JURISDICTION SPECIFIC MEDICARE PART B

LUPRON DEPOT (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 are listed below:

A. Endometriosis
B. Uterine fibroids
C. Prostate cancer
D. Carcinoma of the breast
E. Ovarian cancer

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 in a legible format with patient identification information (e.g., complete name and dates of service) and signature of physician or non-physician practitioner responsible for and providing care to the member, upon request, for all submissions:

A. Relevant medical history
B. Physical examination
C. Results of pertinent diagnostic tests
D. Any relevant procedures

III. CRITERIA FOR APPROVAL

A. **Endometriosis**
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 fibroids when the requested product is Lupron Depot 3.75 mg or 11.25 mg (J1950).

C. **Prostate Cancer**
Authorization of 12 months may be granted for treatment of advanced prostate cancer when both of the following criteria are met:
1. Orchiectomy and/or estrogen administration are either not indicated are unacceptable to the patient.
2. The requested product is Lupron Depot 7.5 mg, 22.5mg, 30 mg or 45 mg (J9217).

D. **Carcinoma of the Breast**
Authorization of 12 months may be granted for treatment of carcinoma of the breast when the requested product is Lupron Depot 7.5 mg, 22.5mg, 30 mg or 45 mg (J9217).

E. **Ovarian Cancer**
Authorization of 12 months may be granted for treatment of ovarian cancer when the requested product is Lupron Depot 7.5 mg, 22.5mg, 30 mg or 45 mg (J9217).

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. Luteinizing Hormone-Releasing Hormone (LHRH) Analogs LCD (L34822) Version R6. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed February 10, 2021.
2. Billing and Coding: Luteinizing Hormone-Releasing Hormone (LHRH) Analogs (A56776) Version R1. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed February 10. 2021.
3. Lupron Depot [package insert]. North Chicago, IL: AbbVie; March 2020.