



# Leuprolide Suspension: Lupron Depot<sup>®</sup>, Lupron Depot-Ped<sup>®</sup>, Eligard<sup>®</sup>, Fensolvi<sup>®</sup>, Camcevi<sup>™</sup>, Lutrate Depot<sup>™</sup>, Leuprolide Acetate Depot Ψ

(Intramuscular/Subcutaneous)

Document Number: IH-0080

Last Review Date: 05/04/2023

Date of Origin: 11/28/2011

Dates Reviewed: 12/11, 03/2012, 06/2013, 09/2012, 12/2012, 03/2013, 06/2013, 09/2013, 12/2013, 03/2014, 06/2014, 09/2014, 12/2014, 03/2015, 05/2015, 08/2015, 11/2015, 02/2016, 5/2016, 8/2016, 11/2016, 2/2017, 5/2017, 8/2017, 11/2017, 02/2018, 05/2018, 04/2019, 04/2020, 06/2020, 04/2021, 07/2021, 08/2021, 03/2022, 10/2022, 01/2023, 04/2023, 05/2023

Treatment of gender dysphoria is exempt from utilization review. [Refer to Chapter 57 of the Laws of 2019 in Insurance Law § 4902 and Public Health Law § 4902]

# I. Length of Authorization

- <u>Endometriosis</u>:
  - Coverage will be provided for 6 months and may be renewed one time only.
- Prevention/Management of Menstrual Bleeding:
  - $\circ$   $\;$  Coverage will be provided for 6 months and may NOT be renewed.
- <u>Uterine Leiomyomata (fibroids)</u>:
  - $\circ$   $\;$  Coverage will be provided for 3 months and may NOT be renewed.
- <u>Fertility Preservation</u>:
  - Coverage will be provided for 12 months and may be renewed while patient is receiving concomitant cytotoxic chemotherapy.
- <u>All Other Indications</u>: Coverage will be provided for 12 months and may be renewed.

# II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

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 1-month	7.5 mg	1 injection	28 days
Lupron Depot-Ped 1-month	11.25  mg	1 injection	28 days
Lupron Depot-Ped 3-Month	11.25  mg	1 injection	84 days
Lupron Depot-Ped 1-month	15  mg	1 injection	28 days
Lupron Depot-Ped 3-Month	30 mg	1 injection	84 days
Lupron Depot-Ped 6-Month	45  mg	1 injection	168 days
Eligard	$7.5~{ m mg}$	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
Fensolvi	$45~{ m mg}$	1 injection	168 days
Camcevi	42 mg	1 injection	168 days
Lutrate Depot	22.5  mg	1 injection	84 days
Leuprolide Acetate Depot	22.5  mg	1 injection	84 days

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

Diagnosis	HCPCS	Product(s)	Billable Units	Days Supply
		Lupron Depot 1-Month & Eligard 7.5	1	28
		mg	T	20
		Lupron Depot 3-Month & Eligard 22.5	3	84
Prostate/Breast/	J9217	mg	0	
Ovarian Cancer		Lupron Depot 4-Month & Eligard 30	4	112
		mg	_	
		Lupron Depot 6-Month & Eligard 45	6	168
		mg	Ũ	100
Head and Neck Cancer		Lupron Depot 1-month & Eligard 7.5	1	28
– Salivary Gland	J9217	mg	-	
Tumors	0011	Lupron Depot 3-Month & Eligard 22.5	3	84
		mg	0	
Breast/Ovarian Cancer;		Lupron Depot 1-Month 3.75 mg	1	28
Endometriosis; Uterine	J1950			
Fibroids		Lupron Depot 3-Month 11.25 mg	3	84
		Lupron Depot-Ped 7.5 mg	2	28
		Lupron Depot-Ped 11.25 mg	3	28
Central Precocious	J1950/	Lupron Depot-Ped 15 mg	4	28
Puberty	J1951	Lupron Depot-Ped 30 mg	8	84
		Lupron Depot-Ped 45 mg	6	168
		Fensolvi 45 mg Kit	180	168
Prostate Cancer	J1952	Camcevi 42 mg Kit	42	168
Prostate Cancer	J1954	Lutrate Depot 22.5 mg Kit	3	84
Prostate Cancer	J1954	Leuprolide Acetate Depot	3	84
Fertility Preservation/				
Prevention/Management	J1950	Lupron Depot 1-Month 3.75 mg	1	28
of Menstrual Bleeding				
Gender Dysphoria		Lupron Depot 1-Month 3.75 mg	1	28

		LEUPROLIDE SUSP (Lupron Depot®, Lupron Depot-Ped®, Eligard®, Fensolvi®, Lutrate Depot™, Leuprolide Acetate Depot) Prior Auth
Page 2	1.1	Criteria
r age 2	1	Proprietary Information. Restricted Access – Do not disseminate or copy without approval.
		©2023, Magellan Rx Management



J1950/	Lupron Depot 3-Month 11.25 mg	3	84
J1950/ J1951	Lupron Depot-Ped 11.25 mg	3	28
01551	Fensolvi 45 mg Kit	180	168

# III. Initial Approval Criteria

Coverage is provided in the following conditions:

• Patient is at least 18 years of age (unless otherwise specified); AND

# Central Precocious Puberty (CPP) ${}^{3,6,14,20-22}$ † $\Phi$ (J1950 and J1951)

- Patient is less than 13 years of age; AND
- Onset of secondary sexual characteristics earlier than age 8 for females and 9 for males associated with pubertal pituitary gonadotropin activation; **AND**
- Diagnosis is confirmed by pubertal gonadal sex steroid levels and a pubertal luteinizing hormone (LH) response to stimulation by native growth hormone-releasing hormone (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 <sup>1,2,12</sup> † (J1950)

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

#### Uterine Leiomyomata (fibroids) 1,2,13 † (J1950)

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

#### Breast Cancer <sup>10,11,15,16</sup> ‡ (J9217 and J1950)

- Patient has invasive or inflammatory disease; AND
- Patient is premenopausal or is a male with suppression of testicular steroidogenesis; AND
- Disease is hormone receptor-positive; AND
  - $\circ$   $\;$  Used in combination with adjuvant endocrine therapy;  $\boldsymbol{OR}$
  - $\circ~$  Used in combination with endocrine the rapy for recurrent unresectable or metastatic disease



#### Ovarian Cancer <sup>10,11,18,19</sup> ‡ (J9217 and J1950)

- Used as a single agent; AND
  - $\circ$   $\,$  Patient has a diagnosis of stage II-IV granulosa cell tumors of the ovary; AND  $\,$ 
    - Patient has relapsed disease; **OR**
  - Patient has a diagnosis of Epithelial Ovarian Cancer OR Fallopian Tube Cancer OR Primary Peritoneal Cancer (includes Mucinous Carcinoma, Clear Cell Carcinoma, Carcinosarcoma-Mixed Malignant Müllerian Tumors, Grade 1 Endometrioid Carcinoma, Low-grade Serous Carcinoma, and Malignant Sex Cord-Stromal Tumors), AND
    - Patient has persistent or recurrent disease (excluding immediate treatment of biochemical relapse)

# Prostate Cancer 4,5,8-10,11,17 **†** (J9217, J1952, and J1954)

• Patient has advanced disease

# Head and Neck Cancer <sup>10,11</sup> ‡ (J9217)

- Patient has salivary gland tumors; AND
- Used as a single agent; AND
- Patient has androgen-receptor positive recurrent disease; AND
  - $\circ$   $\;$  Patient has distant metastases with a performance status score of 0-3;  $\mathbf{OR}$
  - Patient has unresectable locoregional recurrence or second primary with prior radiation therapy

# Prevention/Management of Menstrual Bleeding Associated with Hematopoietic Stem Cell Transplant (HCT) <sup>24-27</sup> ‡ (J1950)

- Patient is premenopausal; AND
  - Patient will receive conditioning myeloablative treatment with cytotoxic chemotherapy;
     OR
  - Patient has menorrhagia due to thrombocytopenia related to delayed platelet engraftment

# Fertility Preservation Prior to Chemotherapy 24-27 ‡ (J1950)

- Patient is premenopausal; AND
- Patient is receiving treatment with cytotoxic chemotherapy with the potential to cause ovarian damage/toxicity (e.g., cyclophosphamide, melphalan, procarbazine vinblastine, imatinib, etc.); **AND**
- Patient has failed or is not a candidate for other fertility preservation methods (e.g., cryopreservation, etc.)

FDA Approved Indication(s); Compendia recommended indication(s); Orphan Drug



# **IV.** Renewal Criteria

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the indication-specific relevant criteria identified in section III; 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.; **AND**

#### Prostate Cancer (J9217, J1952, and J1954); Head and Neck Cancer – Salivary Gland Tumors (J9217); Breast and Ovarian Cancer (J9217 and J1950)

• Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

#### Central Precocious Puberty (CPP) 3,6,14,20-22 (J1950 and J1951)

- Patient is less than 13 years of age; AND
- Disease response as indicated by lack of progression or stabilization of secondary sexual characteristics, decrease in height velocity, a decrease in the ratio of bone age to chronological age (BA:CA), 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 (J1950)

- 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 6month course of therapy; **AND**
- Patient will have bone density assessment prior to retreatment; AND
- Extended GnRH-agonist treatment will be used in combination with norethindrone add-back therapy

#### Uterine Leiomyomata (fibroids) (J1950)

• Coverage may NOT be renewed

#### Prevention/Management of Menstrual Bleeding Associated with HCT (J1950)

• Coverage may NOT be renewed

#### Fertility Preservation Prior to Chemotherapy (J1950)

• Patient is still receiving treatment with cytotoxic chemotherapy



# V. Dosage/Administration <sup>1-9</sup>

Indication	Dose	
Endometriosis	Administer 3.75 mg intramuscularly monthly or 11.25 mg intramuscularly 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)	<ul> <li>Fensolvi subcutaneous kit <ul> <li>Administer 45 mg subcutaneously once every 6 months.</li> </ul> </li> <li>Lupron Depot-Ped intramuscular injection: <ul> <li>Dosing for 1-month administration:</li> <li>&gt;37.5 kg: 15 mg every month (4 weeks)</li> <li>&gt;25-37.5 kg: 11.25 mg every month (4 weeks)</li> <li>≤ 25 kg: 7.5 mg every month (4 weeks)</li> <li>≤ 25 kg: 7.5 mg every month (4 weeks)</li> <li>Dosing for 3-month administration: <ul> <li>11.25 mg or 30 mg every 3 months (12 weeks)</li> </ul> </li> <li>Dosing for 6-month administration: <ul> <li>45 mg every 6 months (24 weeks)</li> </ul> </li> </ul></li></ul>	
Uterine Leiomyomata (fibroids)Administer 3.75 mg intramuscularly monthly or 11.25 mg intram every 3 months*. *The recommended duration of therapy is 3 months or less; retre 		
Prostate Cancer	<ul> <li>Lupron Depot &amp; Eligard <ul> <li>Administer, intramuscularly or subcutaneously, 7.5 mg every 4</li> <li>weeks, 22.5 mg every 12 weeks, 30 mg every 16 weeks, 45 mg every 24 weeks, or 42 mg every 24 weeks.</li> </ul> </li> <li>Camcevi subcutaneous kit <ul> <li>Administer 42 mg subcutaneously once every 6 months.</li> </ul> </li> <li>Lutrate Depot kit &amp; Leuprolide Acetate Depot (Cipla) <ul> <li>Administer 22.5 mg intramuscularly once every 12 weeks.</li> </ul> </li> </ul>	
Salivary Gland tumors of the Head and Neck	Administer, intramuscularly or subcutaneously, 7.5 mg every 4 weeks, 22.5 mg every 12 weeks	
Prevention/Management of Menstrual Bleeding Associated with HCT	Administer 3.75 mg intramuscularly once every 4 weeks up to 6 months Therapy should be started 4-5 weeks prior to conditioning chemotherapy and continued as required until platelets are >50,000 post HCT)	
Fertility Preservation Prior to Chemotherapy	Administer 3.75 mg intramuscularly every 4 weeks	
Gender Dysphoria	<ul> <li>Lupron Depot injection:</li> <li>Administer 3.75 mg intramuscularly once a month in combination with transdermal estradiol 1 or 2 mg/day; OR</li> </ul>	

Page 6	I	LEUPROLIDE SUSP (Lupron Depot <sup>®</sup> , Lupron Depot-Ped <sup>®</sup> , Eligard <sup>®</sup> , Fensolvi <sup>®</sup> , Lutrate Depot <sup>™</sup> , Leuprolide Acetate Depot) Prior Auth Criteria Proprietary Information. Restricted Access – Do not disseminate or copy without approval. ©2023, Magellan Rx Management	Magellan Rx MANAGEMENT
--------	---	---	---------------------------

<ul> <li>Administer 11.25 mg subcutaneously every 3 months</li> </ul>
<ul> <li>Fensolvi subcutaneous kit</li> </ul>
- Administer 45 mg subcutaneously once every 6 months

<u>Note:</u>

- Lupron Depot, and Lutrate Depot/Leuprolide Acetate Depot (Cipla) are administered intramuscularly (IM), Eligard, Fensolvi, and Camcevi are administered subcutaneously (SQ)
- Camcevi must be administered by a healthcare provider.
- Do not use concurrently a fractional dose, or a combination of doses of this or any depot formulation due to different release characteristics.

# 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 1-Month	7.5 mg	J1950	00074-2108-xx
Lupron Depot-Ped 1-Month	11.25  mg	J1950	00074-2282-xx
Lupron Depot-Ped 3-Month	11.25 mg	J1950	00074-3779-xx
Lupron Depot-Ped 1-Month	15  mg	J1950	00074-2440-xx
Lupron Depot-Ped 3-Month	30 mg	J1950	00074-9694-xx
Lupron Depot-Ped 6-Month	45  mg	J1950	00074-3575-xx
Eligard	$7.5~{ m mg}$	J9217	62935-0753-xx
Eligard	$22.5~{ m mg}$	J9217	62935-0223-xx
Eligard	30 mg	J9217	62935-0303-xx
Eligard	45  mg	J9217	62935-0453-xx
Fensolvi	45  mg	J1951	62935-0153-xx
Camcevi	42 mg	J1952	72851-0042-xx
Lutrate Depot/ Leuprolide	99 F	110F4	- 69112-0002-xx
Acetate Depot (Cipla) $oldsymbol{\Psi}$	22.5  mg	J1954	- 69097-0909-xx

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

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

- J1951: Injection, leuprolide acetate for depot suspension (fensolvi), 0.25 mg

– J1952: Leuprolide injectable, camcevi, 1 mg

– J1954: Injection, leuprolide acetate for depot suspension (cipla), 7.5 mg  $\Psi$ 

- \* Some formulations are available as multi-sourced generics.

- P Designated products approved by the FDA as a 505(b)(2) NDA of the innovator product. These products are not rated as therapeutically equivalent to their reference listed drug in the Food and Drug Administration's (FDA) Orange Book and are therefore considered single source products based on the statutory definition of "single source drug" in section 1847A(c)(6) of the Act. For a complete list of all approved 505(b)(2) NDA products please reference the latest edition of the Orange Book:

Approved Drug Products with Therapeutic Equivalence Evaluations / Orange Book / FDA

# VII. References

- 1. Lupron Depot GYN 3 Month 11.25 mg [package insert]. North Chicago, IL; Abbvie Inc.; March 2020. Accessed December 2022.
- 2. Lupron Depot GYN 3.75 mg and 3 Month 11.25 mg [package insert]. North Chicago, IL; Abbvie Inc.; February 2021. Accessed December 2022
- 3. Lupron Depot-Ped [package insert]. North Chicago, IL; Abbvie Inc.; April 2023. Accessed April 2023.
- 4. Lupron Depot URO [package insert.]. North Chicago, IL; Abbvie Inc.; March 2019. Accessed December 2022.
- 5. Eligard [package insert]. Fort Collins, CO; Tolmar Therapeutics, Inc; April 2019. Accessed December 2022.
- 6. Fensolvi [package insert]. Fort Collins, CO; Tolmar Therapeutics, Inc; May 2020. Accessed December 2022.
- 7. Camcevi [package insert]. Taipei City, Taiwan; Foresee Pharmaceuticals Co., Ltd.; May 2021. Accessed December 2022.
- 8. Lutrate Depot [package insert]. Sant Quintí de Mediona, Spain; GP-PHARM, S.A..; February 2023. Accessed March 2023.
- 9. Leuprolide Acetate Depot (Cipla) [package insert]. Sant Quintí de Mediona, Spain; GP-PHARM, S.A..; August 2018. Accessed March 2023.
- 10. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Leuprolide acetate. National Comprehensive Cancer Network, 2022. 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 December 2022.
- 11. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Leuprolide acetate for depot suspension. National Comprehensive Cancer Network, 2022. 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 December 2022.
- Dlugi AM, Miller JD, Knittle J, et al: Lupron depot (leuprolide acetate for depot suspension) in the treatment of endometriosis: a randomized, placebo-controlled, double-blind study. Fertil Steril 1990; 54:419-427.
- 13. Friedman AJ, Barbieri RL, Doubilet PM, et al: A randomized, double-blind trial of a gonadotropin-releasing hormone agonist (leuprolide) with or without medroxyprogesterone acetate in the treatment of leiomyomata uteri. Obstet Gynecol Surv 1988; 43:484-485.

LEUPROLIDE SUSP (Lupron Depot<sup>®</sup>, Lupron Depot-Ped<sup>®</sup>, Eligard<sup>®</sup>,



- 14. Lee PA & Page JG: The Leuprolide Study Group: Effects of leuprolide in the treatment of central precocious puberty. J Pediatr 1989; 114:321-324.
- 15. Harvey HA, Lipton A, Max DT, et al: Medical castration produced by the GnRH analogue leuprolide to treat metastatic breast cancer. J Clin Oncol 1985; 3:1068-1072.
- 16. Boccardo F, Rubagotti A, Amoroso D, et al, "Endocrinological and Clinical Evaluation of Two Depot Formulations of Leuprolide Acetate in Pre- and Perimenopausal Breast Cancer Patients," Cancer Chemother Pharmacol, 1999, 43(6):461-6.
- National Collaborating Centre for Cancer. Prostate cancer: diagnosis and treatment. London (UK): National Institute for Health and Clinical Excellence (NICE); 2008 Feb. 146 p. (NICE clinical guideline; no. 58)
- 18. Fishman A, Kudelka AP, Tresukosol D, et al. Leuprolide acetate for treating refractory or persistent ovarian granulosa cell tumor. J Reprod Med. 1996;41(6):393-396.
- 19. Kavanagh JJ, Roberts W, Townsend P, et al: Leuprolide acetate in the treatment of refractory or persistent epithelial ovarian cancer. J Clin Oncol 1989; 7:115-118.
- 20. Beccuti G, Ghizzoni L. Normal and Abnormal Puberty. Endotext. De Groot LJ, Chrousos G, Dungan K, et al., editors, South Dartmouth (MA): MDText.com, Inc.; 2000-. Accessed at: https://www.ncbi.nlm.nih.gov/books/NBK279024/.
- 21. Brito VN, Spinola-Castro AM, Kochi C, et al. Central precocious puberty: revisiting the diagnosis and therapeutic management. Arch Endocrinol Metab. 2016 Apr;60(2):163-72
- 22. Carel JC, Eugster E, Rogol A, et al. Consensus statement on the use of gonadotropin-releasing hormone analogs in children. Pediatrics. 2009 Apr;123(4):e752-62. doi: 10.1542/peds.2008-1783. Epub 2009 Mar 30.
- 23. Shore N, Mincik I, DeGuenther M, et al. A phase 3, open-label, multicenter study of a 6-month pre-mixed depot formulation of leuprolide mesylate in advanced prostate cancer patients. World J Urol. 2020 Jan;38(1):111-119. doi: 10.1007/s00345-019-02741-7.
- 24. Amsterdam A, et al. Management of menorrhagia. Treatment of menorrhagia in women undergoing hematopoietic stem cell transplantation. Bone Marrow Transplantation 2004; 34:363-66..
- 25. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines<sup>®</sup>) for Adolescent and Young Adult (AYA) Oncology Version 2.2022. National Comprehensive Cancer Network, 2022. NATIONAL COMPREHENSIVE CANCER NETWORK<sup>®</sup>, NCCN<sup>®</sup>, and NCCN GUIDELINES<sup>®</sup> are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed December 2022.
- 26. Options for Prevention and Management of Menstrual Bleeding in Adolescent Patients Undergoing Cancer Treatment: ACOG Committee Opinion, Number 817. Obstet Gynecol. 2021 Jan 1;137(1):e7-e15. doi: 10.1097/AOG.00000000004209.



- Ghalie, R., et al. Prevention of Hypermenorrhea with Leuprolide in Premenopausal Women Undergoing Bone Marrow Transplantation, American Journal of Hematology. 1993;42: 350-353.
- 28. Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab 2017; 102:3869
- 29. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders. 5th ed. Arlington, VA: American Psychiatric Association Publishing.
- 30. The World Professional Association for Transgender Health (WPATH), Standards of Care for the Health of Transsexual, and Gender Nonconforming People. Seventh Version. July 2012. Available at: <u>https://www.wpath.org/media/cms/Documents/SOC%20v7/SOC%20V7\_English2012.pdf?\_t=161\_3669341</u>
- 31. Hembree WC, Cohen-Kettenis PT, Gooren L, et al; Endocrine treatment of genderdysphoric/gender-incongruent persons: an Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab 2017; 102(11):3869-3903.
- 32. Gava G, Cerpolini S, Martelli V, et al; Cyproterone acetate vs leuprolide acetate in combination with transdermal oestradiol in transwomen: a comparison of safety and effectiveness. Clin Endocrinol (Oxf) 2016; 85(2):239-246.
- 33. Coleman E, Radix AE, Bouman WP, et al. Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. Int J Transgend Health. 2022 Sep 6;23(Suppl 1):S1-S259. doi: 10.1080/26895269.2022.2100644.
- 34. Lee PA, Neely EK, Fuqua J, et al. Efficacy of Leuprolide Acetate 1-Month Depot for Central Precocious Puberty (CPP): Growth Outcomes During a Prospective, Longitudinal Study. Int J Pediatr Endocrinol. 2011;2011(1):7. doi: 10.1186/1687-9856-2011-7. Epub 2011 Jul 12.
- 35. Lee PA, Klein K, Mauras N, et al. 36-month treatment experience of two doses of leuprolide acetate 3-month depot for children with central precocious puberty. J Clin Endocrinol Metab. 2014 Sep;99(9):3153-9. doi: 10.1210/jc.2013-4471.
- 36. National Government Services, Inc. Local Coverage Article: Billing and Coding: Luteinizing Hormone-Releasing Hormone (LHRH) Analogs (A52453). Centers for Medicare & Medicaid Services, Inc. Updated on 09/09/2022 with effective date 10/01/2022. Accessed December 2022.

# Appendix 1 – Covered Diagnosis Codes

©2023, Magellan Rx Management

#### J1950

ICD-10	ICD-10 Description		
C48.1	Malignant neoplasm of specified parts of peritoneum		
C48.2	Malignant neoplasm of peritoneum, unspecified	gnant neoplasm of peritoneum, unspecified	
C48.8	Malignant neoplasm of overlapping sites of retroperitoneum and	peritoneum	
	LEUPROLIDE SUSP (Lupron Depot <sup>®</sup> , Lupron Depot-Ped <sup>®</sup> , Eligard <sup>®</sup> ,		
Page 10	Fensolvi <sup>®</sup> , Lutrate Depot <sup>™</sup> , Leuprolide Acetate Depot) Prior Auth Criteria Proprietary Information. Restricted Access – Do not disseminate or copy without approval.		

ICD-10	ICD-10 Description
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
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
	LEUPROLIDE SUSP (Lupron Depot <sup>®</sup> , Lupron Depot-Ped <sup>®</sup> , Eligard <sup>®</sup> ,

LEUPROLIDE SUSP (Lupron Depot<sup>®</sup>, Lupron Depot-Ped<sup>®</sup>, Eligard<sup>®</sup>, Fensolvi<sup>®</sup>, Lutrate Depot<sup>™</sup>, Leuprolide Acetate Depot) Prior Auth Criteria



Proprietary Information. Restricted Access – Do not disseminate or copy without approval. ©2023, Magellan Rx Management

Page 11

Т

CD-10	ICD-10 Description	
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	
C56.3	Malignant neoplasm of bilateral ovaries	
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	
	Intramural leiomyoma of uterus	

# Page 12 Criteria Proprietary Information. Restricted Access – Do not disseminate or copy without approval. ©2023, Magellan Rx Management



ICD-10	ICD-10 Description
D25.2	Subserosal leiomyoma of uterus
D25.9	Leiomyoma of uterus, unspecified
E30.1	Precocious puberty
E30.8	Other disorders of puberty
F64.0	Transsexualism
F64.1	Dual role transvestism
F64.2	Gender identity disorder of childhood
F64.8	Other gender identity disorders
F64.9	Gender identity disorder, unspecified
N80.00	Endometriosis of the uterus, unspecified
N80.01	Superficial endometriosis of the uterus
N80.02	Deep endometriosis of the uterus
N80.03	Adenomyosis of the uterus
N80.101	Endometriosis of right ovary, unspecified depth
N80.102	Endometriosis of left ovary, unspecified depth
N80.103	Endometriosis of bilateral ovaries, unspecified depth
N80.109	Endometriosis of ovary, unspecified side, unspecified depth
N80.111	Superficial endometriosis of right ovary
N80.112	Superficial endometriosis of left ovary
N80.113	Superficial endometriosis of bilateral ovaries
N80.119	Superficial endometriosis of ovary, unspecified ovary
N80.121	Deep endometriosis of right ovary
N80.122	Deep endometriosis of left ovary
N80.123	Deep endometriosis of bilateral ovaries
N80.129	Deep endometriosis of ovary, unspecified ovary
N80.201	Endometriosis of right fallopian tube, unspecified depth
N80.202	Endometriosis of left fallopian tube, unspecified depth
N80.203	Endometriosis of bilateral fallopian tubes, unspecified depth
N80.209	Endometriosis of unspecified fallopian tube, unspecified depth
N80.211	Superficial endometriosis of right fallopian tube
N80.212	Superficial endometriosis of left fallopian tube
N80.213	Superficial endometriosis of bilateral fallopian tubes
N80.219	Superficial endometriosis of unspecified fallopian tube
N80.221	Deep endometriosis of right fallopian tube
N80.222	Deep endometriosis of left fallopian tube
N80.223	Deep endometriosis of bilateral fallopian tubes
N80.229	Deep endometriosis of unspecified fallopian tube
N80.30	Endometriosis of pelvic peritoneum, unspecified
N80.311	Superficial endometriosis of the anterior cul-de-sac
N80.312	Deep endometriosis of the anterior cul-de-sac

I	LEUPROLIDE SUSP (Lupron Depot <sup>®</sup> , Lupron Depot-Ped <sup>®</sup> , Eligard <sup>®</sup> , Fensolvi <sup>®</sup> , Lutrate Depot <sup>™</sup> , Leuprolide Acetate Depot) Prior Auth Criteria
	Proprietary Information. Restricted Access – Do not disseminate or copy without approval.

©2023, Magellan Rx Management

Page 13



ICD-10	ICD-10 Description	
N80.319	Endometriosis of the anterior cul-de-sac, unspecified depth	
N80.321	Superficial endometriosis of the posterior cul-de-sac	
N80.322	Deep endometriosis of the posterior cul-de-sac	
N80.329	Endometriosis of the posterior cul-de-sac, unspecified depth	
N80.331	Superficial endometriosis of the right pelvic sidewall	
N80.332	Superficial endometriosis of the left pelvic sidewall	
N80.333	Superficial endometriosis of bilateral pelvic sidewall	
N80.339	Superficial endometriosis of pelvic sidewall, unspecified side	
N80.341	Deep endometriosis of the right pelvic sidewall	
N80.342	Deep endometriosis of the left pelvic sidewall	
N80.343	Deep endometriosis of the bilateral pelvic sidewall	
N80.349	Deep endometriosis of the pelvic sidewall, unspecified side	
N80.351	Endometriosis of the right pelvic sidewall, unspecified depth	
N80.352	Endometriosis of the left pelvic sidewall, unspecified depth	
N80.353	Endometriosis of bilateral pelvic sidewall, unspecified depth	
N80.359	Endometriosis of pelvic sidewall, unspecified side, unspecified depth	
N80.361	Superficial endometriosis of the right pelvic brim	
N80.362	Superficial endometriosis of the left pelvic brim	
N80.363	Superficial endometriosis of bilateral pelvic brim	
N80.369	Superficial endometriosis of the pelvic brim, unspecified side	
N80.371	Deep endometriosis of the right pelvic brim	
N80.372	Deep endometriosis of the left pelvic brim	
N80.373	Deep endometriosis of bilateral pelvic brim	
N80.379	Deep endometriosis of the pelvic brim, unspecified side	
N80.381	Endometriosis of the right pelvic brim, unspecified depth	
N80.382	Endometriosis of the left pelvic brim, unspecified depth	
N80.383	Endometriosis of bilateral pelvic brim, unspecified depth	
N80.389	Endometriosis of the pelvic brim, unspecified side, unspecified depth	
N80.3A1	Superficial endometriosis of the right uterosacral ligament	
N80.3A2	Superficial endometriosis of the left uterosacral ligament	
N80.3A3	Superficial endometriosis of the bilateral uterosacral ligament(s)	
N80.3A9	Superficial endometriosis of the uterosacral ligament(s), unspecified side	
N80.3B1	Deep endometriosis of the right uterosacral ligament	
N80.3B2	Deep endometriosis of the left uterosacral ligament	
N80.3B3	Deep endometriosis of bilateral uterosacral ligament(s)	
N80.3B9	Deep endometriosis of the uterosacral ligament(s), unspecified side	
N80.3C1	Endometriosis of the right uterosacral ligament, unspecified depth	
N80.3C2	Endometriosis of the left uterosacral ligament, unspecified depth	
N80.3C3	Endometriosis of bilateral uterosacral ligament(s), unspecified depth	
N80.3C9	Endometriosis of the uterosacral ligament(s), unspecified side, unspecified depth	
N80.391	Superficial endometriosis of the pelvic peritoneum, other specified sites	

LEUPROLIDE SUSP (Lupron Depot<sup>®</sup>, Lupron Depot-Ped<sup>®</sup>, Eligard<sup>®</sup>, Fensolvi<sup>®</sup>, Lutrate Depot<sup>™</sup>, Leuprolide Acetate Depot) Prior Auth Criteria



Proprietary Information. Restricted Access – Do not disseminate or copy without approval. ©2023, Magellan Rx Management

Page 14

L

ICD-10	ICD-10 Description	
N80.392	Deep endometriosis of the pelvic peritoneum, other specified sites	
N80.399	Endometriosis of the pelvic peritoneum, other specified sites, unspecified depth	
N80.40	Endometriosis of rectovaginal septum, unspecified involvement of vagina	
N80.41	Endometriosis of rectovaginal septum without involvement of vagina	
N80.42	Endometriosis of rectovaginal septum with involvement of vagina	
N80.50	Endometriosis of intestine, unspecified	
N80.511	Superficial endometriosis of the rectum	
N80.512	Deep endometriosis of the rectum	
N80.519	Endometriosis of the rectum, unspecified depth	
N80.521	Superficial endometriosis of the sigmoid colon	
N80.522	Deep endometriosis of the sigmoid colon	
N80.529	Endometriosis of the sigmoid colon, unspecified depth	
N80.531	Superficial endometriosis of the cecum	
N80.532	Deep endometriosis of the cecum	
N80.539	Endometriosis of the cecum, unspecified depth	
N80.541	Superficial endometriosis of the appendix	
N80.542	Deep endometriosis of the appendix	
N80.549	Endometriosis of the appendix, unspecified depth	
N80.551	Superficial endometriosis of other parts of the colon	
N80.552	Deep endometriosis of other parts of the colon	
N80.559	Endometriosis of other parts of the colon, unspecified depth	
N80.561	Superficial endometriosis of the small intestine	
N80.562	Deep endometriosis of the small intestine	
N80.569	Endometriosis of the small intestine, unspecified depth	
N80.A0	Endometriosis in cutaneous scar	
N80.A1	Endometriosis of bladder, unspecified depth	
N80.A2	Superficial endometriosis of bladder	
N80.A41	Deep endometriosis of bladder	
N80.A42	Superficial endometriosis of right ureter	
N80.A43	Superficial endometriosis of left ureter	
N80.A49	Superficial endometriosis of bilateral ureters	
N80.A51	Superficial endometriosis of unspecified ureter	
N80.A52	Deep endometriosis of right ureter	
N80.A53	Deep endometriosis of left ureter	
N80.A59	Deep endometriosis of bilateral ureters	
N80.A61	Deep endometriosis of unspecified ureter	
N80.A62	Endometriosis of right ureter, unspecified depth	
N80.A63	Endometriosis of left ureter, unspecified depth	
N80.A69	Endometriosis of bilateral ureters, unspecified depth	
N80.B1	Endometriosis of unspecified ureter, unspecified depth	
N80.B2	Endometriosis of pleura	

#### LEUPROLIDE SUSP (Lupron Depot®, Lupron Depot-Ped®, Eligard®, Fensolvi®, Lutrate Depot™, Leuprolide Acetate Depot) Prior Auth Criteria Proprietary Information. Restricted Access – Do not disseminate or copy without approval.

©2023, Magellan Rx Management

Page 15



ICD-10	ICD-10 Description	
N80.B31	Endometriosis of lung	
N80.B32	Superficial endometriosis of diaphragm	
N80.B39	Deep endometriosis of diaphragm	
N80.B4	Endometriosis of diaphragm, unspecified depth	
N80.B5	Endometriosis of the pericardial space	
N80.B6	Endometriosis of the mediastinal space	
N80.C0	Endometriosis of cardiothoracic space	
N80.C10	Endometriosis of the abdomen, unspecified	
N80.C11	Endometriosis of the anterior abdominal wall, subcutaneous tissue	
N80.C19	Endometriosis of the anterior abdominal wall, fascia and muscular layers	
N80.C2	Endometriosis of the anterior abdominal wall, unspecified depth	
N80.C3	Endometriosis of the umbilicus	
N80.C4	Endometriosis of the inguinal canal	
N80.C9	Endometriosis of extra-pelvic abdominal peritoneum	
N80.D0	Endometriosis of other site of abdomen	
N80.D1	Endometriosis of the pelvic nerves, unspecified	
N80.D2	Endometriosis of the sacral splanchnic nerves	
N80.D3	Endometriosis of the sacral nerve roots	
N80.D4	Endometriosis of the obturator nerve	
N80.D5	Endometriosis of the sciatic nerve	
N80.D6	Endometriosis of the pudendal nerve	
N80.D9	Endometriosis of the femoral nerve	
N80.9	Endometriosis, unspecified	
N93.8	Other specified abnormal uterine and vaginal bleeding	
N94.89	Other specified conditions associated with female genital organs and menstrual cycle	
T86.09	Other complications of bone marrow transplant	
Z31.84	Encounter for fertility preservation procedure	

#### J9217

ICD-10	ICD-10 Description	
C06.9	Malignant neoplasm of mouth, unspecified	
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	

Page 16	I	LEUPROLIDE SUSP (Lupron Depot <sup>®</sup> , Lupron Depot-Ped <sup>®</sup> , Eligard <sup>®</sup> , Fensolvi <sup>®</sup> , Lutrate Depot <sup>™</sup> , Leuprolide Acetate Depot) Prior Auth Criteria
Page 10		Proprietary Information. Restricted Access – Do not disseminate or copy without approval. ©2023, Magellan Rx Management



ICD-10	ICD-10 Description	
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	
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	
	LEUPROLIDE SUSP (Lupron Depot <sup>®</sup> , Lupron Depot-Ped <sup>®</sup> , Eligard <sup>®</sup> ,	

LEUPROLIDE SUSP (Lupron Depot<sup>®</sup>, Lupron Depot-Ped<sup>®</sup>, Eligard<sup>®</sup>, Fensolvi<sup>®</sup>, Lutrate Depot<sup>™</sup>, Leuprolide Acetate Depot) Prior Auth Criteria



Proprietary Information. Restricted Access – Do not disseminate or copy without approval. ©2023, Magellan Rx Management

Page 17

Т

ICD-10 ICD-10 Description		
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	
C56.3	Malignant neoplasm of bilateral ovaries	
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	
C61	Malignant neoplasm of prostate	
Z85.43	Personal history of malignant neoplasm of ovary	
	Personal history of malignant neoplasm of prostate	

# Page 18 Criteria Proprietary Information. Restricted Access – Do not disseminate or copy without approval. ©2023, Magellan Rx Management



#### J1951

ICD-10	ICD-10 Description	
E30.1	Precocious puberty	
E30.8	Other disorders of puberty	
F64.0	Transsexualism	
F64.1	Dual role transvestism	
F64.2	Gender identity disorder of childhood	
F64.8	Other gender identity disorders	
F64.9	Gender identity disorder, unspecified	

#### J1952 and J1954

ICD-10	ICD-10 Description	
C61	Malignant neoplasm of prostate	
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), Local Coverage Determinations (LCDs) and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <a href="https://www.cms.gov/medicare-coverage-database/search.aspx">https://www.cms.gov/medicare-coverage-database/search.aspx</a>. Additional indications may be covered

at the discretion of the health plan.

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

#### (J1950, J9217 and J1952)

Jurisdiction(s): 6, K	NCD/LCD Document (s): A52453	
https://www.cms.gov/medicare-coverage-database/new-search/search-		
results.aspx?keyword=a52453&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD		
<u>%2C6%2C3%2C5%2C1%2CF%2CP</u>		

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)		
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.		

Page 19	I	LEUPROLIDE SUSP (Lupron Depot <sup>®</sup> , Lupron Depot-Ped <sup>®</sup> , Eligard <sup>®</sup> , Fensolvi <sup>®</sup> , Lutrate Depot <sup>™</sup> , Leuprolide Acetate Depot) Prior Auth Criteria Proprietary Information. Restricted Access – Do not disseminate or copy	Magellan Rx
		without approval. ©2023, Magellan Rx Management	

Medicare Part B Administrative Contractor (MAC) Jurisdictions			
Jurisdiction	Applicable State/US Territory	Contractor	
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	КҮ, ОН	CGS Administrators, LLC	

