

Lupron Depot®, Lupron Depot-Ped®, Eligard® (leuprolide suspension) (Intramuscular)

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I. Length of Authorization

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

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

Drug Name	Strength	Quantity	Days Supply
Lupron Depot 1-Month	3.75 mg	1 injection	28 days
Lupron Depot 1-Month	7.5 mg	1 injection	28 days
Lupron Depot 3-Month	11.25 mg	1 injection	84 days
Lupron Depot 3-Month	22.5 mg	1 injection	84 days
Lupron Depot 4-Month	30 mg	1 injection	112 days
Lupron Depot 6-Month	45 mg	1 injection	168 days
Lupron Depot-Ped	7.5 mg	1 injection	28 days
Lupron Depot-Ped	11.25 mg	1 injection	28 days
Lupron Depot-Ped 3-Month	11.25 mg	1 injection	84 days
Lupron Depot-Ped	15 mg	1 injection	28 days
Lupron Depot-Ped 3-Month	30 mg	1 injection	84 days
Eligard	7.5 mg	1 injection	28 days
Eligard	22.5 mg	1 injection	84 days
Eligard	30 mg	1 injection	112 days
Eligard	45 mg	1 injection	168 days

B. Max Units (per dose and over time) [Medical Benefit]:

Diagnosis	HCPCS Code	Product(s)	Billable Units	Days Supply
Prostate/Breast/Ovarian Cancer Prostate Cancer	J9217	Lupron Depot 1-Month & Eligard 7.5 mg	1	28
		Lupron Depot 3-Month & Eligard 22.5 mg	3	84

		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	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

III. Initial Approval Criteria

- Coverage for Deseret Protect members is limited to oncology uses ONLY.

Central Precocious Puberty (CPP) (J1950 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)

Endometriosis † (J1950 only)

- Patient older than 18; **AND**
- Documentation patient's diagnosis has been confirmed by a workup/evaluation (versus presumptive treatment)

Uterine leiomyomata (fibroids) † (J1950 only)

- Patient older than 18; **AND**
- Documentation patient's diagnosis has been confirmed by a workup/evaluation (versus presumptive treatment); **AND**
- Documentation patient is receiving iron therapy

Breast Cancer ‡ (J9217 and J1950)

- 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 ‡ (J9217 and J1950)

- 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 † (J9217 only)

Head and Neck Cancer ‡ (J9217 only)

- Patient has a diagnosis of androgen-receptor positive salivary gland tumor; **AND**
- Patient has recurrent disease with distant metastases; **AND**
- Patient has a performance status score of 0-3

† FDA Approved Indication(s); ‡ Compendia recommended indication(s)

IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

Prostate cancer and Salivary Gland tumors (J9217 only); Breast and Ovarian Cancer (J9217 or J1950 only)

- Tumor response with 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) (J1950 only)

- Patient continues to meet criteria identified in section III; **AND**
- Disease response as indicated by lack of progression or stabilization of secondary sexual characteristics, decrease in height velocity, 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.

Endometriosis/Uterine leiomyomata (fibroids)

- May not be renewed

V. Dosage/Administration

Indication	Dose
Endometriosis	Intramuscularly 3.75 mg monthly or 11.25 mg every 3 months for a duration of 6 months
Breast/Ovarian Cancer	Intramuscularly 3.75 mg every/7.5 mg IM monthly or 11.25 mg/22.5 mg every 3 months
Central Precocious Puberty (CPP)	<ul style="list-style-type: none"> Lupron Depot-Ped IM injection: <ul style="list-style-type: none"> >37.5kg: 15 mg every 4 weeks 25-37.5kg: 11.25 mg every 4 weeks ≤ 25kg: 7.5 mg every 4 weeks Ages 2 to 11 yrs: 11.25 mg or 30 mg every 12 weeks
Uterine leiomyomata (fibroids)	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	7.5 mg every 4 weeks, 22.5 mg every 12 weeks, 30 mg every 16 weeks, or 45 mg every 24 weeks <ul style="list-style-type: none"> Lupron is administered intramuscularly; Eligard is administered subcutaneously
Salivary Gland tumors of the Head and Neck	7.5 mg every 4 weeks, 22.5 mg every 12 weeks <ul style="list-style-type: none"> Lupron is administered intramuscularly; Eligard is administered subcutaneously

Lupron Depot is administered intramuscularly (IM), Eligard is administered subcutaneously (SQ)

VI. Billing Code/Availability Information

Drug Name	Strength	HCPCS*	NDC
Lupron Depot 1-Month	3.75 mg	J1950	00074-3641-xx
Lupron Depot 1-Month	7.5 mg	J9217	00074-3642-xx
Lupron Depot 3-Month	11.25 mg	J1950	00074-3663-xx
Lupron Depot 3-Month	22.5 mg	J9217	00074-3346-xx
Lupron Depot 4-Month	30 mg	J9217	00074-3683-xx
Lupron Depot 6-Month	45 mg	J9217	00074-3473-xx
Lupron Depot-Ped	7.5 mg	J1950	00074-2108-xx
Lupron Depot-Ped	11.25 mg	J1950	00074-2282-xx
Lupron Depot-Ped 3-Month	11.25 mg	J1950	00074-3779-xx
Lupron Depot-Ped	15 mg	J1950	00074-2440-xx
Lupron Depot-Ped 3-Month	30 mg	J1950	00074-9694-xx
Eligard	7.5 mg	J9217	62935-0753-xx
Eligard	22.5 mg	J9217	62935-0223-xx
Eligard	30 mg	J9217	62935-0303-xx
Eligard	45 mg	J9217	62935-0453-xx

*J1950: Injection, leuprolide acetate (for depot suspension), per 3.75 mg

*J9217: Leuprolide acetate (for depot suspension), 7.5 mg

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VII. References

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6. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Leuprolide acetate for depot suspension. National Comprehensive Cancer Network, 2018. 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 2018.
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Appendix 1 – Covered Diagnosis Codes

J1950

ICD-10	ICD-10 Description
C48.1	Malignant neoplasm of specified parts of peritoneum
C48.2	Malignant neoplasm of peritoneum, unspecified
C48.8	Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum
C50.011	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast
C50.021	Malignant neoplasm of nipple and areola, right female breast
C50.022	Malignant neoplasm of nipple and areola, left female breast
C50.029	Malignant neoplasm of nipple and areola, unspecified female breast
C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast
C50.119	Malignant neoplasm of central portion of unspecified female breast
C50.121	Malignant neoplasm of central portion of right male breast
C50.122	Malignant neoplasm of central portion of left male breast
C50.129	Malignant neoplasm of central portion of unspecified male breast

ICD-10	ICD-10 Description
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified female breast
C50.221	Malignant neoplasm of upper-inner quadrant of right male breast
C50.222	Malignant neoplasm of upper-inner quadrant of left male breast
C50.229	Malignant neoplasm of upper-inner quadrant of unspecified male breast
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast
C50.319	Malignant neoplasm of lower-inner quadrant of unspecified female breast
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast
C50.322	Malignant neoplasm of lower-inner quadrant of left male breast
C50.329	Malignant neoplasm of lower-inner quadrant of unspecified male breast
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast
C50.419	Malignant neoplasm of upper-outer quadrant of unspecified female breast
C50.421	Malignant neoplasm of upper-outer quadrant of right male breast
C50.422	Malignant neoplasm of upper-outer quadrant of left male breast
C50.429	Malignant neoplasm of upper-outer quadrant of unspecified male breast
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified female breast
C50.521	Malignant neoplasm of lower-outer quadrant of right male breast
C50.522	Malignant neoplasm of lower-outer quadrant of left male breast
C50.529	Malignant neoplasm of lower-outer quadrant of unspecified male breast
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.619	Malignant neoplasm of axillary tail of unspecified female breast
C50.621	Malignant neoplasm of axillary tail of right male breast
C50.622	Malignant neoplasm of axillary tail of left male breast
C50.629	Malignant neoplasm of axillary tail of unspecified male breast
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast
C50.821	Malignant neoplasm of overlapping sites of right male breast
C50.822	Malignant neoplasm of overlapping sites of left male breast
C50.829	Malignant neoplasm of overlapping sites of unspecified male breast
C50.911	Malignant neoplasm of unspecified site of right female breast
C50.912	Malignant neoplasm of unspecified site of left female breast

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ICD-10	ICD-10 Description
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
C50.921	Malignant neoplasm of unspecified site of right male breast
C50.922	Malignant neoplasm of unspecified site of left male breast
C50.929	Malignant neoplasm of unspecified site of unspecified male breast
C56.1	Malignant neoplasm of right ovary
C56.2	Malignant neoplasm of left ovary
C56.9	Malignant neoplasm of unspecified ovary
C57.00	Malignant neoplasm of unspecified fallopian tube
C57.01	Malignant neoplasm of right fallopian tube
C57.02	Malignant neoplasm of left fallopian tube
C57.10	Malignant neoplasm of unspecified broad ligament
C57.11	Malignant neoplasm of right broad ligament
C57.12	Malignant neoplasm of left broad ligament
C57.20	Malignant neoplasm of unspecified round ligament
C57.21	Malignant neoplasm of right round ligament
C57.22	Malignant neoplasm of left round ligament
C57.3	Malignant neoplasm of parametrium
C57.4	Malignant neoplasm of uterine adnexa, unspecified
C57.7	Malignant neoplasm of other specified female genital organs
C57.8	Malignant neoplasm of overlapping sites of female genital organs
C57.9	Malignant neoplasm of female genital organ, unspecified
D25.0	Submucous leiomyoma of uterus
D25.1	Intramural leiomyoma of uterus
D25.2	Subserosal leiomyoma of uterus
D25.9	Leiomyoma of uterus, unspecified
E30.1	Precocious puberty
E30.8	Other disorders of puberty
N80.0	Endometriosis of uterus
N80.1	Endometriosis of ovary
N80.2	Endometriosis of fallopian tube
N80.3	Endometriosis of pelvic peritoneum
N80.4	Endometriosis of rectovaginal septum and vagina
N80.5	Endometriosis of intestine
N80.6	Endometriosis in cutaneous scar
N80.8	Other endometriosis
N80.9	Endometriosis, unspecified
Z85.3	Personal history of malignant neoplasm of breast
Z85.43	Personal history of malignant neoplasm of ovary

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ICD-10	ICD-10 Description
C07	Malignant neoplasm of parotid gland
C08.0	Malignant neoplasm of submandibular gland
C08.1	Malignant neoplasm of sublingual gland
C08.9	Malignant neoplasm of major salivary gland, unspecified
C48.1	Malignant neoplasm of specified parts of peritoneum
C48.2	Malignant neoplasm of peritoneum, unspecified
C48.8	Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum
C50.011	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast
C50.021	Malignant neoplasm of nipple and areola, right female breast
C50.022	Malignant neoplasm of nipple and areola, left female breast
C50.029	Malignant neoplasm of nipple and areola, unspecified female breast
C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast
C50.119	Malignant neoplasm of central portion of unspecified female breast
C50.121	Malignant neoplasm of central portion of right male breast
C50.122	Malignant neoplasm of central portion of left male breast
C50.129	Malignant neoplasm of central portion of unspecified male breast
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified female breast
C50.221	Malignant neoplasm of upper-inner quadrant of right male breast
C50.222	Malignant neoplasm of upper-inner quadrant of left male breast
C50.229	Malignant neoplasm of upper-inner quadrant of unspecified male breast
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast
C50.319	Malignant neoplasm of lower-inner quadrant of unspecified female breast
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast
C50.322	Malignant neoplasm of lower-inner quadrant of left male breast
C50.329	Malignant neoplasm of lower-inner quadrant of unspecified male breast
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast
C50.419	Malignant neoplasm of upper-outer quadrant of unspecified female breast
C50.421	Malignant neoplasm of upper-outer quadrant of right male breast
C50.422	Malignant neoplasm of upper-outer quadrant of left male breast

ICD-10	ICD-10 Description
C50.429	Malignant neoplasm of upper-outer quadrant of unspecified male breast
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified female breast
C50.521	Malignant neoplasm of lower-outer quadrant of right male breast
C50.522	Malignant neoplasm of lower-outer quadrant of left male breast
C50.529	Malignant neoplasm of lower-outer quadrant of unspecified male breast
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.619	Malignant neoplasm of axillary tail of unspecified female breast
C50.621	Malignant neoplasm of axillary tail of right male breast
C50.622	Malignant neoplasm of axillary tail of left male breast
C50.629	Malignant neoplasm of axillary tail of unspecified male breast
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast
C50.821	Malignant neoplasm of overlapping sites of right male breast
C50.822	Malignant neoplasm of overlapping sites of left male breast
C50.829	Malignant neoplasm of overlapping sites of unspecified male breast
C50.911	Malignant neoplasm of unspecified site of right female breast
C50.912	Malignant neoplasm of unspecified site of left female breast
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
C50.921	Malignant neoplasm of unspecified site of right male breast
C50.922	Malignant neoplasm of unspecified site of left male breast
C50.929	Malignant neoplasm of unspecified site of unspecified male breast
C56.1	Malignant neoplasm of right ovary
C56.2	Malignant neoplasm of left ovary
C56.9	Malignant neoplasm of unspecified ovary
C57.00	Malignant neoplasm of unspecified fallopian tube
C57.01	Malignant neoplasm of right fallopian tube
C57.02	Malignant neoplasm of left fallopian tube
C57.10	Malignant neoplasm of unspecified broad ligament
C57.11	Malignant neoplasm of right broad ligament
C57.12	Malignant neoplasm of left broad ligament
C57.20	Malignant neoplasm of unspecified round ligament
C57.21	Malignant neoplasm of right round ligament
C57.22	Malignant neoplasm of left round ligament
C57.3	Malignant neoplasm of parametrium

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ICD-10	ICD-10 Description
C57.4	Malignant neoplasm of uterine adnexa, unspecified
C57.7	Malignant neoplasm of other specified female genital organs
C57.8	Malignant neoplasm of overlapping sites of female genital organs
C57.9	Malignant neoplasm of female genital organ, unspecified
C61	Malignant neoplasm of prostate
Z85.3	Personal history of malignant neoplasm of breast
Z85.43	Personal history of malignant neoplasm of ovary
Z85.46	Personal history of malignant neoplasm of prostate

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

Lupron Depot/Lupron Depot-Ped (J1950) & Lupron Depot/Eligard (J9217)

Jurisdiction(s): N	NCD/LCD Document (s): L33685
https://www.cms.gov/medicare-coverage-database/search/lcd-date-search.aspx?DocID=L33685&bc=gAAAAAAAAAAAA	

Jurisdiction(s): L, H	NCD/LCD Document (s): L34822
https://www.cms.gov/medicare-coverage-database/search/document-id-search-results.aspx?Date=10/17/2017&DocID=L34822&bc=iAAAAAAAAAAAAAA%3d%3d&	

Jurisdiction(s): 6, K	NCD/LCD Document (s): A52453
https://www.cms.gov/medicare-coverage-database/search/document-id-search-results.aspx?DocID=A52453&bc=gAAAAAAAAAAAAAA%3d%3d&	

Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)

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Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC