Pharmacy Drug Policy & Procedure

Policy Name:	Leuprolide Acetate (Fensolvi, Lupron Depot, Lupron Depot-Ped, Leuprolide acetate)	Policy #:	1932P

Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Fensolvi, Lupron Depot, and Lupron Depot-PED.

Statement of the Policy

Health Alliance Medical Plans will approve the use of Fensolvi, Lupron Depot or Lupron Depot-PED under the specialty medical benefit when the following criteria have been met.

Criteria

1. Coverage Criteria for Endometriosis

1.1 Diagnosis of endometriosis
1.2 Member is not currently pregnant
1.3 Failure to respond, intolerance, or contraindication to oral contraceptives (birth control) or non-steroidal anti-inflammatory drugs (NSAIDs such as ibuprofen)
1.4 Member is not concurrently receiving therapy with Orilissa, Myfembree
1.5 Approval Time: 12 months

2. Coverage Criteria for Uterine Fibroids

2.1 Diagnosis of uterine fibroids
2.2 Member is not currently pregnant
2.3 Diagnosis of anemia, and
- HCT < 30% or HGB < 10g/dl
- Concurrent iron supplementation with leuprolide treatment

2.4 Documentation that requested medication will be used prior to surgery for uterine fibroids
2.5 Member is not concurrently receiving therapy with Oriahnn, Myfembree
2.6 Approval Time:
- Initial: 6 months,
- Renewal: 6 months if a volume decrease in fibroids is observed following the first administration, AND
- Member is scheduled for surgery or has a contraindication to surgery at the time of renewal request.

3. Coverage Criteria for GnRHa Stimulation Test in the Diagnosis of Central Precocious Puberty (CPP)

3.1 No PA is required
3.2 Approval Time:
- One time Approval: 1 month

4. Coverage Criteria for Central Precocious Puberty (CPP)

4.1 Onset of symptoms of puberty (breast and genital development, development of pubic hair) before 8 years of age in females and before 9 years of age in males
4.2 Documented pubertal response with a gonadotropin-releasing hormone (GnRH) agonist
- Luteinizing hormone (LH) and follicle-stimulating hormone (FSH) are measured by blood test
- Upper limit for LH is 3.3 to 5 mIU/ml suggest CPP
- LH:FSH ratio > 0.66 suggest CPP

4.3 Bone age is 2 standard deviations (SD) beyond chronological age
4.4 Documented imaging tests to rule out brain tumor or steroid secreting tumor
4.5 Documented lab testing for adrenal steroid levels to rule out congenital adrenal hyperplasia and adrenal tumors:
- Early morning 17-OHP concentration between 82ng/dl and 200ng/dl should indicate non-classical congenital adrenal hyperplasia (CAH) and ACTH stimulation testing should be performed, OR
- Concentrations 200ng/dl indicate a high sensitivity and specificity for non-classical CAH and ACTH testing may still be performed

4.6 Approval Time:
- Initial: 12 months
- Renewal: 12 months if a female and chronological age < 11 or < 12 for males or prescriber submits a statement of medical necessity which indicates the member requires continued therapy to prevent the onset of puberty and this request is approved by a Medical Director.

5. Coverage Criteria for Use of Leuprolide Acetate with Growth Hormone for Children with Growth Failure and Advancing Puberty

5.1 Diagnosis of early onset of puberty
5.2 Member is within 1 SD of mean height for age and sex
5.3 Member meets all criteria for coverage set forth in the Growth Hormone policy
5.4 Approval Time:
- Initial: 12 months,
- Renewal: 12 months if a female and chronological age < 11 or <12 for males or prescriber submits a statement of medical necessity which indicates the member requires continued therapy to prevent the onset of puberty and this request is approved by a Medical Director.

6. Coverage Criteria for Oncology Indications

6.1 See the Pharmacy Oncology Regimen Review policy.

7. Coverage Criteria for Treatment of Infertility

7.1 See the Pharmacy Infertility Medications policy.

8. Coverage Criteria for the Use of Leuprolide for Puberty Suppression in Adolescents with Gender Incongruence (Illinois fully-insured and select Illinois self-funded plans only)

8.1 Prior authorization is prohibited per section 356z.60 of the Illinois Insurance code
8.2 The health plan has measures in place to allow for claims to process at $0 cost share without prior authorization being required
8.3 For further questions, please contact the plan

9. Coverage Criteria for the Use of Leuprolide for Puberty Suppression in Adolescents with Gender Incongruence (all other members)

9.1 A health care provider with experience prescribing or delivering gender-affirming treatment has confirmed all of the following
- The adolescent has demonstrated a long-lasting and intense pattern of gender nonconformity or gender incongruence (whether suppressed or expressed),
- Gender incongruence worsened with the onset of puberty,
- Any coexisting psychological, medical, or social problems that could interfere with treatment (e.g., that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start treatment,
- The adolescent has sufficient mental capacity to give informed consent to this (reversible) treatment

9.2 The adolescent meets all of the following
- Has been informed of the effects and side effects of treatment (including potential loss of fertility if the individual subsequently continues with sex hormone treatment) and options to preserve fertility,
- Has given informed consent

- For members less than 18 years old, informed consent must be provided by the member's legal guardian unless state or federal legislation allows for the treatment without the informed consent of a legal guardian

9.3 A pediatric endocrinologist or other clinician experienced in pubertal assessment indicates the following:
- Agrees with the indication for GnRH agonist treatment,
- Has confirmed that puberty has started in the adolescent (Tanner stage G2/B2),
- Has confirmed that there are no medical contraindications to GnRH agonist treatment.

10. Coverage Criteria for the Use of Leuprolide for Suppression of Testosterone Levels in Transgender Females (Illinois fully-insured and select Illinois self-funded plans only)

10.1 Prior authorization is prohibited per section 356z.60 of the Illinois Insurance code

10.2 The health plan has measures in place to allow for claims to process at $0 cost share without prior authorization being required

10.3 For further questions, please contact the plan

11. Coverage Criteria for the Use of Leuprolide for Suppression of Testosterone Levels in Transgender Females (all other members)

11.1 Documented diagnosis of gender incongruence (defined as a person with a discrepancy between their gender identity and their gender assigned at birth

11.2 Goal of GnRH therapy is to reduce endogenous sex hormone levels and thus reduce male secondary sex characteristics, and replace endogenous sex hormone levels consistent with the female gender identity by using principles of hormone replacement treatment of hypogonadal patients

11.3 Estrogen therapy, unless contraindicated, will accompany GnRH agonist use

11.4 Approval time: 12 months

12. Coverage Criteria for the Use of Leuprolide for Suppression of Estrogen Levels in Transgender Males (Illinois fully-insured and select Illinois self-funded plans only)

12.1 Prior authorization is prohibited per section 356z.60 of the Illinois Insurance code

12.2 The health plan has measures in place to allow for claims to process at $0 cost share without prior authorization being required

12.3 For further questions, please contact the plan

13. Coverage Criteria for the Use of Leuprolide for Suppression of Estrogen Levels in Transgender Males (all other members)

13.1 Documented diagnosis of gender incongruence (defined as a person with a discrepancy between their gender identity and their gender assigned at birth

13.2 Goal of GnRH therapy is to stop menses prior to exogenous testosterone treatment and reduce estrogens to levels found in individuals assigned as male at birth

13.3 Approval time: 12 months

14. Excluded Indications

14.1 Leuprolide is considered experimental for the treatment of ACTH-dependent Cushing's syndrome, amenorrhea induction prior to bone marrow transplantation, catamenial pneumothorax, hypersexuality state (paraphilia), irritable bowel syndrome, malignant neoplasm of endometrium of corpus uteri, menstrual migraines, reduction of secondary sex characteristics following surgical gender reassignment, and all other indications because its effectiveness has not been established.

CPT Codes	

HCPCS Codes	
J1950	Injection, leuprolide acetate (for depot suspension), per 3.75 mg
J1951	Injection, leuprolide acetate for depot suspension (fensolvi), 0.25 mg
J1952	Leuprolide injectable, camcevi, 1 mg
J1954	Injection, leuprolide acetate for depot suspension (cipla), 7.5 mg
J9217	Leuprolide acetate (for depot suspension), 7.5 mg
J9218	Leuprolide acetate, per 1 mg

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