MEDICAL MUTUAL®

Drug Policy

Policy:	Leuprolide Immediate Release (IR)	Annual Review Date: 10/19/2023 Last Revised Date: 10/19/2023

OVERVIEW

Leuprolide is a synthetic nonapeptide analog of naturally occurring gonadotropin-releasing hormone or leutinizing hormone-releasing hormone (GnRH or LHRH), which possesses greater potency compared with the natural hormone (generally considered a GnRH agonist). Single daily doses result in an initial increase in circulating levels of luteinizing hormone (LH) and follicle stimulating hormone (FSH), which lead to a transient increase in testosterone and dihydrotestosterone in males and estrone and estradiol in pre-menopausal females. However, leuprolide acts as a potent inhibitor of gonadotropin secretion when administered continuously in therapeutic dose by decreasing LH and FSH levels. Following initial stimulation of gonadotropins, chronic administration of leuprolide leads to suppression of ovarian and testicular steroidogenesis. These effects are reversible after drug discontinuation.

POLICY STATEMENT

This policy involves the use of Leuprolide IR products. Prior authorization is recommended for pharmacy benefit coverage of leuprolide immediate release products (e.g., Lupron and generic leuprolide). 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. Leuprolide long acting drugs follows their own prior authorization policy. Leuprolide will not be authorized for fertility indications if member does not have plan fertility coverage.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of leuprolide injection is recommended in those who meet the following criteria:

Food and Drug Administration (FDA)-Approved Indications

A. Prostate Cancer. Approve.

B. Central Precocious Puberty (CPP). Approve.

Other Uses with Supportive Evidence

C. Ovarian Cancer. Approve.

D. Female Infertility. Approve if member has fertility coverage and meets the following criteria
- **i.** Requested by an appropriate fertility specialist; AND
- **ii.** The woman does not have evidence of inadequate ovarian reserve from any of the following (Documentation required for at least one of these objective tests):
  - a) Abnormal clomiphene citrate challenge test; OR
  - b) Elevated day 3 FSH level; OR
  - c) Abnormal anti-Mullerian hormone of antral follicle count; OR
  - d) Age 44 years or older; AND
- **iii.** Tubal obstruction is ruled out; AND
- **iv.** An abnormal semen analysis is ruled out; AND
- **v.** Ovulatory dysfunction is ruled out; AND
- **vi.** An inoperable uterine cavity abnormality is ruled out.

E. Prophylaxis or Treatment of Uterine Bleeding in Patients with Hematologic Malignancy or Prior to Bone Marrow/Stem Cell Transplantation (BMT/SCT). Approve.

F. Uterine leiomyoma. Approve.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year (365 days)
B) *Extended Approval:* 1 year (365 days)

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Leuprolide IR has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. 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.

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REFERENCES

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