, I have it" or "No, I don't." And that's why it's so important, as healthcare providers, to provide patients with the right tools to communicate to us how urgency is truly affecting them so that we can get them the help that they need to achieve their treatment goals.

Amy Stewart:
I agree, Dr. Nandi. Having validated tools can help streamline and have a shared understanding of impact on patients.

When it comes to the safety profile, the most common adverse reactions that patients experienced included upper respiratory tract infections, injection site reactions, headache, arthralgia, and elevated liver tests.

Additionally, no new safety signals were identified during 3 years of treatment with Omvoh.

Dr. Nandi:
And Amy, when I look at this safety data, it can be reassuring for me and my patients. The most common adverse events were generally manageable and familiar, and importantly, there were no new safety signals that emerged even with long-term follow-up of 2 to 3 years. And that kind of durability matters because my patients aren't just thinking about weeks or months, they're thinking about living with a therapy for years.

Thank you for joining us. I'm glad we are able to discuss the importance of bowel urgency in patients with moderate to severe CD.

Amy Stewart:
Visit omvoh.lilly.com/hcp to watch additional videos on Omvoh and 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 ageappropriate 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.

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