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

Please continue to submit requests for oncology indications to Eviti.

PROCEDURE

A. Initial Authorization Criteria:

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

1. Endometriosis:

- 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

2. 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 (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

3. Endometrial Thinning:

- Patient must not have received more than 2 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

4. 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 chronological age
    - *Note: MPC will review one-time test dosage requests to confirm CPP per FDA approved indication of use
- 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

5. Gender Dysphoria:

- Member must have a diagnosis of gender dysphoria, according to current DSM criteria
- Must be prescribed by or in consultation with an endocrinologist

B. Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc) listed in the FDA approved labeling.

C. GnRH agonists/antagonists will be considered investigational or experimental for any other use and will not be covered.

D. 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:

MPC Renewal:

1. **Endometriosis:**
   - Injectable products: Must not exceed total of 12 months of cumulative GnRH agonist 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

2. **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

3. **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

4. Gender Dysphoria

- Documentation indicating continued improvement and benefit from treatment

Renewal from Previous Insurer:

- Members who have received prior approval (from insurer other than MPC), or have been receiving medication samples, should be considered under criterion A (Initial Authorization Criteria)
- Provider has documented clinical response of the member to treatment

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	• Endometriosis: 6 months • CPP and Gender Dysphoria: 12 months • Uterine leiomyomata (fibroids): 3 months • Endometrial thinning: 2 months
Reauthorization	• CPP and Gender Dysphoria: 12 months • Endometriosis: 6 months (must not exceed 12 months of cumulative therapy) • Uterine leiomyomata (fibroids): 3 months (must not exceed 6 months of lifetime cumulative therapy) • Endometrial thinning: None

HCPCS Code:

Code	Description
J9226	Histrelin implant (Supprelin LA), 50 mg
J9225	Histrelin implant (Vantas), 50 mg

J3316	Injection, triptorelin extended release, 3.75mg
J9217	Injection, leuprolide acetate, 7.5mg
J1950	Injection, leuprolide acetate, 3.75mg
J9155	Injection, degarelix, 1mg
J3315	Injection, triptorelin pamoate, 3.75mg
J3316	Injection, triptorelin, extended release, 3.75mg
J9218	Injection, leuprolide acetate, 1mg
J9202	Goserelin acetate implant, 3.6mg

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

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review *Addition of MPC Renewal vs Renewal from Previous Insurer*	*02/2024*
Selected Review *Reauthorization duration for* Uterine leiomyomata (fibroids) changed to a lifetime cumulative therapy of 6 months	*01/2024*
Annual review	*02/2023*
Annual review	*02/2022*
Addition of dosing requirements	*12/2021*
P&T Review – update to policy with covered indications and preferred/non-preferred options	*11/2021*
New Policy	*11/2020*