MEDICATION POLICY:

Lupron Depot® and Lupron Depot-PED®

Generic Name: Leuprolide

Therapeutic Class or Brand Name: Lupron Depot® and Lupron Depot-PED®

Applicable Drugs (if Therapeutic Class): N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 6/10/2021

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when ONE of criteria I through IV is met)

I. Documented diagnosis of Advanced Prostate Cancer AND patient is at least 18 years old.

II. Documented diagnosis of Endometriosis AND patient is at least18 years old.

III. Documented diagnosis of Uterine Leiomyomata (Fibroids) and criteria A through C are met:

- A. For treatment of anemia caused by Uterine Leiomyomata (Fibroids) in patients who did not respond to iron therapy (1 month duration).
- B. For concomitant use with iron therapy prior to surgery.
- C. Minimum age requirement: 18 years old.

IV. Documented diagnosis of Central Precocious Puberty and criteria A through D are met:

- A. Onset of secondary sexual characteristics in females younger than 8 years old OR males younger than 9 years old.
- B. Confirmation of diagnosis as defined by a pubertal response to a GnRH stimulation test OR bone age advanced one year beyond the chronological age.
- C. 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).
- D. Minimum age requirement: 2 years old.

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

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Lupron Depot® 1-month kit (3.75mg, 7.5mg): 1 kit every 28 days.
- Lupron Depot® 3-month kit (11.25mg, 22.5mg): 1 kit every 84 days.
- Lupron Depot® 4-month kit (30mg): 1 kit every 112 days.
- Lupron Depot® 6-month kit (45mg): 1 kit every 168 days.
- Lupron Depot-PED® 1-month kit (7.5mg, 11.25mg, 15mg): 1 kit every 28 days.
- Lupron Depot-PED® 3-month kit (11.25mg, 30mg): 1 kit every 84 days.

APPROVAL LENGTH

- **Authorization:**
  - Uterine Leiomyomata (Fibroids): 3 months.
  - Endometriosis: 6 months.
  - Advanced Prostate Cancer: 1 year.
  - Precocious Puberty: 1 year.
- **Re-Authorization:**
  - Uterine Leiomyomata (Fibroids), Endometriosis: N/A
  - Advanced Prostate Cancer: An updated letter of medical necessity or progress notes showing improvement or maintenance on medication.
  - 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

REFERENCES

1. Medi-Span®.
2. http://www.rxabbvie.com/pdf/lupronuro_pi.pdf .
3. http://www.rxabbvie.com/pdf/lupron3_75mg.pdf .
4. http://www.rxabbvie.com/pdf/lupron3month11_25mg.pdf .
5. http://www.rxabbvie.com/pdf/lupronpediatric.pdf .