Medical Policy:

Fensolvi® (leuprolide acetate) injectable suspension for subcutaneous use

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.314	March 4, 2024	September 2, 2020

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

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. It acts as a potent inhibitor of gonadotropin secretion (LH and follicle stimulating hormone (FSH)) when given continuously in therapeutic doses. Following an initial stimulation of GnRH receptors, chronic administration results in downregulation of GnRH receptors, reduction in release of LH, FSH and consequent suppression of ovarian and testicular production of estradiol and testosterone respectively.

Length of Authorization

Initial authorization will be for no more than 6 months and reauthorization will be for no more than 12 months.

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):
180 billable units every 168 days

Guideline

I. INITIAL APPROVAL CRITERIA

Coverage is provided in the following conditions:

1. **Central Precocious Puberty**
    A. Diagnosis of central precocious puberty; **AND**
    B. Onset of secondary sexual characteristics in one of the following:
        i. Females ≤ 8 years of age
        ii. Males ≤ 9 years of age
2. **Gender Dysphoric/Gender-Incongruent Person; Person Undergoing Gender Reassignment (Male-To-Female [MTF])****
    A. Fensolvi is prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of transgender patients.

Limitations/Exclusions

The safety and effectiveness of Fensolvi have not been established in pediatric patients less than 2 years of age.

Applicable Procedure Codes

Code	Description
J1951	Injection, leuprolide acetate (for depot suspension), per 3.75 mg

Applicable NDCs

Code	Description
62935-0153-XX	Fensolvi 45mg subcutaneous kit

ICD-10 Diagnoses

Code	Description
E22.8	Other hyperfunction of pituitary gland (central precocious puberty)
F64.2	Gender identity disorder of childhood
F64.0	Gender identity disorder in adolescence and adulthood
F64.8	Other specified gender dysphoria

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	3/4/2024	Annual Review: updated dosing limits, no criteria changes
EmblemHealth & ConnectiCare	6/30/2023	Annual Review: No criteria changes
EmblemHealth & ConnectiCare	10/27/2022	Added off label use: gender dysphoria
EmblemHealth & ConnectiCare	6/15/2022	Transferred policy to new template. Corrected J Code from J1950 to J1951.

EmblemHealth & ConnectiCare	9/20/2020	New Policy

References

1. Product Information: FENSOLVI® subcutaneous injection, leuprolide acetate subcutaneous injection. Tolmar Inc (per FDA), Fort Collins, CO, 2022.