Effective Date: 05/01/2021
Reviewed: 01/2021, 01/2022 Scope: Medicaid

Fensolvi (leuprolide acetate)

POLICY

I. CRITERIA FOR APPROVAL

An authorization of 12 months may be granted when all the following criteria are met:

A. Patient is ≤ 13 years of age; AND
B. Patient has documented diagnosis of central precocious puberty (CPP); AND
C. Diagnosis is confirmed by a pubertal gonadal sex steroid level and a pubertal LH response to stimulation by native GnRH; AND
D. Onset of secondary sexual characteristics earlier than age 8 for girls and 9 for boys associated with pubertal pituitary gonadotropin activation; AND
E. Bone age advanced greater than 2 standard deviations (SD) beyond chronological age; AND
F. The member has experienced a failure, contraindication or intolerance to all of the following: Triptodur (triptorelin), Supprelin LA (histrelin) and Lupron Depot-Ped (leuprolide); AND
G. Will not be used in combination with growth hormone; AND
H. Fensolvi is prescribed by or in consultation with an endocrinologist; AND
I. Dose does not exceed more than one injection (45mg) given every 6 months

II. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for all members when all the following criteria are met:
A. The patient is tolerating treatment; AND
B. The patient is ≤ 13 years of age; AND
C. Documentation of 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
D. Will not be used in combination with growth hormone

III. QUANTITY LIMIT

Fensolvi 45mg one injection every 6 months

IV. COVERAGE DURATION

- 12 months

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