Reference number(s)
5748-A

JURISDICTION SPECIFIC MEDICARE PART B

LUPRON DEPOT 1-Month 3.75 mg
LUPRON DEPOT 1-Month 7.5 mg
LUPRON DEPOT 3-Month 11.25 mg
LUPRON DEPOT 3-Month 22.5 mg
LUPRON DEPOT 4-Month 30 mg
LUPRON DEPOT 6-Month 45 mg

LUPRON DEPOT-PED 1-Month 7.5 mg
LUPRON DEPOT-PED 1-Month 11.25 mg
LUPRON DEPOT-PED 3-Month 11.25 mg
LUPRON DEPOT-PED 1-Month 15 mg
LUPRON DEPOT-PED 3-Month 30 mg
(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.

A. Endometriosis
B. Uterine fibroids
C. Prostate cancer
D. Head and neck cancer (salivary gland tumors)
E. Ovarian cancer/fallopian tube cancer/primary peritoneal cancer
F. Premenopausal breast cancer
G. Male breast cancer
H. Central precocious puberty (CPP)

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. EXCLUSIONS

It is contraindicated to administer the requested medication if the member has experienced any type of allergic reaction to the requested medication or to any of its ingredients.

CVS caremark®

III. CRITERIA FOR APPROVAL

A. Endometriosis
Authorization of 6 months may be granted for treatment of endometriosis.

B. Uterine Fibroids
Authorization of 6 months may be granted for treatment of uterine fibroids.

C. Prostate Cancer
Authorization of 12 months may be granted for treatment of prostate cancer.

D. Salivary Gland Tumors
Authorization of 12 months may be granted for treatment of salivary gland tumors.

E. Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer
Authorization of 12 months may be granted for treatment of ovarian cancer, fallopian tube cancer, and primary peritoneal cancer.

F. Breast Cancer
Authorization of 12 months may be granted for treatment of breast cancer.

G. Central Precocious Puberty
Authorization of 12 months may be granted for treatment of central precocious puberty.

IV. DOSAGE AND ADMINISTRATION

The dose and frequency of administration must be consistent with the FDA approved labeling. Doses and frequencies that exceed the FDA recommended dosage/frequency as per the prescribing information, are considered not reasonable and necessary.

V. REFERENCES

1. Luteinizing Hormone-Releasing Hormone (LHRH) Analogs LCD (L39387) Original Version. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed January 19, 2023.
2. Billing and Coding: Luteinizing Hormone-Releasing Hormone (LHRH) Analogs (A59160) Original Version. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed January 19, 2023.
3. Lupron Depot 7.5 mg, 22.5 mg, 30 mg, 45 mg [package insert]. North Chicago, IL: AbbVie Inc.; April 2022.
4. Lupron Depot 3.75 mg [package insert]. North Chicago, IL: AbbVie Inc.; July 2022.
5. Lupron Depot 11.25 mg [package insert]. North Chicago, IL: AbbVie Inc.; March 2020.
6. Lupron Depot-Ped 7.5 mg, 11.25 mg, 15 mg, 30 mg [package insert]. North Chicago, IL: AbbVie Inc.; August 2022.
7. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer. Version 1.2023. https://www.nccn.org/professionals/physician_gls/prostate.pdf. Accessed January 19, 2023.
8. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Head and Neck Cancers. Version 1.2023 https://www.nccn.org/professionals/physician_gls/pdf/head-and-neck.pdf. Accessed January 19, 2023.

9. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer. Version 1.2023 https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf. Accessed January 19, 2023.
10. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version 4.2022. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed January 19, 2023.