Drug Coverage Policy

Effective Date……7/15/2026
Coverage Policy Number……IP0803
Policy Title…..Leuprolide Acetate for Injection

Infertility – Leuprolide Acetate for Injection

- Lupron® (leuprolide acetate injection – Tap Pharmaceutical Products, generic)
- Lupron® Depot 3.75 mg (leuprolide acetate for depot suspension for injection, for intramuscular use – AbbVie)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

OVERVIEW
Leuprolide acetate (Lupron®, Lupron Depot® 3.75 mg) is a gonadotropin-releasing hormone (GnRH) agonist used in the treatment of infertility as part of assisted reproductive technology (ART) protocols. In this setting, leuprolide acetate is used for pituitary suppression to prevent premature luteinizing hormone (LH) surge and, in selected protocols, as a GnRH-agonist trigger to induce final oocyte maturation in patients undergoing controlled ovarian stimulation.[1,2]

Leuprolide acetate is also FDA-approved for other indications, including the management of endometriosis and the preoperative treatment of uterine fibroids. Coverage criteria for these non-infertility indications, as well as other uses of leuprolide acetate, are addressed in separate coverage policies.[1,2]

Guidelines
The **American Society for Reproductive Medicine (ASRM)** recommends using a gonadotropin-releasing hormone (GnRH) agonist trigger (for example, leuprolide) as a first-line strategy to reduce the risk of moderate-to-severe ovarian hyperstimulation syndrome (OHSS) in patients at increased risk, with adequate luteal support when a fresh embryo transfer is planned. While long GnRH agonist ("down-regulation") protocols have historically been used for pituitary suppression and prevention of premature LH surge, contemporary guidance favors GnRH antagonist protocols to enable agonist trigger use and further mitigate OHSS risk.[3]

Coverage Policy

Coverage of treatment services for infertility varies across plans. Please refer to the related coverage policy (0089 Infertility Services).

The use of leuprolide acetate, Lupron Depot® for other indications (inclusive of Preservation of Ovarian Function/Fertility in Patients undergoing Chemotherapy) are addressed in a separate coverage policy. Please refer to Gonadotropin-Releasing Hormone Agonists – Lupron Depot IP0109.

The use of leuprolide for the treatment of gender dysphoria is addressed in a separate coverage policy. Please refer to Gonadotropin-Releasing Hormone Agonists - Central Precocious Puberty IP0768.

Policy Statement
Injectable fertility medications are specifically excluded under most benefit plans. Please refer to the applicable benefit plan document to determine benefit availability and the terms and conditions of coverage.

Prior Authorization is required for benefit coverage of leuprolide acetate. In the clinical criteria, as appropriate, an asterisk (*) is noted next to the specified gender. In this context, the specified gender is defined as follows: males are defined as individuals with the biological traits of a male, regardless of the individual's gender identity or gender expression; females are defined as individuals with the biological traits of a female, regardless of the individual's gender identity or gender expression. All approvals are provided for the duration noted below.

I. **Lupron (leuprolide acetate injection), Lupron Depot 3.75 mg (leuprolide acetate for depot suspension for injection, for intramuscular use).** Approve for 1 year if the patient meets the following (1):

FDA Approved Indication

1. **Infertility.** Patient meets ONE of the following (A or B):
   A. *Females undergoing treatment of infertility, use is for ovulation suppression; OR
   B. *Females undergoing treatment of infertility, use is to trigger ovulation; OR

*Refer to the Policy Statement.

Conditions Not Covered

Leuprolide acetate for injection for any other use is considered not medically necessary. Criteria will be updated as new published data are available.

Coding Information

1) This list of codes may not be all-inclusive.
2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
J1950	Injection, leuprolide acetate (for depot suspension), per 3.75 mg
J9218	Leuprolide acetate, per 1mg

References

1. AbbVie Inc., Lupron Depot (leuprolide acetate for depot suspension) [product information]. AbbVie Inc., North Chicago, IL: March 2019.
2. AbbVie Inc., Lupron Depot 3.75 mg (leuprolide acetate for depot suspension) [product information]. AbbVie Inc., North Chicago, IL: September 2025.
3. Practice Committee of the American Society for Reproductive Medicine. Prevention and treatment of moderate and severe ovarian hyperstimulation syndrome: a guideline. *Fertil Steril.* 2023;120(3):437–450. ©2023 by American Society for Reproductive Medicine.

Revision Details

Summary of Changes	Review Date	Effective Date
New policy.	5/14/2026	7/15/2026

The policy effective date is in force until updated or retired.