Reference number(s)
3958-A

JURISDICTION SPECIFIC MEDICARE PART B

LUPRON DEPOT (leuprolide acetate for depot suspension)
leuprolide acetate for depot suspension

POLICY

I. COVERED USES

The indications below are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

The list of covered ICD-10 codes is prohibitively long to include within this policy. A complete list can be found at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. The FDA-labeled indications and recognized compendia (off-label) uses are listed below:

A. Endometriosis
B. Uterine leiomyomata (fibroids)
C. Prostate cancer
D. Carcinoma of the breast
E. Suspected endometriosis
F. Epithelial ovarian cancer/fallopian tube cancer/primary peritoneal cancer
G. Ovarian cancer
H. Malignant sex cord-stromal tumors
I. Salivary gland tumors

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:
A. Relevant medical history, physical examination, results of pertinent diagnostic tests or procedures
B. Medical record with name of drug administered, route of administration, dosage, duration of the administration

III. CRITERIA FOR APPROVAL

A. **Endometriosis**

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Authorization of 6 months may be granted for treatment of endometriosis when the requested product is Lupron Depot 3.75 mg or 11.25 mg (J1950).

B. **Uterine leiomyomata (fibroids)**
Authorization of 6 months may be granted for treatment of uterine leiomyomata (fibroids) when the requested product is Lupron Depot 3.75 mg or 11.25 mg (J1950) OR Lupron Depot 7.5 mg, 22.5 mg, 30 mg or 45 mg (J9217).

C. **Prostate cancer**
Authorization of 12 months may be granted for treatment of prostate cancer when the requested product is Lupron Depot 7.5 mg, 22.5 mg, 30 mg or 45 mg (J9217) OR leuprolide acetate depot 22.5 mg (J1954).

D. **Carcinoma of the breast**
Authorization of 12 months may be granted for treatment of carcinoma of the breast when all of the following criteria are met:
1. The requested product is Lupron Depot 3.75 mg or 11.25 mg (J1950) OR Lupron Depot 7.5 mg, 22.5 mg, 30 mg or 45 mg (J9217).
2. The requested drug will be used as palliative treatment.
3. The member is one of the following:
   i. Premenopausal female
   ii. Perimenopausal female
   iii. Male

E. **Salivary gland tumors**
Authorization of 12 months may be granted for treatment of salivary gland tumors when the requested product is Lupron Depot 7.5 mg, 22.5 mg, 30 mg or 45 mg (J9217).

F. **Suspected endometriosis**
1. Authorization of 3 months may be granted for treatment of suspected endometriosis when all of the following criteria are met:
   i. The requested product is Lupron Depot 3.75 mg or 11.25 mg (J1950).
   ii. The member has experienced chronic pelvic pain for 6 months or more.
   iii. The member has been evaluated to exclude other causes of pelvic pain.
   iv. The member has tried and failed treatment with both of the following:
      a. Oral contraceptives
      b. Non-steroidal anti-inflammatory drugs (NSAIDs)
   v. The member is not currently receiving therapy with the requested drug.

2. Authorization of 3 months may be granted for treatment of suspected endometriosis when both of the following criteria are met:
   i. The member is currently receiving treatment with Lupron Depot 3.75 mg or 11.25 mg (J1950).
   ii. The member has experienced significant symptomatic improvement.

G. **Ovarian cancer**
1. Authorization of 12 months may be granted for treatment of ovarian cancer, malignant sex cord stromal tumors, fallopian tube cancer, and primary peritoneal cancer when the requested product is

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Lupron Depot 3.75 mg or 11.25 mg (J1950) OR Lupron Depot 7.5 mg, 22.5 mg, 30 mg or 45 mg (J9217).
2. Authorization of 12 months may be granted for treatment of epithelial ovarian cancer when the requested product is Lupron Depot 3.75 mg or 11.25 mg (J1950).

IV. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

V. REFERENCES

1. Drugs and Biologicals LCD (L33394) Version R15. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed December 13, 2022.
2. Billing and Coding: LHRH Analogs (A52453) Version R11. Available at: Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed February 1, 2023.
3. Billing and Coding: Drugs and Biologicals (A52855) Version R8. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed December 13, 2022.
4. Lupron Depot 7.5 mg, 22.5 mg, 30 mg, 45 mg [package insert]. North Chicago, IL: AbbVie Inc.; April 2022.
5. Lupron Depot 11.25 mg [package insert]. North Chicago, IL: AbbVie Inc.; March 2020.
6. Lupron Depot 3.75 mg [package insert]. North Chicago, IL: AbbVie.; July 2022.
7. Leuprolide acetate depot 22.5 mg [package insert]. Warren, NJ: Cipla USA, Inc.; August 2018.
8. The NCCN Drugs & Biologics Compendium® © 2022 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed December 13, 2022
9. Micromedex Solutions [database online]. Truven Health Analytics, Greenwood Village, CO. Available at: https://www.micromedexsolutions.com. Accessed December 13, 2022

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