

Fensolvi (leuprolide acetate)

Fensolvi is a gonadotropin releasing hormone (GnRH) agonist indicated for the treatment of pediatric patients 2 years of age and older with central precocious puberty.

I. Criteria for Initial Approval

Fensolvi will be considered for coverage when **ALL** of the criteria below are met, confirmed with supporting medical documentation.

- Patient is older than 2 years of age. Female patients must be younger than 12 years of age and males must be less than 13 years old.
- Onset of secondary sexual characteristics earlier than age 8 for girls and age 9 for boys associated with pubertal pituitary gonadotropin activation.
- Diagnosis is confirmed by a pubertal gonadal sex steroid level and a pubertal LH response to stimulation by native GnRH.
- Bone age advanced greater than 2 standard deviations (SD) beyond chronological age.
- Tumor has been ruled out by lab tests such as diagnostic imaging of the brain (ruling out intracranial tumor), pelvic/testicular/adrenal ultrasound (ruling out steroid secreting tumors), and human chorionic gonadotropin levels (ruling out a chorionic gonadotropin secreting tumor).
- Provider agrees to monitor for development or worsening of psychiatric symptoms or convulsions.
- Provider agrees to monitor for an increase in clinical signs and symptoms of puberty including vaginal bleeding that may be observed during the first weeks of therapy or after subsequent doses. Instruct patients and caregivers to notify



the physician if these symptoms continue beyond the second month after Fensolvi administration.

- Provider agrees to monitor response to Fensolvi with a GnRH agonist stimulation test, basal serum luteinizing hormone (LH) levels or serum concentration of sex steroid levels, 1 to 2 months following initiation of therapy and as needed to confirm adequate suppression of pituitary gonadotropins, sex steroids, and progression of secondary sexual characteristics.
- Exclude pregnancy in women of reproductive potential prior to initiating Fensolvi, if clinically indicated.
- Provider agrees to measure patient height every 3 to 6 months and monitor bone age periodically.
- Will not be used in combination with growth hormone.

II. Criteria for Continuation of Therapy

All of the criteria for initial therapy in Section I must be met; AND

- Patient will not reach 13 years of age during the next 12 months of therapy; AND
- Provider attests to a positive clinical response as indicated by lack of progression or stabilization of secondary sexual characteristics, decrease in growth velocity and bone age advancement, and improvement in final height prediction; AND
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include convulsions, development or worsening of psychiatric symptoms, etc.

III. Dosing/Administration

Fensolvi must be administered according to the current FDA labeling guidelines for dosage and timing.

- Fensolvi subcutaneous kit: Administer 45 mg subcutaneously once every six months.



IV. Length of Authorization For Initial Therapy

Fensolvi will be authorized for 6 months when criteria for initial approval are met. Continuing therapy with Fensolvi will be authorized for 12 months.

V. Billing Code/Information

J3490 - Injection, leuprolide acetate, 45 mg. 1 Kit for subcutaneous Injection.

Prior authorization of benefits is not the practice of medicine nor the substitute for the independent medical judgment of a treating medical provider. The materials provided are a component used to assist in making coverage decisions and administering benefits. Prior authorization does not constitute a contract or guarantee regarding member eligibility or payment. Prior authorization criteria are established based on a collaborative effort using input from the current medical literature and based on evidence available at the time.

Approved by MDH Clinical Criteria Committee: 7/28/2020

Last Reviewed Date: 9/23/2020