## Overview

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

### FDA-Approved Indication

1. 
   Lupron Depot 3.75 mg and Lupron Depot-3 Month 11.25 mg are indicated for management of endometriosis, including pain relief and reduction of endometriotic lesions. Lupron Depot 3.75 mg monthly and Lupron Depot-3 Month 11.25 mg with norethindrone acetate 5 mg daily are also indicated for initial management of endometriosis and for management of recurrence of symptoms. Duration of initial treatment or retreatment should be limited to six months.

2. 
   When used concomitantly with iron therapy, Lupron Depot 3.75 mg and Lupron Depot-3 Month 11.25 mg are indicated 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 may be added if the response to iron alone is considered inadequate. Recommended duration of therapy is up to 3 months, either given as Lupron Depot 3.75 mg monthly or as a single injection of Lupron Depot-3 Month 11.25 mg. Lupron Depot-3 Month 11.25 mg is indicated only for women for whom three months of hormonal suppression is deemed necessary.

### Compendial Uses

<table>
<thead>
<tr>
<th>Plan</th>
<th>Benefit</th>
<th>Specialty Limitations</th>
<th>Specialty Medications</th>
<th>Non-Specialty Medications</th>
<th>Medical Specialty Medications (NLX)</th>
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<tbody>
<tr>
<td>☒ MassHealth</td>
<td>☒ Pharmacy Benefit</td>
<td>This medication has been designated specialty and must be filled at a contracted specialty pharmacy when obtained through the pharmacy benefit.</td>
<td>All Plans Phone: 866-814-5506 Fax: 866-249-6155</td>
<td>MassHealth Phone: 877-433-7643 Fax: 866-255-7569</td>
<td>All Plans Phone: 844-345-2803 Fax: 844-851-0882</td>
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<td>☒ Commercial/Exchange</td>
<td>☒ Medical Benefit (NLX)</td>
<td></td>
<td>Commercial Phone: 800-294-5979 Fax: 888-836-0730</td>
<td>Exchange Phone: 855-582-2022 Fax: 855-245-2134</td>
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### Exceptions

N/A
1. Breast cancer (Lupron Depot 3.75mg, 7.5mg; Lupron Depot-3 Month 11.25mg, 22.5mg)
2. Ovarian Cancer (Lupron Depot 3.75mg, 11.25mg)
   a. Epithelial ovarian cancer/fallopian tube cancer/primary peritoneal cancer
   b. Malignant sex cord-stromal tumors
3. Preoperative use in uterine leiomyomata (fibroids) to facilitate surgery (Lupron Depot 3.75mg, Lupron Depot-3 Month 11.25mg)
4. Gender dysphoria (also known as gender non-conforming or transgender persons) (3.75mg, 7.5mg, 11.25mg, 22.5mg)

Coverage Guidelines

Endometriosis
Authorization may be granted for the initial treatment of endometriosis.

Uterine leiomyomata (fibroids)
Authorization may be granted for the initial treatment of uterine leiomyomata (fibroids) when either of the following criteria is met:
1. Member has anemia due to uterine leiomyomata
   OR
2. Lupron Depot will be used prior to surgery for uterine leiomyomata

Breast Cancer
Authorization may be granted for the treatment of breast cancer.

Ovarian Cancer
Authorization may be granted for treatment of epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer.
   OR
Authorization may be granted for treatment of malignant sex cord-stromal tumors.

Gender dysphoria
Authorization may be granted for pubertal suppression in preparation for gender reassignment in an adolescent member when ALL the following criteria are met:
1. Member has a diagnosis of gender dysphoria.
2. Member has reached Tanner stage 2 of puberty
   OR
Authorization may be granted for gender reassignment in an adult member when ALL the following criteria are met:
1. Member has a diagnosis of gender dysphoria.
2. Member will receive Lupron Depot concomitantly with cross sex hormones.

Continuation of Therapy
Reauthorization may be granted for members, including those who are new to AllWays Health Partners, when ALL initial authorization criteria are met in addition to the following Diagnosis-Specific criteria (if applicable):
1. For endometriosis, reauthorization may be granted for the retreatment of endometriosis.
2. For uterine leiomyomata (fibroids), reauthorization may be granted when either of the following criteria is met:
a. Member has anemia due to uterine leiomyomata.
   **OR**
   b. Lupron Depot will be used prior to surgery for uterine leiomyomata

**Limitations**

1. Initial approvals will be varied based on the treatment:
   a. **For endometriosis**, approvals will be for up to 6 months.
   b. **For uterine leiomyomata**, approvals will be for up to 3 months.
   c. **For breast cancer, ovarian cancer, or gender dysphoria**, approvals will be for 12 months.

2. Reauthorizations will be varied based on the treatment:
   a. **For endometriosis**, approvals will be for up to 6 months.
      i. Note: A lifetime maximum of 12 months total.
   b. **For uterine leiomyomata**, approvals will be for up to 3 months.
      i. Note: A lifetime maximum of 6 months total.

3. Experience with Lupron Depot in females has been limited to women 18 years of age and older.
4. Experience with the Lupron Depot-3 Month 11.25 mg formulation has been limited to treatment for no more than 6 months.
5. Dosing recommendations:

<table>
<thead>
<tr>
<th>Indications</th>
<th>Dose</th>
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<tr>
<td>Endometriosis, including pain relief and reduction of endometriotic lesions</td>
<td>Lupron Depot 3.75 mg</td>
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<td>Lupron Depot-3 Month 11.25 mg</td>
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<tr>
<td>Initial management of endometriosis and management of recurrence of symptoms</td>
<td>Lupron Depot 3.75 mg monthly</td>
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<td>Lupron Depot-3 Month 11.25 mg with norethindrone acetate 5 mg daily</td>
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<tr>
<td>Breast cancer</td>
<td>Lupron Depot 3.75mg, 7.5mg</td>
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<td></td>
<td>Lupron Depot-3 Month 11.25mg, 22.5mg</td>
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<tr>
<td>Ovarian cancer (Epithelial ovarian cancer/fallopian tube cancer/primary peritoneal cancer &amp; Malignant sex cord-stromal tumors)</td>
<td>Lupron Depot 3.75mg, 11.25mg</td>
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<tr>
<td>Preoperative use in uterine leiomyomata (fibroids)</td>
<td>Lupron Depot 3.75mg</td>
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<td>Gender dysphoria (a.k.a. gender non-conforming or transgender persons)</td>
<td>Lupron Depot 3.75mg</td>
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<td>Lupron Depot-3 Month 11.25mg, 22.5mg</td>
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</tbody>
</table>

**References**

1. Lupron (leuprolide) [prescribing information]. North Chicago, IL: AbbVie Inc; December 2018.
2. Lupron Depot 1-month 7.5 mg, 3-month 22.5 mg, 4-month 30 mg, 6-month 45 mg (leuprolide) [prescribing information]. North Chicago, IL: AbbVie Inc; March 2019.
month 11.25 mg (leuprolide) [prescribing information]. North Chicago, IL: AbbVie Inc; April 2018.
4. Lupron Depot-PED (leuprolide) [prescribing information]. North Chicago, IL: AbbVie Inc; May 2017

Review History
06/19/19 – Reviewed

Disclaimer
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