

Generic Name: Leuprolide

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

Applicable Drugs (if Therapeutic Class): N/A

GPI Code: 2140501010, 2140501015, 2140501020, 2140501025, 3008005010, 3008005015

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 2/6/2019

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 least 18 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 of 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.

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> .

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
2/6/2019	<ol style="list-style-type: none"> 1. Changed outline formatting under Prior Authorization Criteria: <ul style="list-style-type: none"> • Deleted item I "Documented diagnosis of one of the following conditions A through D AND must meet criteria listed under applicable diagnosis:" • Changed outline list level by moving each item up one level • Changed header instructions "(may be considered medically necessary when criteria I is met)" to "may be considered medically necessary when ONE of criteria I through IV is met"
12/9/2017	<ol style="list-style-type: none"> 1. Removed "https://www.optumrx.com/rxsol/live/PAGDocs/Guideline_4246.pdf" from References (link no longer valid).
10/7/2016	<ol style="list-style-type: none"> 1. Removed "https://www.bcbsmt.com/medicalpolicies/Policies/Lupron.aspx" from References (link no longer valid).
4/14/2015	<ol style="list-style-type: none"> 1. Added "Undiagnosed abnormal vaginal bleeding" and "Women who are breast-feeding" under Exclusion Criteria. 2. Updated "https://www.bcbsmt.com/MedReview/Policies/Lupron/v101.aspx" to "https://www.bcbsmt.com/medicalpolicies/Policies/Lupron.aspx" under References. 3. Updated "http://www.rxabbvie.com/pdf/lupron7_5mg.pdf" and "http://www.rxabbvie.com/pdf/lupron3_4_6month.pdf" to "http://www.rxabbvie.com/pdf/lupronuro_pi.pdf" under References.
1/8/2014	<ol style="list-style-type: none"> 1. Adapted policy to new format. 2. Added GPI Codes. 3. Changed "Locally Advanced Prostate Cancer" to "Advanced Prostate Cancer" as listed diagnosis under Prior Authorization Criteria. 4. Added "Minimum age requirement: 18 year old" requirement to Advanced Prostate Cancer diagnosis under Prior Authorization Criteria. 5. Changed "For use prior to surgery" to "For concomitant use with iron therapy prior to surgery" to Uterine Leiomyomata (Fibroids) diagnosis under Prior Authorization Criteria. 6. Added "Minimum age requirement: 2 years old" requirement to Central Precocious Puberty diagnosis under Prior Authorization Criteria. 7. Added "Pregnancy" to Exclusion Criteria.

Lupron Depot® and Lupron Depot-PED®

	<p>8. Added "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" to Quantity/Days Supply Restrictions.</p> <p>9. Changed Re-Authorization under Approval Length from: "An updated letter of medical necessity or progress notes showing improvement or maintenance on medication. Also, for Precocious Puberty, must 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."</p> <p>to: "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".</p> <p>10. Updated references to include Medi-Span and all package inserts for all Lupron Depot® products.</p>
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DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.