Leuprolide Acetate for Depot Suspension (Lupron Depot®, Lupron Depot-Ped®, Eligard®, Fensolvi®)

NDC CODE(S)

00074-2108-XX LUPRON DEPOT-PED 7.5MG Kit (ABBVIE)
00074-2282-XX LUPRON DEPOT-PED 11.25MG Kit (ABBVIE)
00074-2440-XX LUPRON DEPOT-PED 15MG Kit (ABBVIE)
00074-3641-XX LUPRON DEPOT 3.75MG Kit (ABBVIE)
00074-3663-XX LUPRON DEPOT 11.25MG Kit (ABBVIE)
00074-3779-XX LUPRON DEPOT-PED 11.25MG Kit (ABBVIE)
00074-9694-XX LUPRON DEPOT-PED 30MG Kit (ABBVIE)
00074-3346-XX LUPRON DEPOT 22.5MG Kit (ABBVIE)
00074-3473-XX LUPRON DEPOT 45MG Kit (ABBVIE)
00074-3642-XX LUPRON DEPOT 7.5MG Kit (ABBVIE)
00074-3683-XX LUPRON DEPOT 30MG Kit (ABBVIE)
62935-0153-XX FENSOLVI 45MG Kit (TOLMAR PHARMACEUTICALS)
62935-0220-XX ELIGARD 22.5MG SYRINGE (TOLMAR PHARMACEUTICALS)
62935-0221-XX ELIGARD 22.5MG SYRINGE (TOLMAR PHARMACEUTICALS)
62935-0223-XX ELIGARD 22.5MG KIT (TOLMAR PHARMACEUTICALS)
62935-0303-XX ELIGARD 30MG KIT (TOLMAR PHARMACEUTICALS)
62935-0305-XX ELIGARD 30MG SYRINGE (TOLMAR PHARMACEUTICALS)
62935-0453-XX ELIGARD 45MG KIT (TOLMAR PHARMACEUTICALS)
62935-0454-XX ELIGARD 45MG SYRINGE (TOLMAR PHARMACEUTICALS)
62935-0753-XX ELIGARD 7.5MG KIT (TOLMAR PHARMACEUTICALS)
62935-0754-XX ELIGARD 7.5MG SYRINGE (TOLMAR PHARMACEUTICALS)

DESCRIPTION

Leuprolide acetate is a synthetic nonapeptide analog of naturally occurring gonadotropin releasing hormone (GnRH or LH-RH) that, when given continuously, inhibits pituitary gonadotropin secretion and suppresses testicular and ovarian steroidogenesis. The analog possesses greater potency than the natural hormone.

POLICY

- Leuprolide acetate for depot suspension for the treatment of the following is considered ***medically necessary*** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**
  - Breast cancer
  - Central precocious puberty (CPP)
  - Endometriosis
  - Ovarian cancer
  - Prostate cancer
  - Salivary Gland Tumors
  - Uterine leiomyomas (fibroid tumors)
- Leuprolide acetate for depot suspension for the treatment or prevention of other conditions/diseases is considered ***investigational.***

MEDICAL APPROPRIATENESS

INITIAL APPROVAL CRITERIA

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INITIAL APPROVAL CRITERIA

- Patient is 18 years or older (unless otherwise specified)**; AND**

Central Precocious Puberty (CPP) (Lupron Depot-Ped or Fensolvi only)

- Patient is less than 13 years old; **AND**
- Onset of secondary sexual characteristics earlier than age 8 for girls and 9 for boys associated with pubertal pituitary gonadotropin activation; **AND**
- Diagnosis is confirmed by a pubertal gonadal sex steroid level and a pubertal LH response to stimulation by native GnRH; **AND**
- Bone age advanced greater than 2 standard deviations (SD) beyond chronological age; **AND**
- Tumor has been ruled out by lab tests such as diagnostic imaging of the brain (to rule out intracranial tumor), pelvic/testicular/adrenal ultrasound (to rule out steroid secreting tumors), and human chorionic gonadotropin levels (to rule out a chorionic gonadotropin secreting tumor); **AND**
- Will not be used in combination with growth hormone

Endometriosis (Lupron Depot 1-Month/3-Month or Lupron Depot-Ped only)

- Documentation patient's diagnosis has been confirmed by a workup/evaluation (versus presumptive treatment)

Uterine leiomyomata (fibroids) (Lupron Depot 1-Month/3-Month or Lupron Depot-Ped only)

- Documentation patient's diagnosis has been confirmed by a workup/evaluation (versus presumptive treatment); **AND**
- Documentation patient is receiving iron therapy

Breast Cancer (Lupron Depot, Lupron Depot-Ped or Eligard only)

- Patient is pre-menopausal or is a male with suppression of testicular steroidogenesis; **AND**
- Disease is hormone receptor positive; **AND**
  - Used in combination with adjuvant endocrine therapy; **OR**
  - Endocrine therapy for recurrent or metastatic disease

Ovarian cancer (Lupron Depot, Lupron Depot-Ped or Eligard only)

- Used as a single agent; **AND**
  - Patient has a diagnosis of stage II-IV granulosa cell tumors of the ovary; **AND**
    - Patient's disease has relapsed; **OR**
  - Patient has a diagnosis of Epithelial Ovarian Cancer OR Fallopian Tube Cancer OR Primary Peritoneal Cancer; **AND**
    - Patient's disease is persistent or recurrent (excluding immediate treatment of biochemical relapse)

Prostate Cancer (Lupron Depot or Eligard only)

Head and Neck Cancer (Lupron Depot or Eligard only)

- Patient has a diagnosis of androgen-receptor positive recurrent salivary gland tumor; **AND**

- Patient has distant metastases with a performance status score of 0-3; **OR**
- Patient has unresectable locoregional recurrence or second primary with prior radiation therapy

RENEWAL CRITERIA

- Patient continues to meet the indication-specific relevant criteria identified in the Initial Approval Criteria;

AND

Prostate cancer and Salivary Gland tumors; Breast and Ovarian Cancer

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: tumor flare, hyperglycemia/diabetes, cardiovascular disease (myocardial infarction, sudden cardiac death, stroke), QT/QTc prolongation, convulsions, etc.

Central Precocious Puberty (CPP)

- Patient is less than 13 years old; **AND**
- Disease response as indicated by lack of progression or stabilization of secondary sexual characteristics, decrease in growth velocity and bone age advancement, and improvement in final height prediction; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: convulsions, development or worsening of psychiatric symptoms, etc.; **AND**
- Will not be used in combination with growth hormone

Endometriosis

- Patient has not received a total of 12 months of therapy of a GnRH-agonist (i.e., leuprolide acetate, etc.); **AND**
- Patient continues to have symptoms of endometriosis or symptoms recur after the initial 6-month course of therapy; **AND**
- Patient will have bone density assessment prior to retreatment; **AND**
- Patient will use in combination with add-back therapy in combination with norethindrone

Uterine leiomyomata (fibroids)

- May not be renewed

DOSAGE/ADMINISTRATION

INDICATION	DOSE
Endometriosis	Administer, intramuscularly, 3.75 mg monthly or 11.25 mg every 3 months for a duration of 6 months only
Breast/Ovarian Cancer	Administer, intramuscularly or subcutaneously, 3.75 mg every/7.5 mg monthly or 11.25 mg/22.5 mg every 3 months.

Central Precocious Puberty (CPP)	• Fensolvi subcutaneous kit
	  ○ Administer 45 mg subcutaneously once every six months.
	• Lupron Depot-Ped intramuscular injection:
	  ○ Weight based
	  ▪ >37.5 kg: 15 mg every 4 weeks
	  ▪ >25-37.5 kg: 11.25 mg every 4 weeks

	▪ ≤ 25 kg: 7.5 mg every 4 weeks; **OR** ○ Ages 2 to 11 years: 11.25 mg or 30 mg every 12 weeks
Uterine leiomyomata (fibroids)	Administer, intramuscularly, 3.75 mg monthly or 11.25 mg every 3 months. The recommended duration of therapy is 3 months or less; retreatment depends on return of symptoms
Prostate Cancer	Administer, intramuscularly or subcutaneously, 7.5 mg every 4 weeks, 22.5 mg every 12 weeks, 30 mg every 16 weeks, or 45 mg every 24 weeks
Salivary Gland tumors of the Head and Neck	Administer, intramuscularly or subcutaneously, 7.5 mg every 4 weeks, 22.5 mg every 12 weeks

- *Lupron Depot is administered intramuscularly (IM), Eligard and Fensolvi are administered subcutaneously (SQ)*
- *Do not use concurrently a fractional dose, or a combination of doses of this or any depot formulation due to different release characteristics.*

LENGTH OF AUTHORIZATION

- Endometriosis: Coverage will be provided for 6 months and is eligible for renewal one time only
- Uterine leiomyomata (fibroids): Coverage will be provided for 3 months and is not eligible for renewal
- All other indications: Coverage will be provided for 12 months and is eligible for renewal.

DOSING LIMITS

Max Units (per dose and over time) [HCPCS Unit]:

Diagnosis	HCPCS	Product(s)	Billable Units	Days Supply
Prostate/Breast/ Ovarian Cancer	J9217	Lupron Depot 1-Month & Eligard 7.5 mg	1	28
		Lupron Depot 3-Month & Eligard 22.5 mg	3	84
Prostate Cancer		Lupron Depot 4-Month & Eligard 30 mg	4	112
		Lupron Depot 6-Month & Eligard 45 mg	6	168
Salivary Gland Tumors of the Head and Neck	J9217	Lupron Depot 1-month & Eligard 7.5 mg	1	28
		Lupron Depot 3-Month & Eligard 22.5 mg	3	84
Breast/Ovarian Cancer; Endometriosis; Uterine Fibroids	J1950	Lupron Depot 1-Month 3.75 mg	1	28
		Lupron Depot 3-Month 11.25 mg	3	84
Central Precocious Puberty	J1950/ J3490	Lupron Depot-Ped 7.5 mg	2	28
		Lupron Depot-Ped 11.25 mg	3	28
		Lupron Depot-Ped 15 mg	4	28
		Lupron Depot-Ped 30 mg	8	84
		Fensolvi 45 mg Kit	(45 mg)	168

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-

label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

SOURCES

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2. Lupron Depot GYN 3.75 mg and 3 Month 11.25 mg [package insert]. North Chicago, IL; AbbVie Inc.; February 2021. Accessed March 2021
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7. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Leuprolide acetate. National Comprehensive Cancer Network, 2021. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2021.
8. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Leuprolide acetate for depot suspension. National Comprehensive Cancer Network, 2021. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2021.
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EFFECTIVE DATE 8/31/2021

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