

Gonadotropin Releasing Hormone Analog

HCPCS: J9217 leuprolide acetate 7.5mg (Eligard, Lupron Depot, Vabrinty); J1950 leuprolide acetate 3.75mg (Lupron Depot, Lupron Depot Peds); J1951 leuprolide acetate 0.25 mg (Fensolvi); J9226 histrelin implant (Supprelin LA), 50 mg; J9202 goserelin acetate implant, per 3.6 mg (Zoladex), J3315 injection, triptorelin pamoate, 3.75 mg (Trelstar); J3316 Injection, triptorelin, extended-release, 3.75 mg (Triptodur); J1952 leuprolide 1mg (Camcevi), J9003 leuprolide injectable (Camcevi ETM), 1 mg

LOB:	MCAL
Duration of Approval:	- Prostate/breast cancer/ovarian cancer/gender dysphoria: One year - Endometriosis: Six months total - Decreasing fibroid size: Six months total - Precocious puberty: One year; discontinuation at age 11 for girls and 12 for boys - Stimulation testing for CPP: One dose/fill - Fertility preservation: One year
Quantity Limit:	Per FDA-Approved/Compendia-Supported Dosing
MCG Available:	Yes
DHCS Drug Policy:	No

Requires Prior Authorization (PA)

- Camcevi (leuprolide)
- Camcevi ETM (leuprolide)
- Eligard (leuprolide acetate)
- Fensolvi (leuprolide acetate)
- Lupron Depot (leuprolide acetate)
- Lupron Depot-Ped (leuprolide acetate)
- Supprelin LA (histrelin acetate)
- Trelstar Mixject (triptorelin pamoate)
- Triptodur (triptorelin pamoate XR)
- Vabrinty (leuprolide acetate)
- Zoladex (goserelin acetate)

PA CRITERIA FOR APPROVAL:

New Therapy

- The member has a diagnosis for an FDA-approved indication (refer to package insert under References), a National Comprehensive Cancer Network (NCCN)-supported indication (for cancer diagnosis only) OR a compendia-supported (Drugdex or AHFS) indication (for noncancer diagnosis only)
AND
- The medication is prescribed or recommended by an oncologist, urologist, OB-GYN, endocrinologist, pediatric endocrinologist or a medical provider experienced in transgender hormone therapy
AND
- For diagnosis of endometriosis:** The member has a history of failure, contraindication or reasons for intolerance to progestins (such as norethindrone and medroxyprogesterone)
OR
- For stimulation testing to diagnose central precocious puberty (CPP) (off-label use for leuprolide acetate 1 mg (J9218) based on peer literature review):** ALL of the following are met (a-c):
 - Member's age is between 2 and 10 years
 - Leuprolide (20 mcg/kg) will be administered following hormonal measurements (such as follicle-stimulating hormone [FSH], luteinizing hormone [LH], estradiol, etc.)

Gonadotropin Releasing Hormone Analog

HCPCS: J9217 leuprolide acetate 7.5mg (Eligard, Lupron Depot, Vabrinty); J1950 leuprolide acetate 3.75mg (Lupron Depot, Lupron Depot Peds); J1951 leuprolide acetate 0.25 mg (Fensolvi); J9226 histrelin implant (Supprelin LA), 50 mg; J9202 goserelin acetate implant, per 3.6 mg (Zoladex), J3315 injection, triptorelin pamoate, 3.75 mg (Trelstar); J3316 Injection, triptorelin, extended-release, 3.75 mg (Triptodur); J1952 leuprolide 1mg (Camcevi), J9003 leuprolide injectable (Camcevi ETM), 1 mg

- c. Chart notes documenting prepubertal early morning hormonal levels, onset of secondary sexual characteristics (minimum of Tanner 2 breasts in girls or Tanner 2 genitalia with >3 cc testes in boys) and concern for morbidity of early puberty without suppression.

OR

- 5. **For diagnosis of gender dysphoria (compendia-supported off-label use for Lupron, Trelstar, Zoladex):** Refer to [DHCS policy for Gender Affirming Care Services](#) for documentation requirements (pg. 4).

OR

- 6. **For diagnosis of CPP:** ALL of the following are met (a-d):
 - a. Members' age is <8 years for girls and <9 years for boys (**Note:** girls may be <12 years if there are issues of intractable uterine bleeding, severe dysmenorrhea or inability to control menses adequately with severe intellectual disability).
 - b. Chart notes documenting onset of secondary sexual characteristics, including a minimum of Tanner 2 breasts in girls or Tanner 2 genitalia with >3 cc testes in boys, and concern for morbidity of early puberty without suppression (**Note:** descriptions of pubic hair, axillary hair or body odor are irrelevant to determining medical necessity for this medication).
 - c. Diagnosis is confirmed by **ONE** of the following:
 - 1) Serum luteinizing hormone (LH) level exceeds prepubertal level (defined as >0.3 IU/L) AND estradiol >10 pg/mL in girls or testosterone >20 ng/dL in boys)
 - 2) Positive response to subcutaneous (SQ) leuprolide acetate (20 mcg/kg) showing pubertal LH levels (defined as ≥5 IU/L) AND estradiol ≥50 pg/mL or testosterone > 25 ng/dL levels)
 - 3) In girls, ultrasound findings with ovarian volume ≥2 cc
 - d. Baseline bone age is more than two standard deviations from chronological age **OR** shows bone age acceleration advancing more than one year per chronological year. (**Note:** the diagnosis is not dependent on the bone age. The bone age factors into the decision to suppress puberty with medication, but earlier age of onset, lower height at onset, length of time in growth spurt and presence of menses are typically more important clinical considerations than bone age to determine if treatment is warranted. The bone age may become the deciding factor when it predicts significant loss of future height without treatment.)

Continuation of Therapy

- 1. The member has a diagnosis for an FDA-approved indication (refer to package insert under References), a NCCN-supported indication (for cancer diagnosis only) OR a compendia-supported (Drugdex or AHFS) indication (for noncancer diagnosis only)

AND

- 2. **For gender dysphoria:** Documentation showing the member has been evaluated for **ONE** of the following:
 - a. Response to therapy and potential adverse changes
 - b. Monitoring of sex steroid hormone levels

OR

- 3. **For CPP:** Documentation has been provided showing gonadotropin-releasing hormone (GnRH) agonist therapy is effective as demonstrated by plateauing or reversal of pubertal changes on physical examination, persistent biochemical suppression of the hypothalamic-pituitary-gonadal axis, continued growth at an age-appropriate nonpubertal rate or decrease in pace of bone age advancement.
 - The GNRH Analog should be discontinued if **ONE** of the following is met:

Gonadotropin Releasing Hormone Analog

HCPCS: J9217 leuprolide acetate 7.5mg (Eligard, Lupron Depot, Vabrinty); J1950 leuprolide acetate 3.75mg (Lupron Depot, Lupron Depot Peds); J1951 leuprolide acetate 0.25 mg (Fensolvi); J9226 histrelin implant (Supprelin LA), 50 mg; J9202 goserelin acetate implant, per 3.6 mg (Zoladex), J3315 injection, triptorelin pamoate, 3.75 mg (Trelstar); J3316 Injection, triptorelin, extended-release, 3.75 mg (Triptodur); J1952 leuprolide 1mg (Camcevi), J9003 leuprolide injectable (Camcevi ETM), 1 mg

- Typically by 10.5 to 11 years of age in girls and by 12 years of age in boys, but may be extended one to two years in shorter children and those with very advanced bone age in whom we cannot yet predict a normal adult height outcome (typically >150 cm [59 inches] in girls or >160 cm [63 inches] in boys).
- Height has exceeded 150 cm [59 inches] in girls or 160 cm [63 inches] in boys.

EXCLUSION:

- Pregnancy (for leuprolide)
- Paraphilia and infertility are not a covered benefit under Medi-Cal

OTHER INFORMATION:

HCPCS	Description	Brand name
J1952	Leuprolide Injectable, 1 mg	Camcevi
J9003	Leuprolide injectable (camcevi etm), 1 mg	Camcevi ETM
J3315	Injection, triptorelin pamoate, 3.75 mg	Trelstar
J3316	Injection, triptorelin, extended release, 3.75 mg	Triptodur
J9202	Goserelin acetate implant, per 3.6 mg	Zoladex implant
J9217	Leuprolide acetate (for depot suspension), 7.5 mg	Eligard
		Lupron Depot
		Vabrinty
J1950	Injection, leuprolide acetate (for depot suspension), per 3.75 mg	Lupron Depot/ Lupron Depot-Ped
J1951	Injection, leuprolide acetate (for depot suspension), 0.25 mg	Fensolvi
J9218	Leuprolide acetate, per 1 mg	N/A
J9226	Histrelin implant (Supprelin LA), 50 mg	Supprelin LA

REFERENCES:

1. The Journal of Clinical Endocrinology & Metabolism. Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. 2017; 102 (11), Pages 3869-3903.
academic.oup.com/jcem/article/102/11/3869/4157558
2. Sathasivam A, Garibaldi L, Shapiro S, et al. Leuprolide stimulation testing for the evaluation of early female sexual maturation. Clin. Endocrinology (Oxf). 2010. pubmed.ncbi.nlm.nih.gov/20184599/
3. Carretto F, Salinas-Vert, Granada-Yvern ML, et al. The usefulness of the leuprolide stimulation test as a diagnostic method of idiopathic central precocious puberty in girls. Horm Metab Res. 2014.
pubmed.ncbi.nlm.nih.gov/25295414/
4. Clowse, ME, Behera MA, Anders CK, et al. Ovarian Preservation by GnRH Agonists during Chemotherapy: A Meta-Analysis. Journal of Women's Health. 2009; 18(3): 311-319.
www.ncbi.nlm.nih.gov/pmc/articles/PMC2858300/#:~:text=Conclusions,GnRHa%20in%20ovarian%20function%20preservation.
5. Poggio F, Lambertini M, Bighin C, et al. Potential Mechanisms of Ovarian Protection with Gonadotropin-Releasing Hormone Agonist in Breast Cancer Patients: A Review. Clinical Medicine Insights: Reproductive Health. 2019; 13: 1-5.
www.ncbi.nlm.nih.gov/pmc/articles/PMC6669835/

Gonadotropin Releasing Hormone Analog

HCPCS: J9217 leuprolide acetate 7.5mg (Eligard, Lupron Depot, Vabrinty); J1950 leuprolide acetate 3.75mg (Lupron Depot, Lupron Depot Peds); J1951 leuprolide acetate 0.25 mg (Fensolvi); J9226 histrelin implant (Supprelin LA), 50 mg; J9202 goserelin acetate implant, per 3.6 mg (Zoladex), J3315 injection, triptorelin pamoate, 3.75 mg (Trelstar); J3316 Injection, triptorelin, extended-release, 3.75 mg (Triptodur); J1952 leuprolide 1mg (Camcevi), J9003 leuprolide injectable (Camcevi ETM), 1 mg

6. Lambertini M, Boni L, Michelotti A, et al. Ovarian Suppression with Triptorelin During Adjuvant Breast Cancer Chemotherapy and Long-term Ovarian Function, Pregnancies, and Disease-Free Survival. JAMA. 2015. 314(24): 2632-2640. jamanetwork.com/journals/jama/fullarticle/2478203
7. ACOG Updates Guideline on Diagnosis and Treatment of Endometriosis. Practice Guidelines. American Academy of Family Physicians. 2011. 83(1): 84-85. www.aafp.org/pubs/afp/issues/2011/0101/p84.pdf
8. Oktay K, Harvey BE, Partridge AH, et al: Fertility Preservation in Patients with Cancer: ASCO Clinical Practice Guideline Update. J Clin Oncol 2018; 36(19):1994-2001. ascopubs.org/doi/pdf/10.1200/JCO.2018.78.1914
9. Moore HC, Unger JM, Phillips KA, et al. Goserelin for Ovarian Protection during Breast-Cancer Adjuvant Chemotherapy. NEJM. 2015. 372: 923-932. www.nejm.org/doi/full/10.1056/NEJMoa1413204
10. Camcevi Prescribing Information. www.accordbiopharma.com/our-therapies/camcevi/camcevi_pi.pdf. 02/2026.
11. Camcevi ETM Prescribing Information. www.accessdata.fda.gov/drugsatfda_docs/label/2025/219745s000lbl.pdf. 08/2025.
12. Eligard Prescribing Information. eligardhcp.com/sites/default/files/pdfs/ELI_Full_PI.pdf. 02/2025.
13. Fensolvi Prescribing Information. fensolvi.com/wp-content/uploads/fensolvi-prescribing-information.pdf. 09/2025.
14. Lupron Depot 3.75mg Prescribing Information. www.rxabbvie.com/pdf/lupron3_75mg.pdf. 09/2025.
15. Lupron Depot 11.25mg Prescribing Information. www.rxabbvie.com/pdf/lupron3month11_25mg.pdf 09/2025.
16. Lupron Depot 7.25mg/22.5mg/30mg/45mg Prescribing Information. www.rxabbvie.com/pdf/lupronuro_pi.pdf. 08/2025.
17. Lupron Depot-Ped Prescribing Information. www.rxabbvie.com/pdf/lupronpediatric.pdf. 11/2025.
18. Supprelin LA Prescribing Information. d1skd172ik98el.cloudfront.net/48a33315-f594-4269-8043-8853d10fb7bf/5c7140ba-1375-4f5c-b803-93a5c6765714/5c7140ba-1375-4f5c-b803-93a5c6765714_source_v.pdf. 09/2025.
19. Trelstar Mixject Prescribing Information. trelstar.com/wp-content/uploads/2025/10/Trelstar_PI_9-2025.pdf. 09/2025.
20. Triptodur Prescribing Information. dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=f41380e7-b830-432d-a5f5-a872932f107e&type=display. 09/2025.
21. Vabrinty Prescribing Information. <https://dailymed.nlm.nih.gov/dailymed/lookup.cfm?setid=008776cc-83f1-4f8c-819b-6471425da15f>. 04/2026.
22. Zoladex Prescribing Information. documents.tercera.com/zoladex-us/3.6mg_MagnumPI.pdf. 09/2025.
23. ESHRE Guideline: Endometriosis. pmc.ncbi.nlm.nih.gov/articles/PMC8951218/pdf/hoac009.pdf

P&T APPROVAL HISTORY

1. August 2022 P&T Drug Review
2. May 2026 P&T Drug Review

UMC REVIEW:

5/2026