MEDICAL MUTUAL®

Drug Policy

Policy: **Impacted Drugs:**	**Gonadotropin-Releasing Hormone Agonists – Central Precocious Puberty** • **Fensolvi® (leuprolide acetate for injectable suspension)** • **Lupron Depot-Ped® (leuprolide acetate for depot suspension)** • **Triptodur™ (triptorelin extended-release injectable suspension)** • **Supprelin® LA (histrelin subcutaneous implant)**	**Annual Review Date:** **4/17/2025** **Last Revised Date:** **4/17/2025**

OVERVIEW

Fensolvi, Lupron Depot-Ped, Triptodur, and Supprelin LA are gonadotropin-releasing hormone (GnRH) agonists indicated for the treatment of children with central precocious puberty.[1-3] Fensolvi is administered by a subcutaneous injection, both Lupron Depot-Ped and Triptodur are administered by intramuscular injection and Supprelin La is a subcutaneous implant. Fensolvi is administered once every 6 months, Lupron Depot-Ped is administered once a month or once every 3 months, Triptodur is administered once every 24 weeks and Supprelin LA is a 12 month implant.

POLICY STATEMENT

This policy involves the use of gonadotropin-releasing hormone agonists (Fensolvi, Lupron Depot-Ped, Triptodur and Supprelin LA). Prior authorization is recommended for pharmacy benefit coverage of a gonadotropin-releasing hormone agonist (Fensolvi, Lupron Depot-Ped, Triptodur and Supprelin LA). Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with a gonadotropin-releasing hormone agonist (Fensolvi, Lupron Depot-Ped, Triptodur and Supprelin LA) as well as the monitoring required for adverse events and long-term efficacy, initial approval requires a gonadotropin-releasing hormone agonist (Fensolvi, Lupron Depot-Ped, Triptodur and Supprelin LA) be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

Automation: When available, the ICD-10 code for Central Precocious Puberty (ICD-10: E22.8) will be used for automation to allow approval of the requested medication.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of a gonadotropin-releasing hormone agonist (Fensolvi, Lupron Depot-Ped, Triptodur and Supprelin LA) is recommended in those who meet the following criteria:

1. Central Precocious Puberty

Criteria. *Approve*.

Other Uses with Supportive Evidence:

2. **Gender-Dysphoric/Gender-Incongruent Persons; Persons Undergoing Gender Reassignment (Female-To-Male or Male-To-Female)**
   Criteria. *Approve if prescribed by or in consultation with an endocrinologist or a physician who specializes in the treatment of transgender patients*

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of a gonadotropin-releasing hormone agonist (Fensolvi, Lupron Depot-Ped, Triptodur and Supprelin LA) is not recommended in the following situations:

1. **Peripheral Precocious Puberty (Also Known as Gonadotropin-Releasing Hormone-Independent Precocious Puberty)**. Children with peripheral precocious puberty do not respond to gonadotropin-releasing hormone agonist therapy.[4] Treatment is directed at removing or blocking the production and/or response to the excess sex steroids, depending on the cause (e.g., surgically removing human chorionic gonadotropin-secreting tumors or using glucocorticoids to treat defects in adrenal steroidogenesis [such as classic congenital adrenal hyperplasia]).

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Lupron Depot-Ped® [prescribing information]. North Chicago, IL; AbbVie, Inc.; May 2017.
2. Triptodur™ [prescribing information]. Atlanta, GA: Arbor Pharmaceuticals, LLC; October 2018.
3. Fensolvi® [prescribing information]. Fort Collins, CO: Tolmar Pharmaceuticals, Inc; May 2020.
4. Supprelin LA (histrelin acetate) [prescribing information]. Malvern, PA: Endo Pharmaceuticals Inc; April 2022.
5. Carel JC, Eugster EA, Rogol A, et al. Consensus statement on the use of gonadotropin-releasing hormone analogs in children. *Pediatrics*. 2009;123(4):e752-762.
6. Krishna KB, Fuqua JS, Rogol AD, et al. Use of gonadotropin-releasing hormone analogs in children: update by an international consortium. *Horm Res Paediatr*. 2019;91:357-372.
7. Eugster EA. Treatment of central precocious puberty. *J Endo Soc*. 2019;3:965-972.
8. Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: an Endocrine Society clinical practice guidelines. *J Clin Endocrinol Metab*. 2017;102:3869-3903.
9. World Professional Association for Transgender Health (WPATH). Standards of Care for the health of transsexual, transgender, and gender non-conforming people (version 7). Available at: https://s3.amazonaws.com/amo_hub_content/Association140/files/Standards%20of%20Care%20V7%20-%202011%20WPATH%20%282%29%281%29.pdf. Accessed on September 10, 2020.
10. Rosenthal SM. Approach to the patient: transgender youth: endocrine considerations. *J Clin Endocrine Metab*. 2014;99:4379-4389.
11. Spack NP. Management of transgenderism. *JAMA*. 2013;309:478-484.