Pharmacy Medical Necessity Guidelines: Leuprolide Acetate

Effective: July 11, 2017

<table>
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<tr>
<th>Prior Authorization Required</th>
<th>✓</th>
<th>Type of Review – Care Management</th>
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<tbody>
<tr>
<td>Not Covered</td>
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<td>Type of Review – Clinical Review</td>
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Pharmacy (RX) or Medical (MED) Benefit

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<th>MB Department to Review</th>
<th>MM</th>
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This Pharmacy Medical Necessity Guideline applies to the following:

**Tufts Health Plan Commercial Plans**
- ☑ Tufts Health Plan Commercial Plans – large group plans
- ☑ Tufts Health Plan Commercial Plans – small group and individual plans

**Tufts Health Public Plans**
- ☑ Tufts Health Direct – Health Connector
- ☑ Tufts Health Together – A MassHealth Plan
- ✗ Tufts Health RITogether – A Rite Care + Rhody Health Partners Plan

**Tufts Health Freedom Plan products**
- ☑ Tufts Health Freedom Plan - large group plans
- ☑ Tufts Health Freedom Plan - small group plans

**Fax Numbers:**
- MM: 888.415.9055

**OVERVIEW**

**FDA-APPROVED INDICATIONS**

- **Eligard (leuprolide acetate) Kit for Subcutaneous Use** is indicated for the palliative treatment of advanced prostate cancer.

- **Leuprolide Injection** (leuprolide acetate) is indicated in the palliative treatment of advanced prostatic cancer.

- **Lupron Depot®** (leuprolide acetate for depot suspension) 7.5 mg for 1-month administration, 22.5 mg for 3-month administration, 30 mg for 4-month administration, and 45 mg for 6-month administration are indicated in the palliative treatment of advanced prostatic cancer.

- **Lupron Depot®** (leuprolide acetate for depot suspension) 3.75 mg for 3-month administration is indicated

  - For management of endometriosis, including pain relief and reduction of endometriotic lesions. Duration of initial treatment or retreatment should be limited to 6 months.
  - Concomitantly with iron therapy for the preoperative hematologic improvement of patients with anemia caused by uterine leiomyomata. The clinician may wish to consider a one-month trial period on iron alone inasmuch as some of the patients will respond to iron alone. Lupron Depot may be added if the response to iron alone is considered inadequate. Experience with Lupron Depot in females has been limited to women 18 years of age and older.

- **Lupron Depot®** (leuprolide acetate for depot suspension) 11.25 mg for 3-month administration is indicated

  - For management of endometriosis, including pain relief and reduction of endometriotic lesions. Duration of initial treatment or retreatment should be limited to 6 months.
  - Concomitantly with iron therapy for the preoperative hematologic improvement of patients with anemia caused by uterine leiomyomata. The clinician may wish to consider a one-month trial period on iron alone inasmuch as some of the patients will respond to iron alone. Lupron Depot may be added if the response to iron alone is considered inadequate. Experience with Lupron Depot–3 Month 11.25 mg in females has been limited to women 18 years of age and older treated for no more than 6 months.

- **Lupron Depot-Ped®** (leuprolide acetate for depot suspension) is indicated in the treatment of children with central precocious puberty.

**COVERAGE GUIDELINES**

The plan may authorize coverage of leuprolide acetate injection, Lupron Depot, Lupron Depot-Ped or Eligard for Members when all the following criteria are met and limitations do not apply:

- **Central Precocious Puberty (Lupron Depot-Ped)**
  1. The Member is a female less than 11 years of age or a male less than 12 years of age.

- **Endometriosis (leuprolide acetate injection, Lupron Depot)**
1. Member has tried and failed therapy with, or there is a contraindication or intolerance to, hormonal therapy with one of the following: oral contraceptives, progestins or androgens

OR

2. Member is new to the plan and was stabilized on leuprolide for endometriosis prior to enrollment.

**Uterine Leiomyomata (leuprolide acetate, Lupron Depot)**
1. Member has diagnosis of uterine leiomyomata.

**Oncology Indications (Eligard, leuprolide acetate, Lupron Depot)**
1. Member has a diagnosis of prostate cancer

OR

2. Member has another form of cancer and treatment guidelines (see below) support the use of leuprolide for the condition.

**Transgender Dysphoria or Status-post Transgender Surgery**
1. Member has a diagnosis of transgender dysphoria or status-post transgender surgery

**Blockade of puberty**
1. Member is a transgender adolescent

AND

2. The prescriber is an endocrinologist

**LIMITATIONS**
1. Initial requests will be approved for the following durations:
   a. Endometriosis: 6 months
   b. Precocious Puberty: Until the age of 11 if female or the age of 12 if male
   c. Uterine Fibroid Tumors: 3 months
   d. Prostate cancer or other forms of cancer: life of plan

2. Subsequent authorizations for endometriosis may be given in 12 month intervals when the Member meets the following criteria:
   a. Member has been on leuprolide therapy for less than 12 months

   AND

   b. Member is concurrently receiving leuprolide with add-back progestin therapy, or add-back estrogen-progestin therapy

   OR

   c. Provider indicates clinical inappropriateness to hormonal therapy and alternative regimens (i.e. low dose leuprolide or longer dosing intervals) or alternative agents being prescribed to address leuprolide's hypoestrogenic (bone density) effects, or is BMD closely monitored.

   OR

   d. Member has been on leuprolide therapy for 12 months or greater

   AND

   e. Member has tried and failed surgical interventions, or did the provider indicate surgical interventions are not indicated for this patient

   AND

   f. Member is concurrently receiving leuprolide with add-back progestin therapy, or add-back estrogen-progestin therapy

   OR

   g. Provider indicates clinical inappropriateness to hormonal therapy and alternative regimens (i.e. low dose leuprolide or longer dosing intervals) or alternative agents being prescribed to address leuprolide's hypoestrogenic (bone density) effects, or is BMD closely monitored.

3. Subsequent authorizations for endometriosis may be given up to 3 months when the Member meets the following criteria:
   a. Member has been on leuprolide therapy for 12 months or greater

   AND

   b. Member has not tried and failed surgical interventions, or did the provider indicate surgical interventions are not indicated for this patient
c. Member has related surgery in the near future.

4. Subsequent authorizations for uterine fibroid tumors may be given in 12 month intervals when the Member meets the following criteria:
   a. Member has tried and failed surgical interventions, or did the provider indicate surgical interventions are not indicated for this patient
   
   AND
   
   b. Member is concurrently receiving leuprolide with add-back progestin therapy, or add-back estrogen-progestin therapy
   
   OR
   
   c. Provider indicates clinical inappropriateness to hormonal therapy and alternative regimens (i.e. low dose leuprolide or longer dosing intervals) or alternative agents being prescribed to address leuprolide’s hypoestrogenic (bone density) effects, or is BMD closely monitored.

5. Subsequent authorizations for endometriosis may be given up to 3 months when the Member meets the following criteria:
   a. Member has not tried and failed surgical interventions, or did the provider indicate surgical interventions are not indicated for this patient
   
   AND
   
   b. Member has related surgery in the near future.

CODES

The following HCPCS/CPT code(s) are:

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<th>Code</th>
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<tr>
<td>J1950</td>
<td>Injection, leuprolide acetate (for depot suspension), per 3.75 mg</td>
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<tr>
<td>J9217</td>
<td>Leuprolide acetate (for depot suspension), 7.5 mg</td>
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<tr>
<td>J9218</td>
<td>Leuprolide acetate, per 1 mg</td>
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REFERENCES


11. Lupron Depot (leuprolide acetate for depot suspension 7.5 mg, 22.5 mg, 30 mg, 45 mg) [package insert]. North Chicago, IL: AbbVie Inc.; June 2014.
12. Lupron Depot-Ped (leuprolide acetate for depot suspension 7.5 mg, 11.25 mg, 15 mg, 30 mg) [package insert]. North Chicago, IL: Abbott Laboratories; June 2013.

**APPROVAL HISTORY**

October 2006: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
- August 12, 2014: No Changes
- November 10, 2015: Changed title from Leuprolide, Lupron®, Lupron-Depot®, Lupron Depot-Ped®, Eligard® (leuprolide) to Leuprolide Acetate. Removed Lupron, product has been discontinued.
- January 1, 2016: Administrative change to rebranded template.
- May 10, 2016: Added indication of blockade of puberty for adolescent members who are transgender. Removed infertility indication as this coverage is only applicable to Commercial plans.
- July 11, 2017: No changes

**BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION**

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with a Member’s benefit document and in coordination with the Member’s physician(s). The plan makes coverage decisions on a case-by-case basis considering the individual Member’s health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member’s benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLink℠ Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

Pharmacy Medical Necessity Guidelines:
Leuprolide Acetate
For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to Member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.