Clinical Policy Title:	leuprolide acetate
Policy Number:	RxA.363
Drug(s) Applied:	Eligard®, Lupron Depot®, Lupron Depot-Ped®, leuprolide
Original Policy Date:	03/06/2020
Last Review Date:	09/24/2025
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. **Initial Approval Criteria**

A. Prostate Cancer (must meet all)**:**

1. Diagnosis of prostate cancer;
2. Request is for leuprolide acetate injection, Eligard, or Lupron Depot (7.5 mg, 22.5 mg, 30 mg, 45 mg).

Approval duration

All Lines of Business (except Medicare): 12 months

B. Endometriosis (must meet all):

1. Diagnosis of endometriosis;
2. Request is for Lupron Depot (3.75 mg, 11.25 mg);
3. Member has tried and failed one of the following, unless contraindicated or clinically significant adverse effects are experienced (a, b, or c):
   a. Nonsteroidal anti-inflammatory drug;
   b. Oral or injectable depot contraceptive;
   c. Progestin.

Approval duration

All Lines of Business (except Medicare): 12 months

C. Uterine Fibroids (must meet all)**:**

1. Diagnosis of anemia secondary to uterine leiomyomata (fibroids);
2. Request is for Lupron Depot (3.75 mg, 11.25 mg);
3. Prescribed preoperatively to reduce fibroid size and improve hematologic control.

Approval duration

All Lines of Business (except Medicare): 12 months

D. Central Precocious Puberty (must meet all)**:**

1. Diagnosis of central precocious puberty confirmed by all the following (a, b, and c):
   a. One of the following (a or b):
      i. Patient has undergone gonadotropin-releasing hormone agonist testing and peak luteinizing hormone is above the pre-pubertal range;
      ii. Patient has a random LH level above the prepubertal range;
   b. Advanced bone age of at least one year compared with chronological age;
   c. Age at onset of secondary sex characteristics is < 8 years old if female or < 9 years old if male;

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

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2. Request is for leuprolide acetate or Lupron Depot Ped.

Approval duration

All Lines of Business (except Medicare): 12 months

II. **Continued Therapy Approval**

A. All Indication in Section I (must meet all)**:**

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for members responding positively to therapy.

Approval duration

All Lines of Business (except Medicare): 12 months

References

1. National Comprehensive Cancer Network. Prostate cancer (Version 4.2024). Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed March 24, 2025.
2. Becker CM, Bokor A, Heikinheimo O, et al. ESHRE guideline: endometriosis. Hum Reprod Open. 2022;2022(2):hoac009. Published 2022 Feb 26. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8951218/. Accessed March 24, 2025.
3. Swayzer DV, Gerriets V. Leuprolide. [Updated 2023 Jul 10]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available at: https://www.ncbi.nlm.nih.gov/books/NBK551662/. Accessed March 24, 2025.
4. Chen M, Eugster EA. Central Precocious Puberty: Update on Diagnosis and Treatment. Pediatric Drugs. 2015;17(4):273-281. doi:10.1007/s40272-015-0130-8. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5870137/. Accessed March 24, 2025.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Clinical Policy Title was updated. 2. Line of Business Policy Applies to was updated to all lines of business. 3. Initial and Continued approval duration was updated to include Medicaid, Commercial & HIM approval duration. 4. Continued therapy criteria II.A.1, II.B.1, II.C.1, II.D.1, II.E.1 & II.F.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance…”. 5. References were reviewed and updated.	07/23/2020	09/14/2020

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Policy was reviewed: 1. Initial Approval Criteria and Continued Therapy Approval Criteria were updated to remove HIM approval duration. 2. Initial Approval Criteria B.6.b was updated to include "Lupron Depot® (3.75 mg) in combination with a norethindrone acetate: 3.75 mg per month with 5 mg tablet of norethindrone acetate daily…" 3. Initial Approval criteria I.D.5 was updated to remove "Diagnostic use: Leuprolide acetate: 20 mcg/kg or as needed…" 4. Initial Approval Criteria I.G was updated to include "Head and Neck Cancers - Salivary Gland Tumors (off-label)…" 5. Continued Therapy Approval Criteria II.G was updated to include "Head and Neck Cancers - Salivary Gland Tumors (off-label)…" 6. References were reviewed and updated.	06/01/2021	09/14/2021
Policy was reviewed: 1. Initial Approval Criteria, I.E: updated max dosing for ovarian and breast cancer to 22.5 mg and 11.25 mg respectively. 2. Initial Approval Criteria, I.G.2: Updated to only include Lupron Depot; removed Eligard. 3. Initial Approval Criteria, I.G: Updated to remove: a. Is the requested drug being used as single-agent systemic therapy for androgen receptor positive recurrent disease; b. Presence of distant metastases in patients with a performance status (PS) of 0-3; c. Disease is unresectable and has locoregional recurrence or second primary with prior radiation therapy; 4. Continued Approval Criteria, II.E: updated max dosing for ovarian and breast cancer to 22.5 mg and 11.25 mg respectively. 5. References were reviewed and updated.	03/15/2022	07/18/2022
Policy was reviewed: 1. Removed prior age criteria. 2. Removed prior dosing criteria. 3. Removed prior disease related criteria for Endometriosis. 4. Restructured try/fail criteria for Endometriosis. 5. Updated approval duration. 6. All indications merged into one for continued therapy approval. 7. Removed reauthorization requirement for positive	11/28/2023	01/01/2024

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response to therapy. 8. References were reviewed and updated.		
Policy was reviewed: 1. Removed prescriber requirements. 2. Removed age requirements. 3. Removed Lupaneta due to manufacturer discontinuation. 4. Added leuprolide acetate to drugs applied. 5. Removed specific LH ranges. 6. Removed off-label uses.	8/14/2024	09/12/2024
Policy was reviewed: 1. References were reviewed and updated.	03/24/2025	04/10/2025
Policy was reviewed: 1. Removed leuprolide acetate from policy.	09/24/2025	n/a

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