RX.PA.012.MPC GnRH Agonists & Antagonists

The purpose of this policy is to define the prior authorization process for the GnRH agonists and antagonists.

DEFINITIONS

PREFERRED	NON-PREFERRED – PA REQUIRED
GnRH Agonists & Antagonists	
Leuprolide soln for inj, kit (generic for Lupron soln for inj)	Firmagon (degarelix)
PREFERRED – PA REQUIRED	Lupron 1 mg/0.2 mL (5 mg/mL) soln for inj (leuprolide)
Eligard (leuprolide)	Supprelin LA (histrelin acetate)
Lupron Depot (leuprolide)	Trelstar (triptorelin pamoate)
Lupron Depot Ped (leuprolide)	Trelstar LA (triptorelin pamoate)
Vantas (histrelin acetate) implant	Triptodur (triptorelin)
Zoladex (goserelin)	Orilissa (elagolix)

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed under the respective diagnosis:

1. Breast Cancer:

- Must be prescribed by or in consultation with a specialist in the field to treat the patient's respective medical condition
- Must be age 18 years or older
    - Exceptions can be made for members less than 18 years of age if clinical rationale is provided from provider
- Prescribed dosing and indication of the requested medication must be within FDA approved indication and/or is supported by the medical compendium
- For Non-Preferred products:
    - Must have a documented adequate trial and failure (at least 3 months, documentation shall include strength, dosage form, dosage, and dates), contraindication, or intolerance to at least ONE preferred product

2. Prostate Cancer:

- Must be prescribed by or in consultation with a specialist in the field to treat the patient's respective medical condition
- Must have a diagnosis of advanced (stage III or IV) prostate cancer
- Must be age 18 years or older
    - Exceptions can be made for members less than 18 years of age if clinical rationale is provided from provider

- Prescribed dosing and indication of the requested medication must be within FDA approved indication and/or is supported by the medical compendium
- For Non-Preferred products:
    - Must have a documented adequate trial and failure (at least 3 months, documentation shall include strength, dosage form, dosage, and dates), contraindication, or intolerance to at least ONE preferred product

3. Endometriosis:

- Orilissa: Patient must not have received more than 24 months of the 150mg once daily dose or more than 6 months of the 200mg twice daily dose
- All other products: Patient must not have received more than 12 months of cumulative doses
- Must be prescribed by or in consultation with a specialist in the field to treat the patient's respective medical condition
- Must be age 18 years or older
    - Exceptions can be made for members less than 18 years of age if clinical rationale is provided from provider
- Prescribed dosing and indication of the requested medication must be within FDA approved indication and/or is supported by the medical compendium
- For Non-Preferred products:
    - Must have a documented adequate trial and failure (at least 3 months, documentation shall include strength, dosage form, dosage, and dates), contraindication, or intolerance to at least ONE preferred product
    - **Note:** Oral contraceptive and long acting reversal contraceptives (LARCs such as the IUDs) will be accepted as preferred medication trials for a diagnosis of endometriosis

4. Uterine Leiomyomata (fibroids):

- Patient must not have received more than 6 months of cumulative doses
- Must be prescribed by or in consultation with a specialist in the field to treat the patient's respective medical condition
- Must be age 18 years or older
- Prescribed dosing and indication of the requested medication must be within FDA approved indication and/or is supported by the medical compendium
- If the patient has anemia (Hgb <10.2 g/dL or Hct <30%), then must have ONE of the following:
    - Documentation of a trial (1-3 months) of iron therapy alone to correct the anemia

    - Patient has a documented medical reason (contraindication, hypersensitivity, intolerance, etc.) not to use iron alone to manage the anemia
- Patient requires the requested medication to decrease uterine volume as a result of uterine fibroids to manage symptoms (i.e., pelvic pressure, pelvic fullness, urinary frequency, nocturia, constipation, and/or anemia) and for shrinkage of size to allow surgical intervention
- For Non-Preferred products:
    - Must have a documented adequate trial and failure (at least 3 months, documentation shall include strength, dosage form, dosage, and dates), contraindication, or intolerance to at least ONE preferred product

5. Endometrial Thinning:

- Patient must not have received more than 3 months of cumulative doses
- Must be prescribed by or in consultation with a specialist in the field to treat the patient's respective medical condition
- Prescribed dosing and indication of the requested medication must be within FDA approved indication and/or is supported by the medical compendium
- Must have documentation that the patient is scheduled for endometrial ablation for dysfunctional uterine bleeding
- For Non-Preferred products:
    - Must have a documented adequate trial and failure (at least 3 months, documentation shall include strength, dosage form, dosage, and dates), contraindication, or intolerance to at least ONE preferred product

6. Central precocious puberty (CPP):

- Must be prescribed by or in consultation with a specialist in the field to treat the patient's respective medical condition
- Must have a diagnosis confirmed by a pubertal response to a GnRH stimulation test AND bone age advanced one year beyond chronicle age
- Must have documented baseline evaluations, including ultrasound, CT, MRI, and laboratory levels, to rule out a tumor
- Prescribed dosing and indication of the requested medication must be within FDA approved indication and/or is supported by the medical compendium
- Must have ONE of the following:
    - For patients assigned female at birth, must have onset of secondary sexual characteristics occur prior to 8 years of age
    - For patients assigned male at birth, must have onset of secondary sexual characteristics occur prior to 9 years of age

- For Non-Preferred products:
    - Must have a documented adequate trial and failure (at least 3 months, documentation shall include strength, dosage form, dosage, and dates), contraindication, or intolerance to at least ONE preferred product

Note: Documentation MUST include either paid claims OR specific dates of use for medication trials AND/OR chart documentation from the provider noting a contraindication, intolerance, or failure to all pre-requisite medications

Reauthorization Criteria:

All prior authorization renewals are reviewed to determine the Medical Necessity for continuation of therapy. Authorization may be based upon meeting the criteria for each diagnosis listed below:

1. **Breast Cancer:**
    - Must be age 18 years or older
    - Must have documentation demonstrating the clinical benefits of the requested medication supporting continued treatment OR the requested medication is being continued in accordance with the recommended time as defined by FDA drug package insert, and/or per recommendations of the medical compendium as described above, and/or per the NCCN, ASCO, ACOG or AAP standard of care guidelines
    - Must be prescribed by a specialist in the field to treat the patient's respective medical condition

2. **Prostate Cancer:**
    - Must have documentation demonstrating the clinical benefits of the requested medication supporting continued treatment OR the requested medication is being continued in accordance with the recommended time as defined by FDA drug package insert, and/or per recommendations of the medical compendium as described above, and/or per the NCCN, ASCO, ACOG or AAP standard of care guidelines
    - Must be prescribed by or in consultation with a specialist in the field to treat the patient's respective medical condition

3. **Endometriosis:**
    - Injectable products: Must not exceed total of 12 months of GnRH agonist treatment
    - Orilissa 200mg: must not exceed a maximum of 6 months treatment

- Orilissa 150mg: must not exceed a maximum of 24 months treatment
- If the patient has had more than 6 months of therapy, then must have ALL the following:
    - Must have chart documentation or claim history indicating member is receiving OR will be receiving add-back hormonal therapy (such as norethindrone 5mg daily or conjugated estrogen therapy), unless contraindicated or is intended to receive anti-osteoporosis therapy
    - Must not have osteoporosis
    - Must be receiving calcium (at least 1,200 mg/day) and vitamin D (400-800 units/day) therapy
- Must have documentation demonstrating the clinical benefits of the requested medication supporting continued treatment OR the requested medication is being continued in accordance with the recommended time as defined by FDA drug package insert, and/or per recommendations of the medical compendium as described above, and/or per the NCCN, ASCO, ACOG or AAP standard of care guidelines
- Must be prescribed by a specialist in the field to treat the patient's respective medical condition

4. Uterine Leiomyomata (fibroids):

- Must not exceed total of 6 months of GnRH agonist treatment
- Must have documentation demonstrating the clinical benefits of the requested medication supporting continued treatment OR the requested medication is being continued in accordance with the recommended time as defined by FDA drug package insert, and/or per recommendations of the medical compendium as described above, and/or per the NCCN, ASCO, ACOG or AAP standard of care guidelines
- Must be prescribed by a specialist in the field to treat the patient's respective medical condition

5. Central precocious puberty (CPP):

- Must have ONE of the following:
    - For patients assigned female at birth, must be younger than 11 years of age
    - For patients assigned male at birth, must be younger than 12 years of age
- Must have documentation demonstrating the clinical benefits of the requested medication supporting continued treatment OR the requested medication is being continued in accordance with the recommended time as defined by FDA drug package insert, and/or per recommendations of the medical compendium as

described above, and/or per the NCCN, ASCO, ACOG or AAP standard of care guidelines

- Must be prescribed by or in consultation with a specialist in the field to treat the patient's respective medical condition

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	• Prostate cancer, breast cancer, CPP: 12 months • Endometriosis: 6 months • Uterine leiomyomata (fibroids), endometrial thinning: 3 months
Reauthorization	• Prostate cancer, breast cancer, CPP: 12 months • Endometriosis: 6 months **Must NOT exceed 12 months of therapy** • Uterine leiomyomata (fibroids): 3 months

If the established criteria are not met, the request is referred to a Medical Director for review.

HCPCS Code:

Code	Description
J9226	Histrelin implant (Supprelin LA), 50 mg

REFERENCES

1. UpToDate. Classification and treatment of endometriosis.
2. Lapp T. Practice Guidelines: ACOG Issues Recommendations for the Management of Endometriosis. *Am Fam Physician*. 2000 Sep;62(6):1431.
3. UpToDate. Treatment of uterine leiomyomas.
4. UpToDate. Overview of precocious puberty.
5. Product Information: ORILISSA(TM) oral tablets, elagolix oral tablets. AbbVie Inc (per FDA), North Chicago, IL, 2018