AETNA BETTER HEALTH®

Prior Authorization guideline for Gonadotropin Releasing Hormone (GnRH) Analogs

- Leuprolide acetate - preferred
- Lupanta Pack (leuprolide and norethindrone)
- Lupron Depot/ Lupron Depot-PED
- Eligard - preferred
- Trelstar
- Triptodur
- Vantas
- Synarel
- Supprelin LA
- Zoladex - preferred

Authorization guidelines

Leuprolide acetate, Eligard and Zoladex are the preferred agents. Requests for non-preferred agents require trial of one of the preferred agents in addition to clinical criteria (exception for gender dysphoria/gender incongruence).

For members who meet the following based on diagnosis:

Endometriosis
A. Prescribed by or in consultation with a gynecologist or obstetrician
B. Member is at least 18 years of age or older
C. Diagnosis of Endometriosis
D. Trial and failure of at least one formulary hormonal cycle control agent (such as Portia, Ocella, Previfem), medroxyprogesterone, or Danazol
E. Trial of one preferred Gonadotropin Releasing Hormone (GnRH) Analog

Uterine Leiomyomata
A. Member is at least 18 years of age or older
B. Prescribed by or in consultation with a gynecologist or obstetrician
C. Prescribed to improve anemia and/or reduce uterine size prior to planned surgical intervention
D. Trial and failure of iron to correct anemia
E. Trial of one preferred Gonadotropin Releasing Hormone (GnRH) Analog OR clinical rationale as to why preferred agent(s) is not appropriate for the member
Endometrial Thinning/Dysfunctional Uterine Bleeding
A. Member is at least 18 years of age or older
B. Prescribed by or in consultation with a gynecologist or obstetrician
C. Prescribed to thin endometrium prior to planned endometrial ablation or hysterectomy within the next 4-8 weeks
D. Trial of one preferred Gonadotropin Releasing Hormone (GnRH) Analog

Central Precocious Puberty (CPP)
A. Prescribed by, or in consultation with an Endocrinologist
B. Magnetic Resonance Imaging (MRI) or Computed Tomography (CT) Scan has been performed to rule out brain lesions or tumors
C. Onset of secondary sexual characteristics earlier than 8 years in females and 9 years in males
D. Response to a GnRH stimulation test (or if not available, other labs to support CPP such as luteinizing hormone levels, estradiol and testosterone level)
E. Bone age advanced 1 year beyond the chronological age
F. Baseline height and weight
G. Trial of one preferred Gonadotropin Releasing Hormone (GnRH) Analog OR clinical rationale as to why preferred agent(s) is not appropriate for the member

Advanced Prostate Cancer
A. Trial of one preferred Gonadotropin Releasing Hormone (GnRH) Analog
B. Member is at least 18 years old
C. Prescribed by, or in consultation with oncologist or urologist

Advanced Breast Cancer
A. Prescribed by, or in consultation with oncologist
B. Member is at least 18 years old
C. Trial of one preferred Gonadotropin Releasing Hormone (GnRH) Analog

Ovarian Cancer
A. Member is at least 18 years of age
B. Trial of one preferred Gonadotropin Releasing Hormone (GnRH) Analog OR clinical rationale as to why preferred agent(s) is not appropriate for the member
C. Prescribed by, or in consultation with an oncologist
D. For recurrent ovarian cancer, member cannot tolerate or does not respond to cytotoxic regimens OR the drug is being used for post-operative management

Gender Dysphoria/Gender Incongruence in adolescents
Documentation of ALL of the following:
A. Prescribed by or in consultation with a pediatric endocrinologist, adolescent medicine specialist or medical provider with experience and/or training in transgender medicine
B. Documentation of collaboration with a (Mental Health Provider) MHP
C. Diagnosed with Gender Dysphoria as supported by Diagnostic and Statistical Manual of Mental Disorders DSM criteria and International Classification of Diseases (ICD-code)
D. Member exhibits signs of puberty with a minimum Tanner stage 2
E. Member has made a fully informed decision and has given consent and parent/guardian has provided consent to treatment [note: when parental consent cannot be obtained, exceptions will be reviewed on a case by case basis and in conjunction with the behavioral health provider]
F. The member’s comorbid conditions are reasonably controlled
G. Member has been educated on any contraindications and side effects to therapy
H. Member has been informed of fertility preservation options prior to treatment

Gender Dysphoria/Gender Incongruence in Adults
Documentation of ALL of the following:
A. Member is 18 years of age or older
B. Prescribed by or in consultation with an endocrinologist, adolescent medicine specialist or medical provider with experience and/or training in transgender medicine
C. Documentation of collaboration with a (Mental Health Provider) MHP
D. Diagnosed with Gender Dysphoria as supported by Diagnostic and Statistical Manual of Mental Disorders DSM criteria and International Classification of Diseases (ICD-code)
E. The member has the capacity to make a fully informed decision and consents to treatment
F. Mental health concerns, if present, are reasonably well controlled
G. Member has been informed of fertility preservation options prior to treatment

Additional Information:
These agents are NOT covered for members with the following criteria:
• Use not approved by the FDA; AND
The use is unapproved and not supported by the literature or evidence as an accepted off-label use.

### Table 1. Accepted Medical Uses by Product

<table>
<thead>
<tr>
<th>LEUPROLIDE ACETATE (Lurpon, Eligard, Viadur)</th>
<th>GOSERELIN ACETATE (Zoladex)</th>
<th>HISTRELI LIN (Vantas, Suppralin LA)</th>
<th>TRIPTORELIN (Trelstar, Triptodur)</th>
<th>DEGARELIX (Firmagon)</th>
<th>NAFARELIN (Synarel) *</th>
<th>LEUPROLIDE ACETATE + NORETHINDRONE (Luneneta Pak)</th>
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</thead>
<tbody>
<tr>
<td>Endometriosis</td>
<td>X</td>
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<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>Uterine Fibroids</td>
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<tr>
<td>Endometrial Thinning</td>
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<tr>
<td>Dysfunctional uterine bleeding</td>
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<tr>
<td>Central Precocious Puberty</td>
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<tr>
<td>Advanced Prostate CA</td>
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<td>Advanced Breast CA</td>
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<tr>
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</table>

**Approval Duration:**

**Initial Approval:**
- **Central Precocious Puberty (CPP)**
  - Supprelin LA: 12 months
  - All others: 6 months
- **Endometriosis:** 6 months
- **Uterine Leiomyomata (fibroids):** 3 months
- **Dysfunctional uterine bleeding:** 2 months
- **Prostate/Breast Cancer:** 2 years
- **Gender Dysphoria:** 6 months

**Renewal:**

**Central Precocious Puberty (CPP)**
- 6 months - 1 year (up to age 11 for females and age 12 for males)
- Requires clinical response to treatment (i.e., pubertal slowing or decline, height velocity, bone age, LH, or estradiol and testosterone level)
Endometriosis Retreatment
- Lupron only (treatment with Synarel and Zoladex not recommended beyond 6 months):
  - 6 months
- Requires:
  - Bone mineral density within normal limits
  - Use in combination with norethindrone acetate

Uterine Leiomyomata (fibroids) or Dysfunctional Uterine Bleeding
- Long-term use is not recommended
- Retreatment may be considered on a case by case basis

Gender Dysphoria
- Approval: 12 months

Requires: lab result to support response to treatment (i.e., FSH, LH, weight, height, tanner stage, bone age)

Medically Necessary — A service or benefit is Medically Necessary if it is compensable under the MA Program and if it meets any one of the following standards:

- The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.

- The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.

- The service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

Determination of Medical Necessity for covered care and services, whether made on a Prior Authorization, Concurrent Review, Retrospective Review, or exception basis, must be documented in writing.

The determination is based on medical information provided by the Member, the Member’s family/caretaker and the Primary Care Practitioner, as well as any other Providers, programs, agencies that have evaluated the Member.
All such determinations must be made by qualified and trained Health Care Providers. A Health Care Provider who makes such determinations of Medical Necessity is not considered to be providing a health care service under this Agreement.

References:


