Oriahnn™ COMPLETE

NAVIGATING PRIOR AUTHORIZATIONS

A prior authorization may be required by the payer for certain treatments

When prescribing new treatment for your patient, determine whether the payer requires a prior authorization.

- It is important to be as thorough and accurate as possible to get approval in a timely manner
- In some cases, the payer may require additional documentation to explain the product of choice

HAVE A QUESTION? CONTACT YOUR DEDICATED ACCESS SPECIALIST

FOR SUPPORT OVER THE PHONE, PLEASE CALL 1-800-ORIAHNN (1-800-674-2466)

This information is presented for informational purposes only and is not intended to provide reimbursement or legal advice. Providers are encouraged to contact third-party payers for specific information about their coverage policies.

SAFETY CONSIDERATIONS[1]

Estrogen and progestin combinations, including ORIAHNN, increase the risk of thrombotic or thromboembolic disorders, including pulmonary embolism, deep vein thrombosis, stroke, and myocardial infarction, especially in women at increased risk for these events.

ORIAHNN is contraindicated in women with current or a history of thrombotic or thromboembolic disorders and in women at increased risk for these events, including women over 35 years of age who smoke and women with uncontrolled hypertension.

Please see additional Important Safety Information, including BOXED WARNING on THROMBOEMBOLIC AND VASCULAR EVENTS, on pages 5-6.

Please click here for full Prescribing Information.

Oriahnn™
elagolix, estradiol and norethindrone acetate capsules and elagolix capsules 300 mg/1 mg/0.5 mg and 300 mg

REQUESTING A PRIOR AUTHORIZATION

CHECKLIST FOR REQUESTING A PRIOR AUTHORIZATION

- **Before beginning the process, confirm that the patient's insurance has not changed since the last visit**
- **Ask what information or form is necessary. While each plan may vary, some payers require:**
  - Payer-specific forms
  - Patient medical records with appropriate chart notes
    - *Note: some plans may require additional clinical tests or records*
- **Some plans may require a DXA bone density scan as part of the PA**
  - Contact your Access Specialist if you need additional support for the DXA prior authorization process
- **Carefully review each diagnostic question, as they may vary between payers**
  - Some criteria may be inclusive while some may be to confirm the absence of a condition. Be sure to read each statement closely
- **Inquire about how long the process will take once the necessary forms and documentation are submitted**
- **Complete all sections of the prior authorization form and any supplemental material, including all required forms and documentation**
- **Determine if the information can be phoned in, faxed, emailed, or submitted through the payer's website**
- **Update your patient on the prior authorization request, in case they receive a call or mail from their insurance company**

CONSIDER USING COVERMYMEDS.COM FOR ELECTRONIC PRIOR AUTHORIZATION SUBMISSION TO THE INSURANCE PLAN

SAFETY CONSIDERATIONS[1]

ORIAHNN may cause a decrease in bone mineral density (BMD), which is greater with increasing duration of use and may not be completely reversible after stopping treatment. Assessment of BMD by dual-energy X-ray absorptiometry (DXA) is recommended at baseline and periodically thereafter. Limit the duration of use to 24 months to reduce the extent of bone loss.

DXA, dual-energy X-ray absorptiometry.

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REQUESTING A PRIOR AUTHORIZATION (CONT'D)

COMMON ORIAHNN PRIOR AUTHORIZATION CRITERIA MAY INCLUDE*

1. Is the patient 18 years or older?
2. Is the patient a premenopausal woman?
3. Does the patient have heavy menstrual bleeding associated with uterine fibroids?
4. Is she a patient over 35 years of age who smokes or has uncontrolled hypertension?
5. Does the patient currently have, or have a history of, thrombotic or thromboembolic disorders?
6. Is the patient pregnant?
7. Does the patient have osteoporosis?
8. Does the patient have known liver impairment?
9. Does the patient have a history of cholestatic jaundice (associated with past estrogen use or with pregnancy)?
10. Is the patient taking concomitant strong OATP 1B1 inhibitors?
11. Does the patient have a history of breast cancer or hormone-sensitive malignancies?
12. Does the patient have undiagnosed abnormal uterine bleeding?
13. Has the patient tried, failed, or is intolerant to oral contraceptives or an over-the-counter medication?
14. Has the patient had a DXA bone density scan?

Some payers may require additional documentation to support prior authorization criteria

*Not a complete list.

DXA, dual-energy X-ray absorptiometry.

INDICATION

ORIAHNN™ (elagolix, estradiol, and norethindrone acetate capsules; elagolix capsules) is indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women. Use of ORIAHNN should be limited to 24 months due to the risk of continued bone loss, which may not be reversible.

SAFETY CONSIDERATIONS[1]

ORIAHNN is contraindicated in women who are at a high risk of arterial, venous thrombotic, or thromboembolic disorders; who are pregnant; with known osteoporosis; current or history of breast cancer or other hormonally sensitive malignancies; known hepatic impairment or disease; undiagnosed abnormal uterine bleeding; known anaphylactic reaction, angioedema, or hypersensitivity to ingredients of ORIAHNN; or with concomitant use of organic anion transporting polypeptide (OATP) 1B1 inhibitors that are known or expected to significantly increase elagolix plasma concentrations.

Please see additional Important Safety Information, including BOXED WARNING on THROMBOEMBOLIC AND VASCULAR EVENTS, on pages 5-6.

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REQUESTING A PRIOR AUTHORIZATION (CONT'D)

BEST PRACTICE TIPS TO TRACK THE PRIOR AUTHORIZATION PROCESS

1. **Log the date and time** of the call, who you spoke with, and their contact information
2. **Keep a copy** of everything submitted for the prior authorization
3. **Log any calls** your facility makes about the request. Note the name of the person you spoke with
4. **Follow up with the payer** if your facility does not receive notification of the decision in a timely manner
5. **Record the prior authorization approval code and date** in the patient's medical record. Also note the expiration date of the prior authorization

Monitor your patients' prior authorization with the PA tracker available for digital or print use at **OriahnnHCP.com/PA-tracker**

Please see Important Safety Information, including BOXED WARNING on THROMBOEMBOLIC AND VASCULAR EVENTS, on pages 5-6.

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INDICATION AND IMPORTANT SAFETY INFORMATION FOR ORIAHNN™ (ELAGOLIX, ESTRADIOL, AND NORETHINDRONE ACETATE CAPSULES; ELAGOLIX CAPSULES)

INDICATION[1]

ORIAHNN™ (elagolix, estradiol, and norethindrone acetate capsules; elagolix capsules) is indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women. Use of ORIAHNN should be limited to 24 months due to the risk of continued bone loss, which may not be reversible.

IMPORTANT SAFETY INFORMATION[1]

THROMBOEMBOLIC AND VASCULAR EVENTS

Estrogen and progestin combinations, including ORIAHNN, increase the risk of thrombotic or thromboembolic disorders, including pulmonary embolism, deep vein thrombosis, stroke, and myocardial infarction, especially in women at increased risk for these events.

ORIAHNN is contraindicated in women with current or a history of thrombotic or thromboembolic disorders and in women at increased risk for these events, including women over 35 years of age who smoke and women with uncontrolled hypertension.

CONTRAINDICATIONS

- ORIAHNN is contraindicated in women at a high risk of arterial, venous thrombotic, or thromboembolic disorders; who are pregnant; with known osteoporosis; current or history of breast cancer or other hormonally sensitive malignancies; known hepatic impairment or disease; undiagnosed abnormal uterine bleeding; known anaphylactic reaction, angioedema, or hypersensitivity to ingredients of ORIAHNN; or with concomitant use of organic anion transporting polypeptide (OATP) 1B1 inhibitors that are known or expected to significantly increase elagolix plasma concentrations.

WARNINGS AND PRECAUTIONS

Thromboembolic Disorders and Vascular Events

- ORIAHNN is contraindicated in women with current or a history of thrombotic or thromboembolic disorders and in women at increased risk for these events. Components of ORIAHNN increase the risk of thrombotic or thromboembolic disorders, including pulmonary embolism, deep vein thrombosis, stroke, and myocardial infarction, especially in women at high risk for these events. In general, the risk is greatest among women over 35 years of age who smoke, and women with uncontrolled hypertension, dyslipidemia, vascular disease, or obesity.
- Discontinue ORIAHNN if an arterial or venous thrombotic, cardiovascular, or cerebrovascular event occurs. If feasible, discontinue ORIAHNN at least 4 to 6 weeks before surgery of the type associated with an increased risk of thromboembolism, or during periods of prolonged immobilization. Stop ORIAHNN if there is sudden, unexplained partial or complete loss of vision, proptosis, diplopia, papilledema, or retinal vascular lesions and evaluate for retinal vein thrombosis immediately.

Bone Loss

- ORIAHNN is contraindicated in women with known osteoporosis. ORIAHNN may cause a decrease in bone mineral density (BMD) in some patients, which is greater with increasing duration of use and may not be completely reversible after stopping treatment.
- The impact of ORIAHNN-associated decreases in BMD on long-term bone health and future fracture risk is unknown. Consider the benefits and risks of ORIAHNN in patients with a history of low-trauma fracture or other risk factors for osteoporosis or bone loss, including those taking medications that may decrease BMD (e.g., systemic or chronic inhaled corticosteroids, anticonvulsants, or proton pump inhibitors).
- Assessment of BMD by dual-energy X-ray absorptiometry (DXA) is recommended at baseline and periodically thereafter. Consider discontinuing ORIAHNN if the risk associated with bone loss exceeds the potential benefit of treatment. Limit the duration of use to 24 months to reduce the extent of bone loss.

Hormonally Sensitive Malignancies

- ORIAHNN is contraindicated in women with current or a history of breast cancer and in women at increased risk for hormonally sensitive malignancies, such as those with mutations in BRCA genes.
- The use of estrogen alone and estrogen plus progestin has been reported to result in an increase in abnormal mammograms requiring further evaluation. Surveillance measures, such as breast examinations and regular mammography, are recommended. Discontinue ORIAHNN if a hormonally sensitive malignancy is diagnosed.

Suicidal Ideation, Suicidal Behavior, and Exacerbation of Mood Disorders

- Depression, depressed mood, and/or tearfulness were reported at a higher incidence in women taking ORIAHNN (3%) compared with placebo (1%) in the Phase 3 clinical trials. Suicidal ideation and behavior, including a completed suicide, occurred in women treated with lower doses of elagolix in clinical trials conducted for a different indication.
- 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.

Please see additional Important Safety Information continued on page 6.

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- Advise patients to seek immediate medical attention for suicidal ideation and behavior. Reevaluate the benefits and risks of continuing ORIAHNN if such events occur.

Hepatic Impairment and Transaminase Elevations

- ORIAHNN is contraindicated in women with known hepatic impairment or disease.
- Transaminase elevations in alanine aminotransferase (ALT) and aspartate aminotransferase (AST) occurred with ORIAHNN in Phase 3 clinical trials. No pattern in time to onset of these liver transaminase elevations was identified. Transaminase levels returned to baseline within 4 months after peak values in these patients.
- Instruct patients to promptly seek medical attention in case of symptoms or signs that may reflect liver injury, such as jaundice.

Elevated Blood Pressure

- ORIAHNN is contraindicated in women with uncontrolled hypertension. Maximum mean increases in systolic blood pressure occurred at Month 5, and a mean maximum increase in diastolic blood pressure occurred at Month 4 in ORIAHNN-treated women, as compared to placebo-treated women.
- For women with well-controlled hypertension, continue to monitor blood pressure and stop ORIAHNN if blood pressure rises significantly. Monitor blood pressure in normotensive women treated with ORIAHNN.

Gallbladder Disease or History of Cholestatic Jaundice

- Studies among estrogen users suggest a small increased relative risk of developing gallbladder disease. For women with a history of cholestatic jaundice associated with past estrogen use or with pregnancy, assess the risk-benefit of continuing therapy. Discontinue ORIAHNN if jaundice occurs.

Change in Menstrual Bleeding Pattern and Reduced Ability to Recognize Pregnancy

- ORIAHNN may delay the ability to recognize the occurrence of a pregnancy because it may reduce the intensity, duration, and amount of menstrual bleeding. Perform pregnancy testing if pregnancy is suspected and discontinue ORIAHNN if pregnancy is confirmed.
- The effect of hormonal contraceptives on the efficacy of ORIAHNN is unknown. Advise women to use non-hormonal contraception during treatment and for 1 week after discontinuing ORIAHNN.

Effects on Carbohydrate and Lipid Metabolism

- ORIAHNN may decrease glucose tolerance and result in increased glucose levels. More frequent monitoring in ORIAHNN-treated women with prediabetes and diabetes may be needed.
- In women with preexisting hypertriglyceridemia, estrogen therapy may be associated with elevations of plasma triglycerides leading to pancreatitis.

Use of elagolix is associated with increases in total cholesterol, low-density lipoprotein cholesterol (LDL-C), high-density lipoprotein cholesterol (HDL-C), and serum triglycerides. Monitor lipid levels and consider discontinuing ORIAHNN if hypercholesterolemia or hypertriglyceridemia worsens.

Alopecia

- In Phase 3 clinical trials, more women experienced alopecia, hair loss, and hair thinning with ORIAHNN (3.5%) compared to placebo (1.0%). In almost one-third of affected ORIAHNN-treated women, alopecia was the reason for discontinuing treatment. No specific pattern was described. In the majority of these women, hair loss was continuing when ORIAHNN was stopped. Whether the hair loss is reversible is unknown. Consider discontinuing ORIAHNN if hair loss becomes a concern.

Effect on Other Laboratory Results

- The use of estrogen and progestin combinations may raise serum concentrations of binding proteins (e.g., thyroid-binding globulin, corticosteroid-binding globulin), which may reduce the free thyroid or corticosteroid hormone levels. Patients with hypothyroidism and hypoadrenalism may require higher doses of thyroid hormone or cortisol replacement therapy, respectively.
- The use of estrogen and progestin may also affect the levels of sex hormone-binding globulin, coagulation factors, lipids, and glucose.

RISK OF ALLERGIC REACTIONS DUE TO THE INACTIVE INGREDIENT (FD&C YELLOW NO. 5)

- ORIAHNN contains FD&C Yellow No. 5 (tartrazine), which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Although the overall incidence of FD&C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.

ADVERSE REACTIONS

- Most common adverse reactions occurring in ≥5% of women receiving ORIAHNN in clinical trials were hot flush, headache, fatigue, and metrorrhagia.

These are not all of the possible side effects of ORIAHNN.

Safety and effectiveness of ORIAHNN in pediatric patients have not been established.

Reference: 1. ORIAHNN [package insert]. North Chicago, IL: AbbVie Inc; 2020.

Please click here for full Prescribing Information.

abbvie

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