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Ocular Management in PROC: Insights on Collaborative Care Across Practice Settings

**Announcer:**
You're listening to ReachMD. This medical industry feature, titled "Ocular Management in PROC: Insights on Collaborative Care Across Practice Settings," is sponsored by AbbVie US Medical Affairs. Here's your host, Dr. Jennifer Caudle.



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**Dr. Caudle:**
Welcome to ReachMD. I'm your host Dr. Jennifer Caudle, and today, we're exploring practical strategies to manage ocular adverse reactions in patients with folate receptor alpha-positive platinum-resistant ovarian cancer, or PROC, who are being treated with mirvetuximab soravtansine-gynx.

Joining me in this discussion are Drs. Ida Micaily and Jeffrey Varanelli. Dr. Micaily is an Assistant Professor of Medical Oncology at the Sidney Kimmel Comprehensive Cancer Center at Thomas Jefferson University in Philadelphia, Pennsylvania. Dr. Micaily, thank you for joining us today.

**Dr. Micaily:**
Thanks for having me.

**Dr. Caudle:**
Also with us is Dr. Varanelli, an optometrist who's board certified in Medical Optometry and practices at the Simone Eye Center in Macomb Township, Michigan. Dr. Varanelli, it's great to have you here.

**Dr. Varanelli:**
Thanks Dr. Caudle, I'm looking forward to our discussion today.

**Dr. Caudle:**
Before we get started, let's take a moment to review the indication and boxed warning for mirvetuximab soravtansine-gynx.

**Announcer:**

**INDICATION**

Mirvetuximab soravtansine-gynx is indicated for the treatment of adult patients with folate receptor-alpha (FRα) positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens. Select patients for therapy based on an FDA-approved test.

**IMPORTANT SAFETY INFORMATION**

**WARNING: OCULAR TOXICITY**

- Mirvetuximab soravtansine-gynx can cause severe ocular toxicities, including visual impairment, keratopathy, dry eye,

photophobia, eye pain, and uveitis.
- Conduct an ophthalmic exam including visual acuity and slit lamp exam prior to initiation of mirvetuximab soravtansine-gynx, every other cycle for the first 8 cycles, and as clinically indicated.
- Administer prophylactic artificial tears and ophthalmic topical steroids.
- Withhold mirvetuximab soravtansine-gynx for ocular toxicities until improvement and resume at the same or reduced dose.
- Discontinue mirvetuximab soravtansine-gynx for Grade 4 ocular toxicities.

**Please see additional Important Safety Information at the end of this program.**

**Dr. Caudle:**
For some background, mirvetuximab is a first-in-class antibody-drug conjugate targeting folate receptor alpha, or FRα. It's indicated as monotherapy in adults with PROC who've received one to three prior systemic treatment regimens and whose tumors show FRα-positivity using an FDA-approved test.[1]

This treatment's approval is based on the MIRASOL trial, which compared mirvetuximab to chemotherapy.[1] In the primary analysis, with a median follow-up of 13.1 months, mirvetuximab demonstrated a significant improvement across multiple outcomes.[1]

These include[1]:

- Median progression-free survival of 5.6 months versus 4 months, with a hazard ratio of 0.65 and a 95 percent confidence interval of 0.52 to 0.81;
- Median overall survival of 16.5 months versus 12.7 months, with a hazard ratio of 0.67 and a 95 percent confidence interval of 0.50 to 0.88;
- And a confirmed overall response rate of 42 percent, with a 95 percent confidence interval of 36 to 49 and a sample size of 95, versus 16 percent in the chemotherapy group, which had a 95 percent confidence interval of 12 to 22 and a sample size of 36.

The most commonly reported adverse reactions of any grade in patients receiving mirvetuximab were fatigue in 47 percent, blurred vision in 45 percent, peripheral neuropathy in 37 percent, and keratopathy in 37 percent. Other adverse reactions included abdominal pain, musculoskeletal pain, diarrhea, dry eye, constipation, and nausea, among others.[1]

Now, as we know, mirvetuximab does carry a boxed warning for ocular toxicity, and that's often top of mind for clinicians. Dr. Micaily, can you walk us through mirvetuximab's ocular adverse reaction profile and explain how these events typically present?

**Dr. Micaily:**
Absolutely. In an integrated safety summary of pooled data from 682 patients treated with mirvetuximab across clinical trials ocular adverse reactions reported in 59 percent of patients who received mirvetuximab. The most common ocular adverse reactions included blurred vision, keratopathy, and dry eye.[1]

The majority of these were low grade and occurred between cycles two and three. Eleven percent of patients experienced grade three events and two patients had grade four events of keratopathy and cataract.[1]

The median time to onset of the first ocular adverse reaction was 5.1 weeks, with a range between 0.1 and 68.6 weeks.[1]

Most cases, 91 percent, resolved to grade one or better, with complete resolution in 53 percent and 38 percent partial resolution at last follow-up. And permanent treatment discontinuation due to ocular adverse reactions occurred in one percent of patients.[1]

So ocular adverse reactions associated with mirvetuximab are generally mild and are manageable with ophthalmic monitoring and dose modifications when indicated.[1,2]

**Dr. Caudle:**
Dr. Micaily, how has this translated into your practice?

**Dr. Micaily:**
I found that closely collaborating with local eye care providers on the management of patients on mirvetuximab was reassuring. Together, we set up a protocol that followed the ocular management guide in the United States Prescribing Information, or USPI.[1] As a result, we've been able to monitor and manage ocular adverse reactions early and effectively.

**Dr. Caudle:**
Now, in an academic center, that kind of care coordination is commonly built into the healthcare system. Given that you care for patients

outside of an academic center, Dr. Micaily, how do you identify eye care professionals for patient care collaboration?

**Dr. Micaily:**
Great question. When I first started with mirvetuximab, I reached out to both ophthalmologists and optometrists in my area—and I've worked with both to help care for these patients. And many patients already have an eye doctor that they see for regular eye exams.

In that initial outreach, I explain our monitoring needs, which include a baseline exam, the follow-up schedule, the prophylactic eyedrop protocol, and the types of findings we'd be looking for.[1]

The first patient took a little extra effort and coordination. But this helped us create a workflow that runs smoothly—my team can now refer patients directly, and we get timely exam reports back. Also, it's been helpful to maintain an open line of communication with eye care providers for any questions that come up.

**Dr. Caudle:**
Now, turning to you, Dr. Varanelli, how do you approach patients who have been referred for mirvetuximab management?

**Dr. Varanelli:**
So when I approach these patients who've been referred, our priority really is to follow the monitoring and prophylaxis plan that's outlined in the USPI.[1] That includes a baseline visit before beginning their treatments, and follow-up exams every other cycle for the first eight—so really, a total of four eye exams, but certainly more often, if needed.[1]

At these visits I'm performing a visual acuity assessment to determine the patient's best-corrected visual acuity, and perform a slit lamp exam, with a special focus on the cornea.[1]

But I'm also coordinating this with the oncologist on prescribing prophylactic steroid eye drops. Patients should be starting them the day before the mirvetuximab infusion at six times daily throughout day four, and four times daily through day eight.[1]

We're also recommending that they use preservative-free lubricating eye drops four times a day—but more often as needed—and avoiding contact lenses while on this therapy.[1]

Following the USPI guidance really helps us monitor and manage the patient's ocular health so that we can intervene when necessary, and help patients remain on their therapy.[1]

**Dr. Caudle:**
Now, let's turn to patient-centered strategies. Dr. Varanelli, how do you help patients starting mirvetuximab understand what to expect on treatment?

**Dr. Varanelli:**
First, I'll explain that symptoms such as blurred vision, dry eye, or light sensitivity may start around cycle two or three—but certainly can occur at any time throughout treatments—and they should report these.[1,2]

Also, I emphasize that these symptoms are typically low grade, generally manageable, and resolvable with our ocular care plan of close monitoring and dose modifications when indicated by their oncologist.[1,2]

So we'll discuss the importance of attending scheduled exams and using their eyedrops as prescribed, for example. And I'll advise patients to call us for any new or worsening ocular symptoms so we can see them promptly.[1]

And finally, I let the patient know that I'll be communicating any of these findings and treatment plans, if necessary, with the oncologist and the NP/PA team, as well.

**Dr. Caudle:**
And on the oncology side, Dr. Micaily, how do you frame these conversations?

**Dr. Micaily:**
I keep it simple. I let them know that some patients do develop eye-related symptoms, but we're watching closely and have strategies in place from day one, including a partnership with a dedicated eye care provider.[1]

That early education really matters. I find that patients are more comfortable when everyone on their care team is reinforcing the same message.

**Dr. Caudle:**

Now, many patients may already have some baseline eye conditions, especially older adults. Dr. Varanelli, how do you approach these patients?

**Dr. Varanelli:**
That's a great point. Many of my patients have pre-existing ocular findings, like dry eye, or age-related changes, such as cataracts. That's pretty common in this patient demographic, but readily managed while patients are on therapy.[2]

For example, I may prescribe these patients standard of care treatments for their dry eye. And if they have cataracts, I'll counsel them that the cataracts are a progressive condition, so while undergoing treatment, we may see their cataracts progress.[3] Now, if that does happen while on treatment, we have ways to monitor and manage it with their oncologist.[2]

**Dr. Caudle:**
So, Dr. Varanelli, when you're evaluating a patient on treatment, what findings might trigger a conversation with the oncology team?

**Dr. Varanelli:**
During the exam, I'm doing a very careful observation of the front of the eye.[1]

If we see nonconfluent corneal findings of keratopathy—which is what we would call grade one on the USPI grading scale—we typically continue with close monitoring, managing any symptoms, and reinforcing eyedrop use with the patient. After communicating these findings to the oncologist, these patients often stay on therapy without changes.[1]

The other scenario, for example, is if the corneal findings progress to what we call confluent, or if there's a loss of three lines or more in the patient's best corrected vision from baseline. In this case, we notify the prescribing oncologist of our exam findings right away.[1]

**Dr. Caudle:**
And from your side, Dr. Micaily, what are your next steps when you get this information from your eye care partner?

**Dr. Micaily:**
If the eye care provider reports confluent findings or a loss of three lines or more in visual acuity from baseline, we'll hold the mirvetuximab dose to allow the eye to recover.[1]

We'll then have the patient re-evaluated by our eye care partner until they've improved to grade one or their baseline because mirvetuximab can be resumed at grade one per the USPI.[1] Keep in mind that in MIRASOL, the median time to resolution for keratopathy and blurred vision to grade one or better was less than three weeks.[4,5]

And in my experience, we're often able to resume treatment safely, sometimes with a dose reduction.[1]

I tell my patients that the goal is to protect their vision and keep them on therapy as long as it's helping.

That's why we rely on clear, timely reports from our eyecare providers to make those decisions. And having open communications with eye care providers and the patients makes all the difference.

So to sum up, we can help manage ocular adverse reactions in patients on mirvetuximab with proactive coordination, ongoing patient education, and collaboration with eye care professionals.[1]

And providers across any care setting can use these strategies to appropriately manage ocular adverse reactions with supportive care and dose modifications, when indicated.[1]

**Dr. Caudle:**
Well that's a great takeaway from our discussion today.

And I'd like to thank my guests, Dr. Ida Micaily and Dr. Jeffrey Varanelli, for an informative conversation on managing ocular adverse reactions in patients on mirvetuximab.

Dr. Micaily and Dr. Varanelli, it was great speaking with you both today.

**Dr. Micaily:**
Thanks for having me.

**Dr. Varanelli:**
Thank you Dr. Caudle and Dr. Micaily. Thanks for the discussion today.

**Dr. Caudle:**
For ReachMD, I'm your host Dr. Jennifer Caudle.

Please stay tuned to hear the additional Important Safety Information.

**Announcer:**

**Important Safety Information**

**WARNINGS AND PRECAUTIONS**

**Ocular Disorders**

Mirvetuximab soravtansine-gynx can cause severe ocular adverse reactions, including visual impairment, keratopathy (corneal disorders), dry eye, photophobia, eye pain, and uveitis.

Ocular adverse reactions occurred in 59% of patients with ovarian cancer treated with mirvetuximab soravtansine-gynx. Eleven percent (11%) of patients experienced Grade 3 ocular adverse reactions, including blurred vision, keratopathy (corneal disorders), dry eye, cataract, photophobia, and eye pain; two patients (0.3%) experienced Grade 4 events (keratopathy and cataract). The most common (≥5%) ocular adverse reactions were blurred vision (48%), keratopathy (36%), dry eye (27%), cataract (16%), photophobia (14%), and eye pain (10%).

The median time to onset for first ocular adverse reaction was 5.1 weeks (range: 0.1 to 68.6). Of the patients who experienced ocular events, 53% had complete resolution; 38% had partial improvement (defined as a decrease in severity by one or more grades from the worst grade at last follow-up). Ocular adverse reactions led to permanent discontinuation of mirvetuximab soravtansine-gynx in 1% of patients.

Premedication and use of lubricating and ophthalmic topical steroid eye drops during treatment with mirvetuximab soravtansine-gynx are recommended. Advise patients to avoid use of contact lenses during treatment with mirvetuximab soravtansine-gynx unless directed by a healthcare provider.

Refer patients to an eye care professional for an ophthalmic exam including visual acuity and slit lamp exam prior to treatment initiation, every other cycle for the first 8 cycles, and as clinically indicated. Promptly refer patients to an eye care professional for any new or worsening ocular signs and symptoms.

Monitor for ocular toxicity and withhold, reduce, or permanently discontinue mirvetuximab soravtansine-gynx based on severity and persistence of ocular adverse reactions.

**ADVERSE REACTIONS**

The most common (≥20%) adverse reactions, including lab abnormalities, were increased aspartate aminotransferase, fatigue, increased alanine aminotransferase, blurred vision, nausea, increased alkaline phosphatase, diarrhea, abdominal pain, keratopathy, peripheral neuropathy, musculoskeletal pain, decreased lymphocytes, decreased platelets, decreased magnesium, decreased hemoglobin, dry eye, constipation, decreased leukocytes, vomiting, decreased albumin, decreased appetite, and decreased neutrophils.

**DRUG INTERACTIONS**

DM4 is a CYP3A4 substrate. Closely monitor patients for adverse reactions with mirvetuximab soravtansine-gynx when used concomitantly with strong CYP3A4 inhibitors.

**USE IN SPECIAL POPULATIONS**

Lactation

Advise women not to breastfeed during treatment with mirvetuximab soravtansine-gynx and for 1 month after the last dose.

**Hepatic Impairment**

Avoid use of mirvetuximab soravtansine-gynx in patients with moderate or severe hepatic impairment (total bilirubin >1.5 ULN).

Dosage Form and Strength: Mirvetuximab soravtansine-gynx is available as a 100 mg/20 mL injection.

Review full prescribing information for additional information at www.rxabbvie.com or contact AbbVie Medical Information at 1-800-633-9110 or go to abbviemedinfo.com.

**Announcer:**
This medical industry feature was sponsored by AbbVie US Medical Affairs. If you missed any part of this discussion, visit Industry Features on ReachMD.com, where you can Be Part of the Knowledge.

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MIRV-US-00008-MC Version 1.0 Approved 05/2026