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)
	Fensolvi (leuprolide acetate)

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
  - Note: The total utilization of all products must not exceed 12 months
- 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 ALL preferred products
  - **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 in addition to trial and failure to all preferred products listed above

2. Uterine Leiomyomata (fibroids):

- Patient must not have received more than 6 months of cumulative doses
  - Note: The total utilization of all products must not exceed 6 months
- 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 ALL preferred products

3. Endometrial Thinning:

- Patient must not have received more than 2 months of cumulative doses
  - Note: The total utilization of all total must not exceed 2 months
- 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 2 months, documentation shall include strength, dosage form, dosage, and dates), contraindication, or intolerance to ALL preferred products

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 ALL preferred products

5. Gender Dysphoria/Incongruence:

- Member must have a documented diagnosis of gender dysphoria or gender incongruence
- Member's experience of gender dysphoria/incongruence is marked and sustained as attested by the provider
- The provider's attestation states they have tried to identify and exclude other possible causes of apparent gender dysphoria/incongruence prior to the initiation of gender affirming services
- Provider attestation that the patient does not have any contraindicating somatic or mental health conditions that would impair their ability to participate in informed consent. In the situation where a patient has a mental health condition that interferes with their capacity to give informed consent and understand the risks, benefits, and alternatives to gender affirming treatment, the provider should facilitate treatment of the underlying condition to support the individual's ability to provide informed consent
- Provider attestation that they have assessed the capacity of the member to

understand the effect of gender affirming treatment on reproduction and explore reproductive options with the member prior to the initiation of treatment

- Provider attestation that any mental health and somatic health conditions that could negatively impact the outcome of gender affirming medical treatments are assessed, with risks and benefits discussed, before a decision is made regarding treatment
- Patient has the desire to make their body as congruent as possible and gender dysphoria/incongruence causes clinically significant distress or impairment in social, occupational, or other important areas of functioning
- Gender dysphoria/incongruence is not a symptom of another medical disorder
- Patients ≥18 years old:
    - Documentation of medical necessity for Gender affirming Care from a Somatic Healthcare professional (SHP)/Primary Care Provider (PCP), or Mental Healthcare Professional (MHP), who has competencies in the assessment of transgender and gender diverse population is required
- Patients < 18 years old:
    - Documentation of medical necessity for Gender affirming Care from a multidisciplinary team that includes both somatic and mental health professionals that have competencies in the assessment of transgender and gender diverse population is required
    - Must have parental consent
    - Adolescent members must demonstrate the emotional and cognitive maturity required to provide informed consent/assent for treatment as attested by the provider
    - Adolescents must have reached Tanner stage 2 for puberty for pubertal suppression to be initiated
- Somatic Healthcare Professional must meet the following criteria:
    - Must possess one of the following degrees: MD, DO,NP, or PA
- Mental Healthcare professionals must meet the following criteria:
    - Must possess one of the following degrees: Ph.D., MD, DO, Ed.D., D.S.W., Psy.D, LCPC, LCSW-C, or NP
    - Must be trained in gender affirming care and have knowledge about gender diverse identities and expressions as attested by the provider
    - 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 ALL preferred products

6. Fertility Preservation:

- Must have documentation attached for a medical authorization approval for fertility preservation from MPC
    - Note: Medical procedural approval for fertility preservation is a separate prior authorization process
- Must have documentation of iatrogenic impairment of fertility due to one of the following:

  - Surgery
  - Radiation
  - Chemotherapy
  - Please provide documentation for other reasons
- Must provide documentation of a medical treatment or intervention that is affecting or expected to affect the reproductive organs or processes causing impairment of fertility
- Must provide documentation for the proposed fertility preservation services the member will receive
- Provider attestation of all FDA precautions/warnings, contraindications to treatment, and any Black Box Warnings have been evaluated
- The patient age must be either:
  - Within reproductive ages of puberty to menopause OR
  - Prepubertal age or there is insufficient time for oocyte retrieval for ovarian tissue cryopreservation

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. *Requests for Non-preferred products: 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 preferred medications*

E. <u>Reauthorization Criteria:</u>

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)
	Fensolvi (leuprolide acetate)

Please continue to submit requests for oncology indications to Eviti.

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
     - Note: The total utilization of all products must not exceed 12 months
   - 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
     - Note: The total utilization of all products must not exceed 6 months
   - 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/Incongruence:

- Documentation indicating continued improvement and benefit from treatment
- Patients ≥18 years old:
  - Documentation of medical necessity for Gender affirming Care from a Somatic Healthcare professional (SHP)/Primary Care Provider (PCP),or Mental Healthcare Professional (MHP), who has competencies in the assessment of transgender and gender diverse population is required
- Patients < 18 years old:
  - Documentation of medical necessity for Gender affirming Care from a multidisciplinary team that includes both somatic and mental health professionals that have competencies in the assessment of transgender and gender diverse population is required
  - Must have parental consent
  - Adolescent members must demonstrate the emotional and cognitive maturity required to provide informed consent/assent for treatment as attested by the provider
- Somatic Healthcare Professionals must meet the following criteria:
  - Must possess one of the following degrees: MD, DO, NP, or PA
- Mental Healthcare professionals must meet the following criteria:
  - Must possess one of the following degrees: Ph.D., MD, DO, Ed.D., D.S.W., Psy.D, LCPC, LCSW-C, or NP
  - Must be trained in gender affirming care and have knowledge about gender diverse identities and expressions as attested by the provider

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
- Doses received from the previous insurer will count towards the cumulative therapy restrictions per indication

Limitations

Length of Authorization (if above criteria met)	
Initial Authorization	• Endometriosis: 6 months • CPP: 12 months • Gender Dysphoria/Incongruence: 3 months • Uterine leiomyomata (fibroids): 3 months • Endometrial thinning: 2 months • Fertility Preservation: 3 months
Reauthorization	• CPP and Gender Dysphoria/Incongruence: 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: Reauthorization not allowed • Fertility Preservation: Reauthorization not allowed

HCPCS Code

Code	Description
J9226	Histrelin implant (Supprelin LA), 50 mg
J9225	Histrelin implant (Vantas), 50 mg
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
Update to include preferred vs non-preferred medication table in the reauthorization criteria	*07/2026*
Annual review	*02/2026*
Addition of criteria requirements for fertility preservation	*06/2025*
Annual review	*02/2025*
Additional criteria requirements for gender dysphoria/Incongruence *Addition of Fensolvi (leuprolide acetate) as a non-preferred agent*	*12/2024*
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*