Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 240.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Fensolvi (leuprolide injection)

I. Policy:
Fensolvi (leuprolide injection)

II. Purpose/Objective:
To provide a policy of coverage regarding Fensolvi (leuprolide injection)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) the service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.

(ii) the service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.

(iii) the service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age

DESCRIPTION:
Leuprolide is an agonist of gonadotropin releasing hormone (GnRH) receptors. Acting as a potent inhibitor of gonadotropin secretion, leuprolide produces an initial increase in luteinizing hormone (LH) and follicle stimulating hormone (FSH), which leads to a transient increase in testosterone and dihydrotestosterone (in males) and estrone and estradione (in premenopausal females). Continuous leuprolide administration then results in suppression of ovarian and testicular steroidogenesis due to decreased levels of LH and FSH with subsequent decrease in testosterone (male) and estrogen (female) levels. In males, testosterone levels are reduced to below castrate levels. Leuprolide may also have a direct inhibitory effect on the testes, and act by a different mechanism not directly related to reduction in serum testosterone.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Fensolvi (leuprolide injection) will be considered medically necessary when all of the following criteria are met:

- Medical record documentation of a diagnosis of central precocious puberty (CPP) **AND**
- Prescription written by or in consultation with a pediatric endocrinologist **AND**
- Medical record documentation of age greater than or equal to 2 years of age **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Lupron Depot-Ped, Triptodur* and Supprelin LA*.

*Prior authorization required

AUTHORIZATION DURATION: None

QUANTITY LIMITS: One (1) Kit (45mg) per 6 months

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 7/20/21

Revised:

Reviewed: 7/14/22