This Coverage Policy applies to Individual Health Insurance Marketplace benefit plans only.

LUPRON and LUPRON DEPOT™ (leuprolide)

COVERAGE POLICY

Lupron and Lupron Depot are covered for members who meet one of the following Food and Drug Administration (FDA)-approved diagnosis criteria:

A. Central precocious puberty (CPP): Treatment of children with CPP. Coverage should be determined using the following criteria:
   1. Clinical diagnosis of CPP (idiopathic or neurogenic) with onset of secondary sexual characteristics earlier than eight years of age in females and 9 years of age in males
   2. Clinical diagnosis confirmed prior to initiation of therapy using the following parameters:
      a) Pubertal response to a GnRH stimulation test
      b) Bone age advanced one year beyond the chronological age
   3. Baseline evaluation should include:
      a) Height and weight measurements
      b) Sex steroids levels
      c) Adrenal steroid level to exclude congenital adrenal hyperplasia
      d) Beta human chorionic gonadotropin level to rule out a chorionic gonadotropin-secreting tumor
      e) Pelvic/adrenal/testicular ultrasound to rule out a steroid secreting tumor
      f) Computerized tomography of the head to rule out intracranial tumor

B. Endometriosis: [Lupron Depot only] Management of endometriosis, including pain relief and reduction of endometriotic lesions (experience is limited to women 18 years of age or older)

C. Uterine leiomyomata (fibroids): [Lupron Depot only] Concomitantly with iron therapy for the preoperative hematologic improvement of patients with anemia caused by uterine leiomyomata (experience is limited to women 18 years of age or older).

D. Advanced breast cancer: [Lupron Depot only] Palliative treatment of advanced breast cancer in pre- and perimenopausal women (the estrogen and progesterone receptor values may help predict whether the therapy is likely to be beneficial)

Of note, Lupron is a gonadotropin releasing hormone analog (LHRH analog) with mechanism of action similar to Zoladex™ (goserelin) for the treatment of advanced breast cancer. Zoladex is FDA approved for use in the palliative treatment of advanced breast cancer in pre- and perimenopausal women. Zoladex is more commonly used than Lupron for this indication.

E. Reduction of endometrial thickness prior to endometrial ablation. Lupron has been shown to be effective preoperative adjunct to decrease endometrial thickness prior to endometrial ablation.

F. Reduction of fibroid size prior to surgery. Short term use of Lupron has been studied for the treatment of uterine fibroids (leiomyoma uteri) as a preoperative adjunct to surgical treatment. The available literature states that it has effectively reduced the fibroid size, but it does not prevent or replace the eventual need for surger.

G. Chronic pelvic pain of the female and suspected endometriosis

H. Ovarian Cancer

I. Premenstrual Syndrome

J. Prostate Cancer
AUTHORIZATION PERIOD AND LIMITATIONS

Initial Approval: 1 year
Extended Approval: 1 year; Annual review based on submitted documentation of therapeutic response.

Notes:
1. Discontinuation of Lupron or Lupron Depot for the treatment of CPP should be considered before age 11 for females and age 12 for males
2. If the symptoms of endometriosis recur after the first course of therapy, a second treatment with a six-month course of Lupron Depot monthly and norethindrone acetate 5 mg daily may be considered. Restrictions to consider are:
   a. Lupron Depot alone is not recommended for retreatment
   b. If norethindrone acetate is contraindicated for the individual patient, then retreatment is not recommended
   c. Bone density is recommended before retreatment begins to ensure that values are within normal limits
   d. Further treatment beyond the two treatments is not covered; 12 months of Lupron is a lifetime limit

PROCUREMENT

Lupron
Specialty pharmacy source: Aetna Specialty Pharmacy (ASRx)
Contact:
ASRx toll free number: (866) 782-2779
ASRx toll free fax number: (866) 329-2779
ASRx e-mail address: www.AetnaSpecialtyPharmacy.com

Lupron Depot
J code: J1950, J9217
Buy & Bill or
Specialty pharmacy source: AbbVie
Contact: AbbVie toll free number: (888) 857-0668

NON-COVERAGE

Lupron and Lupron Depot are NOT covered for members with the following criteria:
   A. Use not approved by the FDA; and
   B. The use is unapproved and not supported by the literature or evidence as an accepted off-label use. (see Off-Label Use Policy for determining ‘accepted use’)
   C. Treatment of the following indications:
      1. Polycystic ovarian disease
      2. Hypermenorrhea
      3. Endometrial cancer
      4. Precocious puberty alone, or pseudoprecocious puberty (gonadotropin independent precocious puberty)
      5. Female infertility
      6. In vitro fertilization
      7. Premature ovarian failure secondary to chemotherapy
      8. Early stage breast cancer in premenopausal women
      9. Chronic pelvic pain of unknown etiology status post hysterectomy
     10. Amenorrhea induction prior to bone marrow transplantation
     11. ACTH-dependent Cushing’s Syndrome
     12. Catamenial pneumothorax
     13. Hypersexuality state
     14. Benign prostatic hyperplasia
     15. Stuttering priapism
16. Hyperandrogenism
17. Infiltrating ductal breast cancer
18. Preservation of fertility in the reproductive age woman undergoing chemotherapy
19. Growth hormone deficiency
20. Irritable bowel syndrome

REFERENCES
7. Lethaby A, Vollenhoven B, Sowter M. Efficacy of pre-operative gonadotropin hormone releasing analogues for women with uterine fibroids undergoing hysterectomy or myomectomy: a systematic review.

Disclaimer: Coventry Health Care, Inc. (CHC) medical policies, technology assessments, and medical reviews (collectively “CHC Policies”) are developed by CHC to provide guidance in administering plan benefits and constitute neither offers of coverage nor medical advice. Access to CHC Policies is provided for general reference purposes only and does not infer guaranteed coverage. CHC does not provide health care services or supplies. Providers are expected to exercise their independent medical judgment in rendering the most appropriate care. State and federal law, as well as benefit plan terms and conditions and CHC Policies in effect on the date that any service is rendered, including but not limited to definitions and specific inclusions/exclusions, take precedence over clinical policy and must be considered first in determining eligibility for coverage. The terms of the member's benefit plan shall determine coverage. Some benefit plans exclude coverage for services or supplies that Coventry may consider medically necessary. If there is a discrepancy between this policy and a member's benefit plan, the benefits shall govern. Coverage may also differ for CHC Medicare and/or Medicaid members based on any applicable Centers for Medicare & Medicaid Services (CMS) coverage statements including National Coverage Determination (NCD), Local Medical Review Policies (LMRP), and/or Local Coverage Determinations (LCD). As clinical technology is continually updated, CHC policies are subject to periodic updates. Do not rely on printed versions of CHC policies as they may be outdated. No part of this publication may be reproduced, stored in a retrieval system, or transmitted in any form or means without the written consent of CHC.