Pharmacy Medical Necessity Guidelines: Gonadotropin-releasing Hormone (GnRH) Agonists: Fensolvi (leuprolide), Lupron Depot 3.75 mg and 11.25 mg (leuprolide), Lupron Depot-Ped (leuprolide), and Supprelin LA (histrelin)

Effective: January 1, 2021

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX/MED	Department to Review	MM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink[SM] – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:

MM: 888.415.9055

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Fensolvi (leuprolide acetate) is indicated for treatment of pediatric patients 2 years of age and older with central precocious puberty.

Lupron Depot (leuprolide acetate for depot suspension) 3.75 mg for 1-month and 11.25 mg for 3-month administration is indicated:
- For management of endometriosis, including pain relief and reduction of endometriotic lesions.
- For use with iron therapy before fibroid surgery to improve anemia from fibroids.

Lupron Depot-Ped (leuprolide acetate for depot suspension) is indicated in the treatment of children with central precocious puberty.

Supprelin LA (histrelin) is indicated for the of children with central precocious puberty.

COVERAGE GUIDELINES

Central Precocious Puberty

The plan may authorize coverage of Fensolvi or Lupron Depot-Ped for Members when all of the following criteria are note met:

1. Documented diagnosis of central precocious puberty

AND

2. Documentation of one of the following:
   a. Fensolvi and Lupron Depot-Ped: The Member is ≤18 years of age
   b. Supprelin LA: The Member is ≤12 years of age

AND

3. If the request is for Fensolvi, documentation of an inadequate response to or clinical inappropriateness to all of the following: Triptodur (triptorelin), Supprelin LA (histrelin) and Lupron Depot-Ped (leuprolide)

Endometriosis
The plan may authorize coverage of Lupron-Depot 3.75 mg and 11.25 mg for Members when all of the following criteria are met:
1. Documented diagnosis of endometriosis

AND

2. Documentation of **one (1) of the following**:
    a. The Member has tried and failed therapy with or the provider has indicated clinical inappropriateness or contraindication to treatment with nonsteroidal anti-inflammatory drugs and at least two different hormonal contraceptives
    b. The Member is new to the plan and stable on Lupron Depot for endometriosis prior to enrollment

Fibroids
The plan may authorize coverage of Lupron-Depot 3.75 mg and 11.25 mg for Members when all of the following criteria are met:
1. Documented diagnosis of anemia due to fibroids (uterine leiomyomata)

AND

2. Documentation Lupron Depot will be used prior to surgery for fibroids (uterine leiomyomata)

Gender Dysphoria in Adolescents
The plan may authorize coverage of a Lupron Depot-Ped or Supprelin LA for Members when all of the following criteria are met:
1. Documented diagnosis of gender dysphoria

AND

2. Documentation the Member is an adolescent

AND

3. Documentation the Member has experienced puberty development to at least Tanner stage 2

Gender Reassignment in Adults
The plan may authorize coverage of a Lupron Depot-Ped or Supprelin LA for Members when all of the following criteria are met:
1. Documented diagnosis of gender dysphoria

AND

2. Documentation the Member is at least 18 years of age

AND

3. Documentation the Member will receive the requested agent concomitantly with cross sex hormones (testosterone or estrogen and spironolactone)

LIMITATIONS

- The plan does not provide coverage for Fensolvi, Lupron Depot, Lupron Depot-Ped, or Supprelin LA for the treatment of idiopathic short stature.
- Requests for central precocious puberty will be approved based on the following:
    - Fensolvi and Lupron Depot-Ped: Until 19 years of age
    - Supprelin LA: Until 13 years of age
- Requests for endometriosis will be authorized for 6 months. Based on package labeling concerns regarding the adverse impact of long-term treatment on bone thinning, Members will be approved for a total of two 6-month authorizations total if coverage criteria is met.
- Requests for fibroids will be authorized as a one-time 3-month approval.

CODES

The following HCPCS/CPT code(s) are:

Code	Description
J9226	Histrelin implant (Supprelin LA), 50 mg
J1950	Injection, leuprolide acetate (for depot suspension), per 3.75 mg

REFERENCES

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APPROVAL HISTORY

October 2006: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- August 12, 2014: No Changes
- December 2, 2014: Added diagnosis of gender reassignment.
- November 10, 2015: Changed title from Leuprolide, Lupron, Lupron-Depot®, Lupron Depot-Ped®, Eligard® (leuprolide) to Leuprolide Acetate. Removed Lupron, product has been discontinued.
- January 1, 2016: Administrative change to rebranded template.
- May 10, 2016: Added indication of blockade of puberty for adolescent members who are transgender. Removed infertility indication as this coverage is only applicable to Commercial plans.
- April 11, 2017: Administrative update, adding Tufts Health RITogether to the template.
- July 11, 2017: No changes
- July 10, 2018: No changes

- May 7, 2019: Effective May 13, 2019, the Medical Necessity Guideline applies to Tufts Health RITogether. Updated coverage criteria for central precocious puberty to all for coverage until the age of 18 years of age for both males and females. Added the following limitation "The plan does not provide coverage for Lupron Depot for the treatment of idiopathic short stature."
- September 15, 2020: Added Fensolvi to the Medical Necessity Guideline. Effective January 1, 2021, updated title of Medical Necessity Guideline to "Gonadotropin-releasing Hormone (GnRH) Agonists: Fensolvi (leuprolide), Lupron Depot 3.75 mg and 11.25 mg (leuprolide), Lupron Depot-Ped (leuprolide), and Supprelin LA (histrelin)." Added Supprelin LA (histrelin) to and removed leuprolide, Lupron Depot and Eligard from the Medical Necessity Guideline. Updated prerequisite criteria for endometriosis to include a trial and failure, clinical inappropriateness or contraindication to nonsteroidal anti-inflammatory drugs and at least two different hormonal contraceptives. Updated coverage criteria for fibroids to require documentation of anemia due to fibroids and documentation Lupron Depot will be used prior to surgery for fibroids. Removed reauthorization criteria for endometriosis and fibroids and updated duration of approval rules. Expanded use in gender dysphoria in adolescents and gender assignment in adults.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.