Effective Date: 05/01/2021
Reviewed: 01/2021, 01/2022, 05/2023, 05/2024 Scope: Medicaid

FENSOLVI (leuprolide acetate)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication
Fensolvi is indicated for the treatment of pediatric patients 2 years of age and older with central precocious puberty (CPP).

B. Compendial Use
Gender dysphoria (also known as gender non-conforming or transgender persons)

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: For central precocious puberty, laboratory report or medical record of a pubertal response to a gonadotropin releasing hormone (GnRH) agonist test or a pubertal level of a third generation luteinizing hormone (LH) assay.

III. PRESCRIBER SPECIALTIES

For gender dysphoria, the medication must be prescribed by or in consultation with a provider specialized in the care of transgender youth (e.g., pediatric endocrinologist, family or internal medicine physician, obstetrician-gynecologist) that has collaborated care with a mental health provider for patients less than 18 years of age.

IV. CRITERIA FOR INITIAL APPROVAL

A. Central precocious puberty (CPP)

1. Authorization of 12 months may be granted for treatment of CPP in a female member that is ≤ 13 years of age when all of the following criteria are met:
   i. The diagnosis of CPP has been confirmed by a pubertal response to a gonadotropin releasing hormone (GnRH) agonist test or a pubertal level of a third generation luteinizing hormone (LH) assay.

ii. The assessment of bone age versus chronological age supports the diagnosis of CPP.
iii. The member was less than 8 years of age at the onset of secondary sexual characteristics.
iv. 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
v. Will not be used in combination with growth hormone.

2. Authorization of 12 months may be granted for treatment of CPP in a male member ≤ 13 years of age when all of the following criteria are met:
i. The diagnosis of CPP has been confirmed by a pubertal response to a GnRH agonist test or a pubertal level of a third-generation LH assay.
ii. The assessment of bone age versus chronological age supports the diagnosis of CPP.
iii. The member was less than 9 years of age at the onset of secondary sexual characteristics.
iv. 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
v. Will not be used in combination with growth hormone; AND

B. Gender dysphoria

Authorization of 12 months may be granted for pubertal suppression in preparation for gender reassignment when all of the following are met:

1. Patient has a diagnosis of gender dysphoria as confirmed by a qualified mental health professional (MHP) OR the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) Criteria ; **AND**
2. A qualified MHP has confirmed all of the following:

a. Patient has demonstrated a long-lasting and intense pattern of gender nonconformity or gender dysphoria (whether suppressed or expressed); **AND**
b. Gender dysphoria worsened with the onset of puberty; **AND**
c. 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; **AND**
d. Patient has sufficient mental capacity to give informed consent to this (reversible) treatment; **AND**

3. Patient 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; **AND**
4. Patient has given informed consent and (particularly when the adolescent has not reached the age of legal medical consent, depending on applicable legislation) the parents or other caretakers or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process; **AND**
5. A pediatric endocrinologist or other clinician experienced in pubertal assessment has confirmed all of the following:

a. Agreement in the indication for treatment; **AND**
b. Puberty has started in the adolescent (e.g., Tanner stage ≥G2/B2); **AND**
c. There are no medical contraindications to treatment

V. CONTINUATION OF THERAPY

A. Central precocious puberty (CPP)

1. Authorization of up to 12 months may be granted for continuation of therapy for CPP in a female member if the member is currently less than 13 years of age or younger and the member meets both of the following:
   i. The member is currently receiving the requested medication through a paid pharmacy or medical benefit.
   ii. The member is not experiencing treatment failure (e.g., clinical pubertal progression, lack of growth deceleration, continued excessive bone age advancement).
   iii. Will not be used in combination with growth hormone.
2. Authorization of up to 12 months may be granted for continuation of therapy for CPP in a male member if the member is currently less than 13 years of age or younger and the member meets both of the following:
   i. The member is currently receiving the requested medication through a paid pharmacy or medical benefit.
   ii. The member is not experiencing treatment failure (e.g., clinical pubertal progression, lack of growth deceleration, continued excessive bone age advancement).
   iii. Will not be used in combination with growth hormone.

B. Gender dysphoria

Authorization of 12 months if patient has shown a beneficial response to treatment as evidenced by routine monitoring of clinical pubertal development and applicable laboratory parameters.

VI. QUANTITY LIMIT

Fensolvi 45mg one injection every 6 months

VII. REFERENCES

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5. Houk CP, Kunselman AR, Lee PA. Adequacy of a single unstimulated luteinizing hormone level to diagnose central precocious puberty in girls. *Pediatrics.* 2009;123:e1059-e1063.
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