MDWISE PRIOR AUTHORIZATION PROTOCOL FOR
GONADOTROPIN RELEASING HORMONE AGONISTS (GnRH)

Eligard® 7.5 mg, 22.5 mg, 30 mg, and 45 mg
Firmagon® 80mg and 120mg vial
Leuprolide Acetate (Lupron®) injection 5 mg/mL (2.8 mL)
Lupron Depot®: 3.75 mg, 7.5 mg
Lupron Depot®-3 Month: 11.25 mg, 22.5 mg
Lupron Depot®-4 Month: 30 mg
Lupron Depot-Pedo®: 7.5 mg, 11.25 mg, 15 mg
Supprelin® LA 50 mg
Trelstar®: 3.75mg, 11.25mg, 22.5mg
Vantas Implant® 50 mg
Zoladex® 3.6 mg and 10.8 mg

Initial Approval:

- The request for the medication is for an Food and Drug Administration (FDA) approved indication, and/or is used for a medical condition that is supported by the medical compendium (Micromedex, American Hospital Formulary Service (AHFS), Drug Points, Drug Package Insert) as defined in the Social Security Act 1927 and/or per the National Comprehensive Cancer Network (NCCN), the American Society of Clinical Oncology (ASCO), The American College of Obstetricians and Gynecologists (ACOG), or the American Academy of Pediatrics (AAP) standard of care guidelines.

- If the medication request is for any other GnRH agonist other than Lupron, the patient has a documented treatment failure after receiving an adequate trial (including dates of 3 months or more of therapy) of Lupron and/or has another documented medical reason (intolerance, hypersensitivity, contraindication, etc) for not utilizing Lupron to treat their medical condition.

- If the medication request is for the treatment of a confirmed diagnosis of endometriosis, the patient is an adult female (.18 y/o) who does not have documented Osteoporosis.

- If the medication request is for the treatment of fibroids, the patient is an adult female (.18 y/o) and ONE of the following apply to the patient:
  1. The patient is anemic (Hgb < 10.2 g/dl or Hct of < 30%) attributed to fibroids and the patient has had a one to three month trial of iron therapy alone which is (consistent with pharmacy claims data, OR for new members to the health plan consistent with medical chart history) to try and correct the anemia or there is a medical reason (intolerance, hypersensitivity, contraindication, etc) for not using iron alone to manage the anemia.
  2. The patient requires the 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.

- If the medication request is for the treatment of endometrial thinning, documentation was submitted indicating the patient is scheduled for endometrial ablation for dysfunctional uterine bleeding.

- If the medication request is for the treatment of central precocious puberty (CPP), there is a clinical diagnosis of CPP with onset of secondary sexual characteristics less than age 8 in females and age 9 in males and ALL of the following apply to the patient:
  1. Diagnosis is confirmed by a pubertal response to a GnRH stimulation test, bone age advanced 1 year beyond chronicle age.
  2. There are documented baseline evaluations (including ultrasound, CT, MRI, and laboratory levels) to rule out a tumor.

- Prescribed dosing of GnRH agonist is within FDA approved indications and/or is supported by the medical compendium as defined by the Social Security Act and/or per the NCCN, ASCO, ACOG or AAP standard of care guidelines.

- The medication is recommended and prescribed by a specialist in the field to treat the patient’s respective medical condition

If all of the above conditions are met, the request will be approved for up to 6 months for treatment of prostate cancer or central precocious puberty and up to 3 months or as recommended per FDA approved indications and/or as defined by the medical compendium as defined above and/or per the NCCN, ASCO, ACOG or AAP standard of care guidelines; if all of the above criteria are not met, the request is referred to a Medical Director for medical necessity review.

Reauthorization of Medication:

- The prescribing physician has provided documentation as to the clinical benefits of the medication supporting continued treatment, OR the 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.

- If the medication reauthorization is for endometriosis ALL of the following apply to the patient:
  1. If the request is for a continuation of treatment exceeding 6 months, the patient is receiving or will be prescribed “add back” hormonal therapy (norethindrone acetate 5 mg daily or conjugated estrogen therapy) (consistent with pharmacy claims data, OR for new members to the health plan consistent with medical chart history), OR if the patient has a documented medical reason for not being able to take “add back” therapy, the patient is receiving or is intended to receive anti-osteoporosis therapy (e.g. alendronate or risedronate) (consistent with pharmacy claims data, OR for new members to the health plan consistent with medical chart history).
  2. If the patient received > 6 to 11 months cumulative doses of the GnRH agonist a Dexa scan was performed and the results were submitted with the medication request, indicating that the patient does not have documented Osteoporosis AND the patient is receiving calcium supplementation (1200 mg/day) and vitamin D (400-800 units/day), which is (consistent with pharmacy claims data, OR for new members to the health plan consistent with medical chart history).
  3. The patient has not received cumulative doses of the GnRH agonist up to or greater than 12 months of therapy.

- If the medication reauthorization is for fibroids, the patient has not received cumulative doses of the GnRH agonist up to or greater than 6 months of therapy.

- If the medication reauthorization is for central precocious puberty, the child is male and < 12 years or female and < 11 years of age OR the child is male and is ≥ 12 years of age or a female that is ≥ 11 years of age, and has an acceptable documented medical reason to continue treatment.

- The medication is recommended and prescribed by a specialist in the field to treat the member’s respective medical condition

- Prescribed dosing of medication is within FDA approved indications and/or supported by the medical compendium as defined by the Social Security Act and/or per the NCCN, ASCO, ACOG or AAP standard of care guidelines.

If all of the above conditions are met, the request will be approved for up to 6 months for treatment of prostate cancer or central precocious puberty and up to 3 months or as recommended per FDA approved indications and/or as defined by the medical compendium as defined above and/or per the NCCN, ASCO, ACOG or AAP standard of care guidelines; if all of the above criteria are not met, the request is referred to a Medical Director for medical necessity review.

**FDA Approved Indications and Dosage and Administration**

**Leuprolide Acetate (Lupron), Lupron Depot, Lupron Depot-Ped:**

- **Endometriosis (decrease pain/lesions):** 11.25mg IM Q 3months x 6 months; 3.75mg IM Q month x 6 months
- **Premenstrual Dysphoric Disorder:** 3.75 mg IM once a month x 3months
- **Prostate Cancer-Advanced:** 1mg SC once a Day (available generically); 22.5mg IM Q3months
  - 30mg IM Q4months; 7.5mg IM once a month
- **Uterine Leiomyoma (Fibroids):** 11.25mg IM 3 months depot x 1; 3.75mg IM once a month x 3mos
- **Central Precocious Puberty (CPP):** For injection: 50mcg/kg/day SC x 1 dose, if down regulation is not achieved, repeat by titrating dose up by 10mcg/kg/day to final titrated maintenance dose. May be administered by a patient/parent or health care professional; For depot: give 300mcg/kg (Min dose 7.5mg) IM Q4 wks as depot x 1 injection, if down regulation is not achieved, repeat by titrating dose up by 3.75mg Q4wks, the final titrated dose is the maintenance dose). Must be administered under physician supervision.

<table>
<thead>
<tr>
<th>Leuprolide Depot Starting Dose for CPP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight (kg)</td>
</tr>
<tr>
<td>&lt;= 25</td>
</tr>
<tr>
<td>&gt; 25 to 37.5</td>
</tr>
<tr>
<td>&gt; 37.5</td>
</tr>
</tbody>
</table>

- **Chronic Pelvic Pain:** 3.75mg IM Q4wks x 3 months
- **Prostate Cancer, Neoadjuvant Tx:** 7.5mg IM once a month plus flutamide TID PO x 3-8months
- **Breast Cancer:** 3.75mg IM once a month; 11.25mg IM Q3months

**Leuprolide Acetate (Eligard)**

- **Prostate Cancer-Advanced:** 7.5mg SC once a month; 22.5mg SC Q3months; 30mg SC Q4months; 45mg SC Q6months

**Firmagon®**

- Advanced Prostate Cancer: 240mg given once (as two injections of 120mg each) followed by a single 80mg injection every once 28 days.

**Goserlin (Zoladex)**

- **Advanced Breast Cancer:** 3.6mg SC Q28 days long term.
- **Endometriosis (decrease pain/lesions):** 3.6mg SC Q28 days x 6months.
- **Endometrial Thinning:** 3.6mg SC 4 wks prior to ablative surgery; 3.6mg SC given 4 wks apart w/2nd inject given 2-4wks before ablative.
- **Advanced Prostate Cancer - palliative care:** 3.6mg SC Q28 days OR 10.8mg SC Q3mos.
- **Prostate Cancer-stageB2-C local:** 3.6mg SC then in 28days 10.8mg SC 8 wks prior to XRT in combination with flutamide OR 3.6mg Q28 days x 4 (2 prior/2 during XRT)

**Triptorelin Pamnoate (Trelstar Depot/Trelstar LA)**
- **Advanced Prostate Cancer – palliative care:** 3.75mg IM every 4 weeks, 11.25mg IM every 12 weeks, 22.5mg IM every 24 weeks

**Histrelin Acetate (Vantus Implant)**
- **Prostate Cancer- Advanced:** 50mg SC Q12 months

**Supprelin LA**
- **Central precocious puberty:** 1 implant (50mg) every 12 months: Remove after 12 months.

* Note: Use of these medications to promote fertility, is not a covered benefit under the Medical Assistance Program, except when prescribed for certain diagnosis, such as regulation of menstrual cycle.

**References:**

Revision/Review Date: MAC 10/12/2011
Associated Policy: Prior Authorization of Medications 236.200
NOTE: Clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.