Therapeutic Class or Brand Name:
Gonadotropin-Releasing Hormone Agonist

Applicable Drugs: Camcevi ™ (leuprolide mesylate), Eligard ® (leuprolide acetate), Fensolvi (leuprolide acetate), Lupron® (leuprolide acetate), Synarel (Nafarelin), Supprelin LA (histrelin), Trelstar Mixject ® (triptorelin), Triptodur (triptorelin), Zoladex (goserelin)

Preferred: Leuprolide acetate (generic, Cipla)

Non-preferred: Camcevi ™ (leuprolide mesylate), Eligard ® (leuprolide acetate), Fensolvi (leuprolide acetate), Lupron® (leuprolide acetate), Synarel (Nafarelin), Supprelin LA (histrelin), Trelstar Mixject ® (triptorelin), Triptodur (triptorelin), Zoladex (goserelin)

Date of Origin: 10/16/2024

Date Last Reviewed / Revised: 10/16/2024

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through III are met)

I. Documented diagnosis of one of the following A through F and must meet the criteria under applicable diagnosis:

A. Advanced breast cancer

i. Documentation of hormone receptor-positive, HER2-negative disease.

ii. Documentation of recurrent, unresectable, or metastatic disease.

iii. Patient is a pre/perimenopausal woman or natal male with suppression of testicular steroidogenesis and documentation of one of the following 1 or 2:

1. Documentation that GNRH will be used in combination with endocrine therapy (i.e., exemestane, fulvestrant, or tamoxifen).

2. For palliative treatment in pre- and perimenopausal women

iv. Minimum age requirement: 18 years old.

v. Treatment must be prescribed by or in consultation with an oncologist

B. Advanced Prostate Cancer

i. If the request is for Zoladex, it is for palliative treatment of advanced prostate cancer

ii. If the request is for Zoladex, it is locally confined stage T2b to T4 (stage B2 to C) and will be used with flutamide 8 weeks prior to initiating radiation therapy and continue during radiation therapy.

iii. Minimum age requirement: 18 years old.

iv. Treatment must be prescribed by or in consultation with an oncologist or urologist.

C. Central Precocious Puberty
   i. Onset of secondary sexual characteristics in females younger than 8 years old OR males younger than 9 years old.
   ii. Confirmation of diagnosis as defined by a pubertal response to a GnRH stimulation test OR bone age advanced one year beyond the chronological age.
   iii. Verification that other clinical diagnoses have been ruled out via all the following tests 1 through 4:
      1. Adrenal steroid levels (to rule out congenital adrenal hyperplasia).
      2. Beta human chorionic gonadotropin level (to exclude a chorionic gonadotropin secreting tumor).
      3. Pelvic/adrenal/testicular ultrasound (to exclude a steroid secreting tumor).
      4. Computerized tomography of the head (to exclude intracranial tumor).
   iv. Minimum age requirement: 2- 11 years for girls and 2-12 years for boys.
   v. If the request is for Supprelin or Synarel, documentation that member has had a trial and failure (at least 6 months) of leuprolide acetate (Lupron Depot).
   vi. Treatment must be prescribed by or in consultation with an endocrinologist or pediatrician.

D. Dysfunctional uterine bleeding
   i. Prescribed as an endometrial-thinning agent prior to endometrial ablation
   ii. Minimum age requirement: 18 years old.
   iii. Treatment must be prescribed by or in consultation with a gynecologist/obstetrician.

E. Endometriosis
   i. Documentation of moderate to severe pain associated with endometriosis.
   ii. Documented trial and insufficient response to at least 2 of the following:
      1. Oral hormonal contraceptives or depot medroxyprogesterone for a minimum of 6 months.
      2. Levonorgestrel releasing intra-uterine device (IUD).
      3. Etonogestrel implant.
   iii. Minimum age requirement: 18 years old.
   iv. If the request is for Synarel, documentation that member has had a trial and failure (at least 6 months) of leuprolide acetate (Lupron Depot).
   v. Treatment must be prescribed by or in consultation with a gynecologist/obstetrician.

F. Uterine Leiomyomata (Fibroids)

i. For treatment of anemia caused by Uterine Leiomyomata (Fibroids) in patients who did not respond to at least 4 weeks of iron therapy.

ii. Documentation of concomitant use with iron therapy prior to surgery.

iii. Minimum age requirement: 18 years old.

II. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines. See Table 1 in Other Criteria.

III. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Infertility treatment.
- Pregnancy.
- Undiagnosed abnormal vaginal bleeding.
- Women who are breast-feeding.
- Lupron Depot should not be used (in combination with norethindrone acetate add-back therapy) for the preoperative hematologic improvement of women with anemia caused by heavy menstrual bleeding due to fibroids.

OTHER CRITERIA

Table 1. Select FDA indications and quantity limits for Gonadotropin-Releasing Hormone Agonist

Gonadotropin-Releasing Hormone Agonist
Advanced Prostate Cancer
• Camcevi: 42 mg once every 6 months • Eligard: 7.5 mg every month, 22.5 mg every 3 months, 30 mg every 4 months, 45 mg every 6 months • Leuprolide Depot 22.5 [generic, Cipla]: every 3 months (12 weeks) • Lupron Depot: 7.5mg every month (4 weeks), 22.5mg every 3 months (12 weeks), 30mg every 4 months(16 weeks), and 45 mg every 6 months (24 weeks) • Trelstar: 3.75 mg injection every 4 weeks, 11.25 mg injection every 12 weeks, and 22.5 mg injection every 24 weeks • Zoladex: 3.6 mg every 4 weeks or 10.8 mg every 12 weeks
Advanced breast cancer
• Zoladex: 3.6 mg every 4 weeks
Endometrial thinning in dysfunctional uterine bleeding
• Zoladex: 3.6 mg every 4 weeks for 1 or 2 doses prior to endometrial ablation

Endometriosis
• Lupron Depot: 3.75 every month, 11.25 mg every 3 months for up to 6 months. • Synarel: 800 micrograms per day for up to 6 months • Zoladex: 3.6 mg every 4 week for up to 6 months
Uterine Leiomyomata (Fibroids)
• Lupron Depot: 3.75 every month and 11.25 mg every 3 months up to 3 months
Central Precocious Puberty
• Fensolvi: 45 mg every 6 months • Lupron Depot-Ped monthly: 7.5 mg every 4 week (Weight ≤25 kg), 11.25 mg every 4 weeks (Weight >25 to 37.5 kg), or 15 mg every 4 weeks (Weight >37.5 kg). • Lupron Depot-Ped 3-month: 11.25 mg, 22.5 mg, or 30 mg every 12 weeks • Lupron Depot-Ped 6-month: 45 mg every 24 weeks • Supprelin LA: 50 mg implant every 12 months • Synarel: 1800 micrograms per day • Triptodur: 22.5 mg every 24 weeks

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Requested quantities not exceeding limits listed in Table 1.

APPROVAL LENGTH

- **Authorization:**
  - Uterine Leiomyomata (Fibroids): 3 months.
  - Endometriosis: 6 months.
  - Endometrial thinning: 2 months.
  - Advanced Prostate Cancer: 1 year.
  - Advanced breast cancer: 1 year.
  - Precocious Puberty: 1 year.
- **Re-Authorization:**
  - Uterine Leiomyomata (Fibroids), Endometriosis, Endometrial thinning may not be re-authorized.
  - Advanced Prostate Cancer and advanced breast cancer: An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.
  - Precocious Puberty: An updated letter of medical necessity or progress notes showing improvement or maintenance on medication. Must also submit bone age estimation

(should be monitored every 6-12 months after therapy initiation) OR height velocity calculation. Lupron Depot-PED will not be continued in females older than 12 years old or in males older than 13 years old, unless requested by an endocrinologist or endocrinologist recommendation.

APPENDIX

- N/A

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