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Elagolix/Relugolix Prior Authorization with Quantity Limit Criteria

FDA APPROVED INDICATIONS AND DOSAGE[1-3]

Agent(s)	Indication(s)	Dosage
Myfembree® (relugolix, estradiol hemihydrate, norethindrone acetate) Tablet	The management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women	• Exclude pregnancy • Limit use to 24 months due to the risk of continued bone loss which may not be reversible **Dosing:** One tablet orally once daily, starting as early as possible after onset of menses but no later than 7 days after menses has started
Oriahnn™ (elagolix, estradiol, norethindrone acetate) Capsule	The management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women	• Exclude pregnancy before starting Oriahnn or start Oriahnn within 7 days from the onset of menses • Limit the duration of use to 24 months due to risk of continued bone loss, which may not be reversible **Dosing:** One elagolix, estradiol, norethindrone acetate capsule orally in the morning and one elagolix capsule orally in the evening
Orilissa® (elagolix) Tablet	Management of moderate to severe pain associated with endometriosis	• Exclude pregnancy before starting Orilissa or start Orilissa within 7 days from the onset of menses. • Limit the duration of use (based on the dose and coexisting condition) due to bone loss **Dosing:** • No coexisting conditions: 150 mg once daily for a max of 24 months • Coexisting dyspareunia: 200 mg twice daily for a max of 6 months • Coexisting moderate hepatic impairment (Child-Pugh Class B): 150 mg once daily for a max of 6 months

CLINICAL RATIONALE

Endometriosis

Endometriosis is an estrogen-dependent, benign, inflammatory disease that affects women during their premenarcheal, reproductive, and postmenopausal hormonal stages. While endometriosis is a common and nonmalignant process, ectopic endometrial tissue and resultant inflammation can cause dysmenorrhea, dyspareunia, chronic pain, and infertility. Symptoms can range from minimal to severely debilitating. While definitive diagnosis of endometriosis requires tissue biopsy and histologic confirmation, the combination of symptoms, signs, and imaging findings can be used to make a presumptive, nonsurgical diagnosis of endometriosis.[4,5]

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The first line option for the treatment of mild and moderate pain associated with endometriosis is non-steroidal anti-inflammatory drug (NSAID) and continuous hormonal contraceptives (estrogen/progestin, or progestin only) as this therapy has low risk with few side effects and provides symptom relief for many women. The use of gonadotropin-releasing hormone (GnRH) for initial therapy may be reasonable. For those who have severe pain or continue to experience symptoms on NSAID and continuous hormone therapy, a GnRH may be included in therapy. Women who do not respond to medical treatment may move on to laparoscopy or hysterectomy for treatment.[5]

Uterine Leiomyomas

Uterine Leiomyomas, also known as myomata or fibroids, are the most common gynecologic benign tumors. Uterine leiomyomas are classified based on their location in the uterine wall and are referred to as submucous, intramural, and subserosal. Uterine leiomyomas are monoclonal tumors that arise from the muscular layer of the uterus and consist of large amounts of collagen, fibronectin, and proteoglycan. Leiomyomas can become enlarged causing significant distortion of the uterine surface or cavity.[6,7]

Many patients with uterine leiomyomas are asymptomatic, but symptomatic patients may experience significant symptoms that interfere with daily living. The clinical characteristics can be broken down into three categories:

- Heavy or abnormal uterine bleeding (the most common symptom)
- Pelvic pressure and pain
- Reproductive dysfunction (i.e., infertility, miscarriages, preterm labor)

Uterine leiomyomas are generally diagnosed via pelvic examination and pelvic ultrasound. Other imagining, such as saline-infused sonogram, MRI, and hysteroscopy, are used if further evaluation of the leiomyomas is needed.[8]

Hysterectomy remains the most common treatment for symptomatic leiomyomas as it is the only definitive treatment and eliminates the possibility of recurrence. The American College of Gynecology and Obstetrics indicates the following are alternative options to hysterectomy:[9]

- Contraceptives are widely used for control of abnormal menstruation and are often first line therapy, however, they only offer short term relief
- Gonadotropin releasing hormone agonists cause amenorrhea in most women and lead to a short term reduction in leiomyoma volume within 3 months. These agents are often use preoperatively to improve surgical outcomes

Efficacy

Myfembree[3]

The efficacy and safety of Myfembree were evaluated in two replicate, 24-week, multinational, randomized, double-blind, placebo-controlled studies in a total of 768 premenopausal women with heavy menstrual bleeding associated with uterine fibroids in Study L1 (NCT03049735) and Study L2 (NCT03103087). For study inclusion, women had to have uterine fibroids confirmed by ultrasound examination, and menstrual blood loss (MBL) volume of greater than or equal to 80 mL per cycle for two menstrual cycles or greater than or equal to 160 mL during one cycle to be included in the studies. Women with hemoglobin less than 8.0 g/dL were excluded from the study. Iron therapy was required for women with hemoglobin greater than or equal to 8 g/dL and less than or equal to 10 g/dL. Women were allowed, but not required, to take calcium and vitamin D during the study. Treatment was initiated within the first seven days after the onset of menses.

The primary endpoint of both studies was the proportion of women in the Myfembree group compared with women in the placebo group, who achieved menstrual blood loss volume of less than 80 mL and at least a 50% reduction from baseline MBL volume over the last 35

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days of treatment. Key secondary endpoints were related to amenorrhea, MBL volume, and change in hemoglobin. In both Study L1 and Study L2, a statistically higher proportion of women treated with Myfembree achieved the primary endpoint of both an MBL volume of less than 80 mL and at least a 50% reduction from baseline in MBL volume over the last 35 days of treatment compared with placebo. In Studies L1 and L2, 50.0% and 50.4% of women treated with Myfembree, respectively, achieved amenorrhea compared to 6.2% and 3.1% treated with placebo, respectively, over the last 35 days of treatment. The mean MBL volumes in Studies L1 and L2 at baseline were 243.8 mL and 246.7 mL in the Myfembree group and 223.2 mL and 211.8 mL in the placebo group, respectively. The mean reduction in MBL volume from baseline to Week 24 in the Myfembree group was 82.0% in Study L1 and 84.3% in Study L2, compared with placebo which was 19.1% and 15.1%, respectively. A hemoglobin response was defined as a hemoglobin increase greater than 2 g/dL from baseline to Week 24 in the subgroup of women with anemia at baseline (hemoglobin less than or equal to 10.5 g/dL). A statistically higher proportion treated with Myfembree compared with placebo had greater than 2 g/dL improvement in hemoglobin levels.

Orilissa[1,11]

The efficacy of Orilissa 150 mg once daily and 200 mg twice daily for the management of moderate to severe pain associated with endometriosis was demonstrated in two multinational double-blind, placebo-controlled trials in 1686 premenopausal women [Study EM-1 (NCT01620528) and Study EM-2 (NCT01931670)]. Each placebo-controlled trial assessed the reduction in moderate to severe endometriosis-associated pain over 6 months of treatment. Each element is scored from 0 (absent) to 3 (severe) for a maximum total score of 15. Subjects were required to have non-menstrual pelvic pain for at least four days in the preceding 35 days, a bone mineral density (BMD) greater then -1.5, and the diagnosis of endometriosis was surgically confirmed. Women were excluded if they had clinically significant gynecologic conditions (e.g., persistent or complex ovarian cyst(s), cancer, pelvic inflammatory disease), a history of osteoporosis, or other metabolic bone disease.

The co-primary efficacy endpoints were (1) the proportion of subjects whose dysmenorrhea responded to treatment at Month 3 and (2) the proportion of subjects whose pelvic pain not related to menses (also known as non-menstrual pelvic pain) responded to treatment at Month 3. A higher proportion of women treated with Orilissa 150 mg once daily or 200 mg twice daily were responders for dysmenorrhea and non-menstrual pelvic pain compared to placebo in a dose-dependent manner at Month 3.

Women in these studies also provided a daily self-assessment of their endometriosis pain using a numeric rating scale (NRS) that asked subjects to rate their endometriosis pain at its worst over the last 24 hours on a scale from 0 (no pain) to 10 (worst pain ever). In Study EM-1, baseline NRS scores were 5.7 for Orilissa 150 mg once daily, 5.5 for Orilissa 200 mg twice daily and 5.6 for placebo. In Study EM-2, baseline NRS scores were 5.7 for Orilissa 150 mg once daily, 5.3 for Orilissa 200 mg twice daily and 5.6 for placebo. Women taking Orilissa 150 mg once daily and 200 mg twice daily reported a statistically ($p<0.001$) significant reduction from baseline in NRS scores compared to placebo at Month 3 in both Studies EM-1 and EM-2 (Study EM-1: 0.7 points for Orilissa 150 mg once daily and 1.3 points for Orilissa 200 mg twice daily; Study EM-2: 0.6 points for Orilissa 150 mg once daily and 1.2 points for Orilissa 200 mg twice daily). In addition, both Orilissa treatment groups showed statistically significantly greater mean decreases from baseline compared to placebo in dysmenorrhea and non-menstrual pelvic pain scores at Month 6.

Oriahnn[2,10]

The efficacy of Oriahnn in the management of heavy menstrual bleeding (HMB) associated with uterine fibroids was demonstrated in two randomized, double-blind, placebo-controlled studies [Study UF-1 (NCT02654054) and Study UF-2 (NCT02691494)] in which 790 premenopausal women with heavy menstrual bleeding received Oriahnn (elagolix 300 mg,

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estradiol 1 mg, and norethindrone acetate 0.5 mg in the morning and elagolix 300 mg in the evening) or placebo for 6 months. Patients were eligible if they were premenopausal females, had ultrasound confirmed diagnosis of uterine fibroids with heavy bleeding. Heavy menstrual bleeding at baseline was defined as having at least two menstrual cycles with greater than 80 mL of menstrual blood loss (MBL) as assessed by alkaline hematin (AH) method (an objective, validated measure to quantify MBL volume on sanitary products). Eligible patients were required to complete a washout period if previously treated with hormonal/antihormonal therapies. Women were excluded if they had persistent or complex ovarian cyst(s), cancer, pelvic inflammatory disease, history of osteoporosis, or a bone mineral density (BMD) T score of -1.5 or less.

The primary endpoint in both studies was the proportion of responders, defined as women who achieved both 1) MBL volume less than 80 mL at the Final Month and 2) 50% or greater reduction in MBL volume from baseline. A higher proportion of Oriahnn-treated women were responders compared to placebo-treated women.

	Study UF-1		Study UF-2	
	Oriahnn N=206	Placebo N=102	Oriahnn N=189	Placebo N=94
Women with MBL volume < 80 mL and ≥ 50% reduction in MBL volume from Baseline to the Final Month	68.5%	8.7%	76.5%	10.5%
Difference from placebo % 95% CI P-value	59.8% (51.1, 68.5) < 0.001		66.0% (57.1, 75.0) < 0.001	

In Study UF-1, mean baseline MBL was 238 mL for Oriahnn and 255 mL for placebo. In Study UF-2, mean baseline MBL was 228 mL for Oriahnn and 254 mL for placebo. Women taking Oriahnn had a mean reduction of MBL volume from Baseline to Final Month in both Studies UF-1 and UF-2 compared to women taking placebo (Study UF-1: -177 mL for Oriahnn and 1 mL for placebo; Study UF-2: -169 mL for Oriahnn and -4 mL for placebo). In Studies UF-1 and UF-2, a greater proportion (57% and 61%, respectively) of women receiving Oriahnn experienced suppression of bleeding, defined as no bleeding (but spotting allowed), at Final Month, compared to 4% and 5%, respectively, of women receiving placebo. In Studies UF-1 and UF-2, a greater proportion of Oriahnn-treated women who were anemic with baseline Hgb ≤ 10.5 g/dL achieved an increase > 2 g/dL in Hgb from Baseline to Month 6 compared to placebo-treated women. Over 90% of women with baseline Hgb ≤ 10.5 g/dL took supplemental iron.

Safety

Myfembree has the following black box warnings:[3]

- Estrogen and progestin combinations, including Myfembree, increase the risk of thrombotic or thromboembolic disorders, especially in women at increased risk for these events
- Myfembree 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 or women with uncontrolled hypertension

Myfembree has the following contraindications:[3]

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- With a high risk of arterial, venous thrombotic, or thromboembolic disorders [see Boxed Warning and Warnings and Precautions (5.1)]. Examples include women over 35 years of age who smoke, and women who are known to have:
    - current or history of deep vein thrombosis or pulmonary embolism
    - vascular disease (e.g., cerebrovascular disease, coronary artery disease, peripheral vascular disease)
    - thrombogenic valvular or thrombogenic rhythm diseases of the heart (for example, subacute bacterial endocarditis with valvular disease, or atrial fibrillation)
    - inherited or acquired hypercoagulopathies
    - uncontrolled hypertension
    - headaches with focal neurological symptoms or migraine headaches with aura if over 35 years of age
- Who are pregnant. Exposure to Myfembree early in pregnancy may increase the risk of early pregnancy loss
- With known osteoporosis, because of the risk of further bone loss
- With current or history of breast cancer or other hormone-sensitive malignancies, and with increased risk for hormone-sensitive malignancies
- With known hepatic impairment or disease
- With undiagnosed abnormal uterine bleeding
- With known anaphylactic reaction, angioedema, or hypersensitivity to Myfembree or any of its components. Anaphylactoid reactions have been reported

Orilissa has no black box warnings.[1]

Orilissa has the following contraindications:[1]
- Pregnancy
- Known osteoporosis
- Severe hepatic impairment
- Taking inhibitors of organic anion transporting polypeptide (OATP) 1B1 that are known or expected to significantly increase elagolix plasma concentrations
- With known hypersensitivity reaction to Orilissa of any of its inactive components

Oriahnn has the following black box warnings:[2]
- 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
- 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

Oriahnn has the following contraindications:[2]
- With a high risk of arterial, venous thrombotic, or thromboembolic disorders. Examples include women over 35 years of age who smoke, and women who are known to have:
    - current or history of deep vein thrombosis or pulmonary embolism
    - vascular disease (e.g., cerebrovascular disease, coronary artery disease, peripheral vascular disease)
    - thrombogenic valvular or thrombogenic rhythm diseases of the heart (for example, subacute bacterial endocarditis with valvular disease, or atrial fibrillation)
    - inherited or acquired hypercoagulopathies
    - uncontrolled hypertension

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    - headaches with focal neurological symptoms or have migraine headaches with aura if over age 35
- Who are pregnant. Exposure to Oriahnn early in pregnancy may increase the risk of early pregnancy loss
- With known osteoporosis because of the risk of further bone loss
- With current or history of breast cancer or other hormonally-sensitive malignancies, and with increased risk for hormonally-sensitive malignancies
- With known hepatic impairment or disease
- With undiagnosed abnormal uterine bleeding.
- With known anaphylactic reaction, angioedema, or hypersensitivity to Oriahnn or any of its components.
- Taking inhibitors of organic anion transporting polypeptide (OATP)1B1 (a hepatic uptake transporter) that are known or expected to significantly increase elagolix plasma concentrations

Elagolix causes a dose-dependent decrease in bone mineral density (BMD). BMD is greater with increasing duration of use and may not be completely reversible after stopping treatment. The impact of these BMD decreases on long-term bone health and future fracture risk are unknown. Consider assessment of BMD in patients with a history of a low-trauma fracture or other risk factors for osteoporosis or bone loss, and do not use in women with known osteoporosis.[1]

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Document History

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Annual Review Prime Standard criteria, with changes, to be approved by P&T UM Committee 09/2020
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Document History – BCBS KS

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Client Specific Annual Review, Prime Standard criteria, with changes, approved by BCBS KS 09/2020
Client Specific Annual Review Prime Standard criteria, with changes to criteria, to be approved by BCBS KS 10/2021

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Elagolix/Relugolix Prior Authorization with Quantity Limit

TARGET AGENT(S)

Myfembree® (relugolix, estradiol hemihydrate, norethindrone acetate)
Oriahnn™ (elagolix, estradiol, norethindrone acetate)
Orilissa® (elagolix)

Brand (generic)	GPI	Multisource Code	Quantity Limit (per day or as listed)
Myfembree (relugolix, estradiol hemihydrate, norethindrone acetate)			
40 mg-1 mg-0.5 mg tablet	24993503800320	M, N, O, or Y	1 tablet
Oriahnn (elagolix, estradiol, norethindrone acetate)			
300 mg-1 mg-0.5 mg capsule and 300 mg capsule therapy pack	2499350340B220	M, N, O, or Y	56 capsules (1 box)/ 28 days
Orilissa (elagolix)			
150 mg tablet	30090030100320	M, N, O, or Y	1 tablet
200 mg tablet	30090030100330	M, N, O, or Y	2 tablets

PRIOR AUTHORIZATION AND QUANTITY LIMIT CRITERIA FOR APPROVAL

Orilissa

Initial Evaluation

Target Agent(s) will be approved when ALL of the following are met:

1. The patient has a diagnosis of moderate to severe pain associated with endometriosis
   AND
2. The patient is premenopausal
   AND
3. ONE of the following:
   a. The patient has tried and had an inadequate response to ONE hormonal contraceptive used for the treatment of moderate to severe pain associated with endometriosis
      OR
   b. The patient has an intolerance or hypersensitivity to hormonal contraceptive therapy
      OR
   c. The patient has an FDA labeled contraindication to ALL hormonal contraceptive therapy (i.e., oral, topical patches, implants, injections, IUD)

   AND
4. The prescriber has confirmed the patient's bone health allows for initiating therapy with the requested agent
   AND
5. The patient will NOT be using the requested agent in combination with another GnRH antagonist agent targeted in this program (e.g., elagolix, relugolix) for the requested indication
   AND
6. The patient does NOT have any FDA labeled contraindications to the requested agent
   AND
7. ONE of the following:
   a. The patient does NOT have coexisting moderate hepatic impairment (Child-Pugh [CP]/ Child-Turcotte-Pugh [CTP] Class B) AND ONE of the following:
      i. The patient is initiating therapy with the requested agent and strength
         OR
      ii. The patient is not initiating therapy with the requested agent and strength and BOTH of the following:

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1. The prescriber has provided information indicating the number of months the patient has been on therapy
   AND
2. ONE of the following:
   a. The requested strength is 150 mg AND the total duration of treatment with the requested strength has NOT exceeded 24 months per lifetime
      OR
   b. The requested strength is 200 mg AND the total duration of treatment with the requested strength has NOT exceeded 6 months per lifetime

OR

b. The patient does have coexisting moderate hepatic impairment (Child-Pugh [CP]/ Child-Turcotte-Pugh [CTP] Class B) AND BOTH of the following:
   i. The requested strength is 150 mg
      AND
   ii. ONE of the following:
      1. The patient is initiating therapy with the requested agent and strength
         OR
      2. The patient is not initiating therapy with the requested agent and strength and BOTH of the following:
         a. The prescriber has provided information indicating the number of months the patient has been on therapy
            AND
         b. The total duration of treatment with the requested strength has NOT exceeded 6 months per lifetime

AND

8. The requested quantity (dose) does NOT exceed the program quantity limit

Length of Approval: Up to 6 months with a lifetime maximum of 24 months with the 150 mg without coexisting moderate hepatic impairment, a lifetime maximum of 6 months with the 150 mg with coexisting moderate hepatic impairment, and a lifetime maximum of 6 months with the 200 mg

Renewal Evaluation

Target Agent(s) will be approved when ALL of the following are met:

1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process (*please note requests for 200 mg strength should always be reviewed under initial criteria)
   AND
2. The patient is premenopausal
   AND
3. The patient has had clinical benefit with the requested agent
   AND
4. The prescriber has assessed the patient's bone health AND confirmed the patient's bone health allows for continued therapy with the requested agent
   AND
5. The patient has NOT had a fragility fracture since starting therapy with the requested agent
   AND
6. The patient will NOT be using the requested agent in combination with another GnRH antagonist agent targeted in this program (e.g., elagolix, relugolix) for the requested indication

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AND

7. The patient does NOT have any FDA labeled contraindications to the requested agent
   AND
8. BOTH of the following:
   a. The prescriber has provided information indicating the number of months the patient has been on therapy with the requested agent and strength
      AND
   b. ONE of the following:
      i. The patient does NOT have coexisting moderate hepatic impairment (Child-Pugh [CP]/ Child-Turcotte-Pugh [CTP] Class B) AND the total duration of treatment with the requested strength has NOT exceeded 24 months per lifetime
         OR
      ii. The patient does have coexisting moderate hepatic impairment (Child-Pugh [CP]/ Child-Turcotte-Pugh [CTP] Class B) AND the total duration of treatment with the requested strength has NOT exceeded 6 months per lifetime

   AND
9. The requested quantity (dose) does NOT exceed the program quantity limit

Length of Approval: Up to 6 months with a lifetime maximum of 24 months with the 150 mg without coexisting moderate hepatic impairment OR a lifetime maximum of 6 months with the 150 mg with coexisting moderate hepatic impairment

Oriahnn and Myfembree
Initial Evaluation
Target Agent(s) will be approved when ALL of the following are met:

1. The patient has a diagnosis of heavy menstrual bleeding associated with uterine leiomyomas (fibroids)
   AND
2. The patient's diagnosis of uterine fibroids was confirmed via imaging (e.g., ultrasound)
   AND
3. The patient is premenopausal
   AND
4. The prescriber has confirmed the patient's bone health allows for initiating therapy with the requested agent
   AND
5. The patient has NOT had a hysterectomy
   AND
6. ONE of the following:
   a. The patient has tried and had an inadequate response to at least ONE hormonal contraceptive used in the treatment of heavy menstrual bleeding
      OR
   b. The patient has an intolerance or hypersensitivity to at least ONE hormonal contraceptive used in the treatment of heavy menstrual bleeding
      OR
   c. The patient has an FDA labeled contraindication to ALL hormonal contraceptive therapy (i.e., oral, topical patches, implants, injections, IUD)

   AND
7. The patient will NOT be using the requested agent in combination with another GnRH antagonist agent targeted in this program (e.g., elagolix, relugolix) for the requested indication
   AND
8. The patient does NOT have any FDA labeled contraindications to the requested agent

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AND

9. ONE of the following:
    a. The patient is initiating therapy with the requested agent
    OR
    b. The patient is not initiating therapy with the requested agent and BOTH of the following:
        i. The prescriber has provided information indicating the number of months the patient has been on therapy
        AND
        ii. The total duration of treatment with the requested agent has NOT exceeded 24 months per lifetime

AND

10. The requested quantity (dose) does NOT exceed the program quantity limit

Length of Approval: Up to 6 months, with a lifetime maximum of 24 months

Renewal Evaluation

Target Agent(s) will be approved when ALL of the following are met:

1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process
AND
2. The patient has had clinical benefit with the requested agent
AND
3. The prescriber has assessed the patient's bone health AND confirmed the patient's bone health allows for continued therapy with the requested agent
AND
4. The patient has NOT had a fragility fracture since starting therapy with the requested agent
AND
5. The patient will NOT be using the requested agent in combination with another GnRH antagonist agent targeted in this program (e.g., elagolix, relugolix) for the requested indication
AND
6. The patient does NOT have any FDA labeled contraindications to the requested agent
AND
7. BOTH of the following:
    a. The prescriber has provided information indicating the number of months the patient has been on therapy
    AND
    b. The total duration of treatment with the requested agent has NOT exceeded 24 months per lifetime

AND

8. The requested quantity (dose) does NOT exceed the program quantity limit

Length of Approval: Up to 6 months, with a lifetime maximum of 24 months

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Elagolix/Relugolix Prior Authorization with Quantity Limit

ELECTRONIC EDIT
The overall process for a prior authorization will not allow the targeted agents to adjudicate through the claims system. When a patient requests a targeted agent, the system will reject the claim with the message indicating that prior authorization is necessary.

CLINICAL OPERATIONS PROGRAM SET-UP TYPE

☐ **Attestation only** – Skip table 1, no documentation requirements allowed
☒ **Validation** – Go to table 1
☐ **Documentation -**requirements as noted within the policy

If selecting Attestation, it must be selected alone. Neither Validation nor Documentation can be used with Attestation.

Attestation: Prescriber answers questions in reviewing system. Clinical Operations accepts answers as provided.

Validation: Prescriber inputs free text information in reviewing system or there is a requirement to validate data in RxClaims. Information is reviewed by Clinical Operations.

Documentation: Prescriber must submit documentation such as medical records, chart notes or lab reports. Documented information is reviewed by Clinical Operations. Use "medical record required" wording for general use. If a specific document type, such as lab reports or logs, is needed, specifically call it out instead of "medical record required"

Table 1 – Validation Requirements

Baseline validation*
• Previous Plan PA • FDA max dose • Dose optimization
Validation options
☐ Prerequisites • Claims validation- specific look-back defined in program summary. • New to plan or indefinite look-back **and** > 1 prerequisite, then collect information from prescriber. ☐ Continuation of Therapy • Claims validation-specific lookback defined in program summary • New to plan, indefinite look-back, or under medical drug benefit, then attestation • Risk with change (if applicable)-collect information from prescriber ☐ Required Concomitant Therapy • Claims validation to assess if overlap • New to plan or under medical drug benefit, then attestation ☐ Diagnosis (general FDA labeled, or compendia supported)- collect information ☐ Diagnostic criteria- collect test results from prescriber ☐ Lab values- collect lab values from prescriber ☒ Contraindication, intolerance, or hypersensitivity to prerequisites- prescriber to explain ☐ Age verification • Verify age is within label/compendia for indication listed in criteria • Verify information provided by prescriber justifying use of requested agent in the patient's age (if applicable)

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☐ Renewal – check for specific efficacy/improvement
☒ Other
☒ prescriber has provided information on how long the patient has already been on therapy with the requested agent and strength
_____

*Baseline validation applies to all programs with validation and/or documentation

Table 2- Other information

Other (RxClaims system set-up, additional instruction for CRU etc.)	**Formularies Applied to** (include implementation date if some delayed): This program applies to Commercial and HIM. **Program types implemented by client (check all that apply):** ☐ PA ☐ QL ☒ PAQL ☐ MDC ☐ ST ☐ Other_____ ☐ STQL **Preferred Product** (if client allowed to specify and not specifically noted in criteria): ☒ Not applicable ☐ Yes: [List preferred(s)] **Target Drugs** (if varies or client allowed to specify and not specifically noted in criteria): ☒ Not applicable ☐ Yes: [List targets] **NDC level set-up in RxClaim:** ☐ Yes ☒ No **PA Required at NDC Level:** ☐ Yes ☒ No **Other**

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