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/talking-about-a-therapy-approach-with-your-patients-with-moderate-to-severe-endo-pain/11701/

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Talking About a Therapy Approach With Your Patients With Moderate to Severe Endo Pain

I'm Dr. Jessica Shepherd, a minimally invasive gynecologist and a women's health expert. As you know, endometriosis affects about 1 in 10 women of reproductive age, and in one survey, 90% of diagnosed women ages 18-49 had moderate or severe pain.[1*] This chronic condition can negatively affect many aspects of women's lives. It's our responsibility to properly treat this disease and bring pain relief to our patients. When we're recommending or prescribing ORILISSA to patients, the way we talk about it is critical to their acceptance. It's essential to make patients a part of the decision-making process to ensure they feel that, together, we can make a well-informed decision. With our help, patients can leave the office with a complete understanding of why ORILISSA was prescribed to them, or how it can help bring relief for moderate or severe pain associated with their endometriosis. It is important that all patients with endometriosis have a basic understanding of the pathophysiology, namely that this disease is chronic and fueled by estrogen.[2] Throughout their disease, we have a variety of medical and surgical options to choose from. Laying this foundation will provide support for your later discussions.

Counseling patients on ORILISSA for the first time

Here's what I recommend focusing on initially when explaining ORILISSA therapy to a patient. Share why you're recommending ORILISSA at this particular time based on their treatment history and goals. Explain simply how ORILISSA works to lower their estrogen level, linking back to the groundwork you have already laid. I explain to my patients that the goal is to reduce estrogen to a level that can help reduce moderate or severe pain associated with their endometriosis. Highlight that ORILISSA helps reduce the three most common types of endometriosis pain, which are painful periods, pelvic pain in between periods, and pain with sex. Tell your patients that ORILISSA was proven to provide pain relief at three months in clinical trials and balance the discussion with potential risk as well as benefits of the treatment. Patients want to hear about women I have personally treated with ORILISSA and how they did on the therapy. So, I share what I've seen in my practice and heard from other colleagues. I include that ORILISSA has been prescribed to more than 30,000 patients. I also ask if they have any questions or anything they want to discuss, so they feel fully informed.

Prescribing ORILISSA

When we decide on ORILISSA and I write the prescription, I tell patients that I'm prescribing ORILISSA at a dosage tailored to their needs. I remind them that ORILISSA is not like a pain medication, and that it works differently, and they should continue taking ORILISSA as prescribed regardless of whether pain relief has begun. If your patients have concerns about their pain levels when they begin taking ORILISSA, encourage them to continue taking it and return for a follow-up visit to reevaluate. I advise patients that it might take time for them to obtain ORILISSA, so they may have to wait a few weeks, or I can provide samples for them right away. It depends on the patient's needs. As I review the insurance process with them, I will proactively submit a PA form, and try to set some expectations around cost. I may share other available resources, including brochures, providing additional treatment information, and a savings card.

Following up

To ensure a patient has a successful start on ORILISSA, my office staff plans two follow-up appointments. I want to see them first in four to six weeks to ensure they got their prescription filled and started taking ORILISSA. It's important to follow up to make sure the initiation is going smoothly. I use that first follow-up appointment to assure them they're not alone in their pain relief journey. I also like to see patients at three months to evaluate changes to their pain score from their initial visit, since the coprimary efficacy endpoints of ORILISSA were measured at month three. As with the first follow-up visit, I'll discuss any side effects they're encountering. Treatment

with ORILISSA should be a shared decision between you and your patients, so you have their buy-in. Instead of making guarantees, you will be able to say, “Here’s what we discussed. Here is where you are on your journey. At this point, this option may be best for you. We are in this process together.” This helps ensure that patients understand their medication, are taking it as prescribed, and are off to a good start with ORILISSA.

INDICATION

ORILISSA® (elagolix) is indicated for the management of moderate to severe pain associated with endometriosis.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

- ORILISSA is contraindicated in women who are pregnant (exposure to ORILISSA early in pregnancy may increase the risk of early pregnancy loss), in women with known osteoporosis or severe hepatic impairment, or with concomitant use of strong organic anion transporting polypeptide (OATP) 1B1 inhibitors (e.g., cyclosporine and gemfibrozil).

WARNINGS AND PRECAUTIONS

Bone Loss

- ORILISSA causes a dose-dependent decrease in bone mineral density (BMD), which is greater with increasing duration of use and may not be completely reversible after stopping treatment.
- The impact of ORILISSA-associated decreases in BMD on long-term bone health and future fracture risk is unknown. Consider assessment of BMD in patients with a history of low-trauma fracture or other risk factors for osteoporosis or bone loss, and do not use in women with known osteoporosis.
- Limit the duration of use to reduce the extent of bone loss.

Change in Menstrual Bleeding Pattern and Reduced Ability to Recognize Pregnancy

- Women who take ORILISSA may experience a reduction in the amount, intensity, or duration of menstrual bleeding, which may reduce the ability to recognize the occurrence of pregnancy in a timely manner. Perform pregnancy testing if pregnancy is suspected, and discontinue ORILISSA if pregnancy is confirmed.

Suicidal Ideation, Suicidal Behavior, and Exacerbation of Mood Disorders

- Suicidal ideation and behavior, including one completed suicide, occurred in subjects treated with ORILISSA in the endometriosis clinical trials.
- ORILISSA users had a higher incidence of depression and mood changes compared to placebo and ORILISSA users with a history of suicidality or depression had an increased incidence of depression. Promptly evaluate patients with depressive symptoms to determine whether the risks of continued therapy outweigh the benefits. Patients with new or worsening depression, anxiety, or other mood changes should be referred to a mental health professional, as appropriate.
- Advise patients to seek immediate medical attention for suicidal ideation and behavior. Reevaluate the benefits and risks of continuing ORILISSA if such events occur.

Hepatic Transaminase Elevations

- In clinical trials, dose-dependent elevations of serum alanine aminotransferase (ALT) at least 3 times the upper limit of the reference range occurred with ORILISSA.
- Use the lowest effective dose and instruct patients to promptly seek medical attention in case of symptoms or signs that may reflect liver injury, such as jaundice.
- Promptly evaluate patients with elevations in liver tests to determine whether the benefits of continued therapy outweigh the risks.

Reduced Efficacy with Estrogen-Containing Contraceptives

- Based on the mechanism of action of ORILISSA, estrogen-containing contraceptives are expected to reduce the efficacy of ORILISSA. The effect of progestin-only contraceptives on the efficacy of ORILISSA is unknown.
- Advise women to use non-hormonal contraceptives during treatment and for one week after discontinuing ORILISSA.

ADVERSE REACTIONS

- The most common adverse reactions (>5%) in clinical trials included hot flushes and night sweats, headache, nausea, insomnia, amenorrhea, anxiety, arthralgia, depression-related adverse reactions, and mood changes.

These are not all the possible side effects of ORILISSA.
Safety and effectiveness of ORILISSA in patients less than 18 years of age have not been established.
For more information, see accompanying full prescribing information.

References:

1.Fuldeore MJ, Soliman AM. Prevalence and symptomatic burden of diagnosed endometriosis in the United States: national estimates from a cross-sectional survey of 59,411 women. *Gynecol Obstet Invest* 2017;82(5):453-461. **2.** Giudice LC. Clinical practice: endometriosis. *N Engl J Med*. 2010;362(25):2389-2398.

*Based on a cross-sectional survey in the US of 48,020 women (ages 18-49), 2922 of whom had received a diagnosis of endometriosis. Results were from a market research survey.