Clinical Policy: Leuprolide Acetate (Eligard, Fensolvi, Lupron Depot, Lupron Depot-Ped, Vabrinty, Vobrig), Leuprolide Mesylate (Camcevi, Camcevi ETM)

Reference Number: CP.PHAR.173
Effective Date: 10.01.16
Last Review Date: 11.26
Line of Business: Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Leuprolide acetate (Eligard®, Fensolvi®, Lupron Depot®, Lupron Depot-Ped®, Vabrinty™, Vobrig™) and leuprolide mesylate (Camcevi™, Camcevi ETM®) are gonadotropin-releasing hormone (GnRH) receptor agonists.

FDA Approved Indication(s)

Leuprolide acetate is indicated for:

- Palliative treatment of advanced prostate cancer:
  - Leuprolide acetate injection
- Treatment of advanced prostate cancer:
  - Lupron Depot (7.5, 22.5, 30, 45)
  - Eligard
  - Vabrinty
- Management of endometriosis, including pain relief and reduction of endometriotic lesions; In combination with a norethindrone acetate for initial management of the painful symptoms of endometriosis and for management of recurrence of symptoms:
  - Lupron Depot (3.75, 11.25)

  Limitation(s) of use: total duration of therapy plus add-back therapy should not exceed 12 months due to concerns about adverse impact on bone mineral density
- Concomitant use with iron therapy for preoperative hematologic improvement of women with anemia caused by uterine leiomyomata [fibroids] for whom three months of hormonal suppression is deemed necessary:
  - Lupron Depot (3.75, 11.25)

  Limitation of use: not indicated for combination use with norethindrone acetate add-back therapy for the preoperative hematologic improvement of women with anemia caused by heavy menstrual bleeding due to fibroids
- Treatment of children with central precocious puberty (CPP):
  - Fensolvi
  - Leuprolide acetate
  - Lupron Depot-Ped (7.5, 11.25, 15, 30, 45)
  - Vobrig

Camcevi and Camcevi ETM are indicated for the treatment of adult patients with advanced prostate cancer.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results, or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that leuprolide acetate, Camcevi, Camcevi ETM, Eligard, Fensolvi, Lupron Depot, Lupron Depot-Ped, Vabrinty, and Vobrig are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Prostate Cancer (must meet all)**:**

1. Diagnosis of prostate cancer;
2. Request is for one of the following (a, b, c, d, or e):
   a. Leuprolide acetate injection;
   b. Camcevi/Camcevi ETM;
   c. Eligard;
   d. Lupron Depot;
   e. Vabrinty;
3. Prescribed by or in consultation with an oncologist or urologist;
4. Age ≥ 18 years;
5. For Lupron Depot requests through the pharmacy benefit, failure of Eligard, unless contraindicated, clinically significant adverse effects are experienced, or request is for treatment associated with cancer for a State with regulations against step therapy in certain oncology settings *(see Appendix F)*;
6. Request meets one of the following (a, b, c, or d):*
   a. Leuprolide acetate injection (SC): Dose does not exceed 1 mg per day;
   b. Camcevi/Camcevi ETM (SC): Dose does not exceed 21 mg per 3 months or 42 mg per 6 months;
   c. Eligard (SC), Lupron Depot (IM), or Vabrinty (SC): Dose does not exceed 7.5 mg per month, 22.5 mg per 3 months, 30 mg per 4 months, 45 mg per 6 months;
   d. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

B. Endometriosis (must meet all)**:**

1. Diagnosis of endometriosis;
2. Request is for Lupron Depot (3.75 mg, 11.25 mg);
3. Prescribed by or in consultation with a gynecologist;
4. One of the following (a or b):
   a. Age ≥ 18 years;
   b. Age < 18 years and member is postpubertal (request is following puberty);
5. Endometriosis as a cause of pain is one of the following (a or b):
   a. Surgically confirmed;
   b. Both of the following (i and ii):
      i. Clinically suspected;

ii. Failure of a 3-month trial of one of the following within the last year, unless clinically adverse effects are experienced or all are contraindicated (1, 2, or 3):
1) A nonsteroidal anti-inflammatory drug *(see Appendix B for examples)*;
2) An oral or injectable depot contraceptive *(see Appendix B for examples)*;
3) A progestin *(see Appendix B for examples)*;

6. For members currently receiving treatment with leuprolide, total duration of therapy has not exceeded 12 months;
7. Dose does not exceed 3.75 mg per month or 11.25 mg per 3 months.

Approval duration: 6 months

C. Uterine Fibroids (must meet all)**:**
1. Diagnosis of anemia secondary to uterine leiomyomata (fibroids);
2. Diagnosis is confirmed by ultrasound;
3. Request is for Lupron Depot (3.75 mg, 11.25 mg);
4. Prescribed by or in consultation with gynecologist;
5. One of the following (a or b):
   a. Age ≥ 18 years;
   b. Age < 18 years and member is postpubertal (request is following puberty);
6. Lupron Depot is prescribed concurrently with iron therapy;
7. Prescribed preoperatively to reduce fibroid size and improve hematologic control;
8. For members currently receiving treatment with leuprolide, total duration of therapy has not exceeded 3 months per treatment course;
9. Dose does not exceed 3.75 mg per month or 11.25 mg per 3 months.

Approval duration: 3 months

D. Central Precocious Puberty (must meet all)**:**
1. Member meets one of the following (a or b):
   a. Diagnosis of CPP confirmed by all of the following (i, ii, and iii):
      i. Elevated basal luteinizing hormone (LH) level > 0.2 - 0.3 mIU/mL (dependent on type of assay used) and/or elevated leuprolide-stimulated LH level > 3.3 - 5 IU/L (dependent on type of assay used);
      ii. Difference between bone age and chronological age was > 1 year (bone age-chronological age);
      iii. Age at onset of secondary sex characteristics (1 or 2):
         1) Female: < 8 years;
         2) Male: < 9 years;
   b. Request is for diagnostic use;
2. Request is for one of the following (a, b, c, or d):
   a. Fensolvi;
   b. Leuprolide acetate;
   c. Lupron Depot-Ped: 7.5 mg, 11.25 mg, 15 mg, 30 mg, 45 mg;
   d. Vobrig;
3. Prescribed by or in consultation with a pediatric endocrinologist;
4. Member meets one of the following age requirements (a or b):
   a. Female: 2 - 11 years;
   b. Male: 2 - 12 years;

5. Dose does not exceed the following (a, b, c, d, or e):
   a. Diagnostic use: Leuprolide acetate: 20 mcg/kg or as needed;
   b. Therapeutic use: Fensolvi: 45 mg per 6 months;
   c. Therapeutic use: Leuprolide acetate (SC): Initial: 50 mcg/kg per day; titrate dose upward by 10 mcg/kg per day if down-regulation is not achieved (higher mg/kg doses may be required in younger children);
   d. Therapeutic use: Lupron Depot-Ped (IM): 15 mg per month (1-month formulation), 30 mg per 3 months (3-month formulation) or 45 mg per 6 months (6-month formulation) (dosing is weight-based for a 1-month and a 3-month formulations);
   e. Therapeutic use: Vobrig (SC): Weight-based daily dosing (*see Section V. Dosage and Administration*).

Approval duration: 12 months

E. Breast and Ovarian Cancer (off-label) (must meet all)**:**
1. Diagnosis of hormone receptor-positive breast cancer or ovarian cancer (including epithelial ovarian, fallopian tube and primary peritoneal cancer, malignant sex cord-stromal tumors, carcinosarcoma (malignant mixed Müllerian tumors), low-grade serous carcinoma, endometrioid carcinoma, mucinous neoplasms of the ovary);
2. Request is for one of the following (a, b, or c):
   a. Lupron Depot;
   b. Eligard for breast cancer;
   c. Vabrinty;
3. Prescribed by or in consultation with an oncologist;
4. Age ≥ 18 years;
5. For breast cancer, both of the following (a and b):
   a. Member is premenopausal or male;
   b. Prescribed in combination with endocrine therapy;
6. Request meets one of the following (a, b, or c):*
   a. Lupron Depot: Dose does not exceed 3.75 mg per month, 7.5 mg per month, 11.25 mg per 3 months, or 22.5 mg per 3 months;
   b. Eligard or Vabrinty: Dose does not exceed 7.5 mg per month, 22.5 mg per 3 months, 30 mg per 4 months, 45 mg per 6 months;
   c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

F. Gender Dysphoria, Gender Transition (off-label) (must meet all)**:**
1. Diagnosis of gender dysphoria or request is for gender transition;
2. Prescribed by or in consultation with both of the following (a and b):
   a. An endocrinologist;
   b. A provider with expertise in gender dysphoria and transgender medicine based on a certified training program or affiliation with local transgender health services (e.g., mental health professional such as psychologist, psychiatrist, see *Appendix D*);

3. Age and pubertal development - meets one of the following (a or b):
   a. Member is < 18 years of age and has reached or passed through Tanner Stage 2*;
      **Age ranges approximating Tanner Stage 2 pubertal development extend from 8 to 13 years of age in girls and 9 to 14 years of age in boys.*
   b. Member is ≥ 18 years of age and has failed to achieve physiologic hormone levels with gender-affirming hormonal therapy (e.g., estrogen, testosterone) unless contraindicated or clinically significant adverse effects are experienced;
4. Member demonstrates understanding of expected GnRH analogue treatment outcomes and has given consent for such treatment;
5. If member has a psychiatric comorbidity, member is followed by mental health provider;
6. Psychosocial support will be provided during treatment;
7. Provider attestation of understanding current State regulations regarding transgender-related health care and such care is coverable under the State regulations (see *Appendix D*);
8. Dose is within FDA maximum limit for any FDA-approved indication (see Section V) or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

G. Salivary Gland Tumors (off-label) (must meet all)**:**
1. Diagnosis of salivary gland tumors;
2. Disease is androgen receptor positive and recurrent, unresectable, or metastatic;
3. Prescribed by or in consultation with an oncologist;
4. Age ≥ 18 years;
5. Request is for one of the following (a, b, c, or d):
   a. Eligard;
   b. Lupron Depot;
   c. Camcevi/Camcevi ETM;
   d. Vabrinty;
6. Dose is within FDA maximum limit for any FDA-approved indication (see Section V) or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).
   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

H. Uterine Sarcoma (off-label) (must meet all)**:**
1. Diagnosis of uterine sarcoma;
2. Request is for Lupron Depot;
3. Prescribed by or in consultation with an oncologist;
4. Age ≥ 18 years;
5. Member has endometrial stromal sarcoma or adenosarcoma without sarcomatous overgrowth;
6. Member is premenopausal;
7. Prescribed in combination with anastrozole, letrozole or exemestane;
8. Request meets one of the following (a or b):*
   a. Dose does not exceed 3.75 mg per month or 11.25 mg per 3 months;

b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

I. Infertility and Fertility Preservation, Female* (off-label) (must meet all)**:**

1. Member must have infertility/fertility preservation coverage (optional pharmacy benefit);
2. Request is for a leuprolide acetate containing product;
3. Member is premenopausal;
4. Member is undergoing one of the following (a, b, or c):
   a. Assisted reproductive technology (ART: IVF or ICSI);
   b. Ovulation induction (OI);
   c. Ovarian suppression for fertility preservation during cancer treatment;
5. Request is for one of the following (a, b, c, or d):
   a. Prevention of premature LH surge (pituitary suppression);
   b. Ovulation trigger in a GnRH-antagonist cycle;
   c. Dual-trigger strategy with low-dose human chorionic gonadotropin (hCG);
   d. Ovarian suppression during cancer treatment and one of the following (i or ii):
      i. Member has breast cancer and leuprolide will be used as adjunctive therapy;
      ii. Member requires emergent oncologic therapy;
6. Age ≥ 18 years;
7. Prescribed by or in consultation with a reproductive endocrinologist or oncologist;
8. If request is for ART, both of the following (a and b):*

   ** For Illinois HIM requests, the step therapy requirements below do not apply as of 1/1/2026 per IL HB 5395*

   a. If infertility is secondary to an ovulatory disorder, member has failed OI or is not a candidate for OI (e.g., member has been diagnosed with tubal blockage, uterine cavity abnormality, diminished ovarian reserve; member's partner has been diagnosed with severe male factor infertility).
   b. If unexplained infertility, failure of at least 3 cycles of clomiphene citrate or letrozole (*see Appendix B*) combined with intrauterine insemination, unless contraindicated or clinically significant adverse effects are experienced;
9. If request is for fertility preservation during cancer treatment, provider attestation that leuprolide will not be used in place of established fertility preservation methods such as oocyte, embryo, or ovarian tissue cryopreservation;

Approval duration: 30 days or up to specified trial duration if available

J. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or

b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Prostate Cancer (must meet all)**:**

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving leuprolide acetate injection, Camcevi/Camcevi ETM, Eligard, or Lupron Depot for prostate cancer and has received this medication for at least 30 days;
2. Request is for one of the following (a, b, c, d, or e):
   a. Leuprolide acetate injection;
   b. Camcevi/Camcevi ETM;
   c. Eligard;
   d. Lupron Depot;
   e. Vabrinty;
3. Member is responding positively to therapy;
4. If request is for a dose increase, request meets one of the following (a, b, c, or d):*
   a. Leuprolide acetate injection (SC): New dose does not exceed 1 mg per day;
   b. Camcevi/Camcevi ETM (SC): New dose does not exceed 21 mg per 3 months or 42 mg per 6 months;
   c. Eligard (SC), Lupron Depot (IM), or Vabrinty (SC): New dose does not exceed 7.5 mg per month, 22.5 mg per 3 months, 30 mg per 4 months, 45 mg per 6 months;
   d. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

B. Endometriosis (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
2. Request is for Lupron Depot (3.75 mg, 11.25 mg);
3. Member is responding positively to therapy as evidenced by improvement in <u>any</u> of the following parameters, including but not limited to: dysmenorrhea, dyspareunia, pelvic pain/induration/tenderness, or size of endometrial lesions;
4. Total duration of leuprolide therapy has not exceeded 12 months;

5. If request is for a dose increase, new dose does not exceed 3.75 mg per month or 11.25 mg per 3 months.

Approval duration: up to a total treatment duration of 12 months

C. Uterine Fibroids:

1. Re-authorization is not permitted. Members must meet the initial approval criteria.
   Approval duration: Not applicable

D. Central Precocious Puberty (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
2. Request is for one of the following (a, b, c, or d):
   a. Fensolvi;
   b. Leuprolide acetate;
   c. Lupron Depot-Ped: 7.5 mg, 11.25 mg, 15 mg, 30 mg, 45 mg;
   d. Vobrig;
3. Member is responding positively to therapy as evidenced by, including but not limited to, improvement in any of the following parameters: decreased growth velocity, cessation of menses, softening of breast tissue or testes, arrested pubertal progression;
4. Member meets one of the following age requirements (a or b):
   a. Female: ≤ 11 years;
   b. Male: ≤ 12 years;
5. If request is for a dose increase, new dose does not exceed one of the following (a, b, c, or d):
   a. Leuprolide acetate (SC): Initial: 50 mcg/kg per day; titrate dose upward by 10 mcg/kg per day if down-regulation is not achieved (higher mg/kg doses may be required in younger children);
   b. Lupron Depot-Ped (IM): 15 mg per month (1-month formulation), 30 mg per 3 months (3-month formulation) or 45 mg per 6 months (6-month formulation) (dosing is weight-based for a 1-month and a 3-month formulations);
   c. Fensolvi: 45 mg per 6 months;
   d. Vobrig (SC): Weight-based daily dosing (*see Section V. Dosage and Administration*).

Approval duration: 12 months

E. Breast and Ovarian Cancer (off-label) (must meet all)**:**

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Lupron Depot or Eligard for hormone receptor-positive breast cancer or ovarian cancer and has received this medication for at least 30 days;
2. Request is for one of the following (a, b, or c):
   a. Lupron Depot;

b. Eligard for breast cancer;
c. Vabrinty;

3. Member is responding positively to therapy;
4. If request is for a dose increase, request meets one of the following (a, b, or c):*
   a. Lupron Depot: New dose does not exceed 3.75 mg per month, 7.5 mg per month, 11.25 mg per 3 months, or 22.5 mg per 3 months;
   b. Eligard or Vabrinty: New dose does not exceed 7.5 mg per month, 22.5 mg per 3 months, 30 mg per 4 months, 45 mg per 6 months;
   c. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

F. Gender Dysphoria, Gender Transition (off-label) (must meet all):

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
2. Member is responding positively to therapy (e.g., member continues to meet their individual goals of therapy for gender dysphoria);
3. If request is for a dose increase, new dose is within FDA maximum limit for any FDA-approved indication (see Section V) or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

G. Salivary Gland Tumors (off-label) (must meet all)**:**

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Eligard, Lupron Depot, or Camcevi/Camcevi ETM for salivary gland tumors and has received this medication for at least 30 days ;
2. Request is for one of the following (a, b, c, or d):
   a. Eligard;
   b. Lupron Depot;
   c. Camcevi/Camcevi ETM;
   d. Vabrinty;
3. Member is responding positively to therapy;
4. If request is for a dose increase, new dose is within FDA maximum limit for any FDA-approved indication (see Section V) or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

H. Uterine Sarcoma (off-label) (must meet all)**:**
1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Lupron Depot for uterine sarcoma and has received this medication for at least 30 days;
2. Request is for Lupron Depot;
3. Member is responding positively to therapy;
4. If request is for a dose increase, new dose is within FDA maximum limit for any FDA-approved indication (see Section V) or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

I. Infertility and Fertility Preservation, Female (must meet all)**:**
1. Member must have infertility/fertility preservation coverage (optional pharmacy benefit);
2. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B);*
3. Member is responding positively to therapy;
4. Request is for a leuprolide acetate containing product;
5. Request is for an OI, ART, or cancer treatment cycle currently underway.

Approval duration: 30 days or up to specified trial duration if available
(For additional reproductive attempts please refer to the initial approval criteria.)

J. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ART: assisted reproductive technology
CPP: central precocious puberty
DSM-5: Diagnostic and Statistical Manual of Mental Disorders, 5th edition
FDA: Food and Drug Administration
GnRH: gonadotropin-releasing hormone
ICSI: intracytoplasmic sperm injection
IVF: in vitro fertilization
LH: luteinizing hormone
NCCN: National Comprehensive Cancer Network
OI: ovulation induction
WPATH: World Professional Association for Transgender Health

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
NSAIDs*: ibuprofen, naproxen, fenoprofen, ketoprofen, mefenamic acid, meclofenamate, indomethacin, tolmetin, diclofenac, etodolac, diflunisal, meloxicam, piroxicam	Endometriosis Varies – refer to specific prescribing information	Varies – refer to specific prescribing information
Combined oral estrogen-progesterone contraceptives: ethinyl estradiol + (desogestrel, ethynodiol diacetate, drospirenone, etonogestrel, levonorgestrel, norelgestromin, norethindrone, norgestimate, or norgestrel); estradiol valerate + dienogest; mestranol + norethindrone	Endometriosis 1 tablet PO QD (may vary per specific prescribing information)	1 tablet per day (may vary per specific prescribing information)
Progestin-only oral contraceptives: norethindrone	Endometriosis 0.35 mg PO QD	0.35 mg per day
Progestin-only oral contraceptives: Slynd® (drospirenone)	Endometriosis 1 tablet PO QD	1 tablet PO QD
Depot injection progestin contraceptives: medroxyprogesterone acetate	Endometriosis IM: 150 mg per 3 months (every 13 weeks) SC: 104 mg per 3 months (every 12 to 14 weeks)	See regimen
clomiphene citrate	**Treatment of ovulatory dysfunction in**	150 mg/day per expert review

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	women desiring pregnancy (labeled): Initial: 50 mg PO once daily for 5 days. Begin on or about the fifth day of cycle if progestin-induced bleeding is scheduled or spontaneous uterine bleeding occurs prior to therapy. Therapy may be initiated at any time in patients with no recent uterine bleeding. Subsequent doses may be increased to 100 mg once daily for 5 days only if ovulation does not occur at the initial dose. If needed, the 5-day cycle may be repeated as early as 30 days after the previous one. Exclude the presence of pregnancy. The lowest effective dose should be used. Maximum dose: 100 mg once daily for 5 days for up to 6 cycles.	Durations: 5 to 7 days per expert review

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
**Examples provided may not be all-inclusive*

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Known hypersensitivity to GnRH, GnRH agonist analogs, or any of the components of the individual products (all leuprolide products);
  - Pregnancy (all leuprolide products except Camcevi/Camcevi ETM, Eligard);
  - Lupron Depot 3.75 mg/11.25 mg:

    - Undiagnosed abnormal vaginal bleeding;
    - Breast-feeding;
    - If used with norethindrone acetate:
        - Thrombophlebitis, thromboembolic disorders, cerebral apoplexy, or a past history of these conditions;
        - Markedly impaired liver function or liver disease;
        - Known or suspected carcinoma of the breast.
- Boxed warning(s): None reported

Appendix D: General Information

- World Professional Association for Transgender Health (WPATH) offers their Global Education Institute (GEI) Certified Training Courses: Best Practices in Transgender Medical and Mental Health Care. Additionally, the following link provides a search tool to locate WPATH member providers: https://app.wpath.org/provider/search
- Transgender Care Therapy Certification Training is also offered by the International Transgender Certification Association (ITCA). Professionals with expertise in transgender care can be located using the following search tool: https://transgendercertification.com/locate-a-professional/
- The WPATH Standards of Care Version 8 recommend that adolescents are managed by a multidisciplinary care team that involves both medical and mental health professionals. The list of key disciplines includes but is not limited to: adolescent medicine/primary care, endocrinology, psychology, psychiatry, speech/language pathology, fertility, social work, support staff, and the surgical team. The need to include a healthcare professional with some expertise in mental health does not dictate the inclusion of a psychologist, psychiatrist, or social work in every assessment. Instead, a general medical practitioner, nurse or other qualified health care professional could also fulfill this requirement if they have sufficient expertise to diagnose gender incongruence, recognize mental health concerns, distinguish between these concerns and gender dysphoria, incongruence, and diversity, assist a transgender person in care planning and preparing for gender affirmative medical and surgical treatments, and refer to a mental health professional if needed.
- The Movement Advancement Project can be referenced to confirm transgender-related health care is coverable under the State regulations. This can be accessed at: https://www.lgbtmap.org/equality-maps/healthcare/youth_medical_care_bans
- ART procedures include but are not limited to 1) in vitro fertilization (IVF), 2) intracytoplasmic sperm injection (ICSI), and 3) assisted reproductive hatching. IVF is the most common type of ART. An IVF interval generally is two weeks in length and includes 1) ovarian stimulation with fertility medications to induce development of multiple ovarian follicles/oocytes (i.e., COH), 2) aspiration and fertilization of oocyte(s) in the laboratory setting ("in vitro"), and then 3) transfer of the embryo(s) into the uterine cavity.

Appendix E: Additional Information on Diagnosis-specific HCPCS Codes, Billable Units, and Day Supply

Diagnosis	Requested Product	HCPCS Code	Billable Units	Day Supply
Prostate Cancer	Leuprolide acetate, per 1 mg	J9218	14	14
	Lupron Depot 1-Month & Eligard 7.5 mg	J9217	1	28
	Lupron Depot 3-Month & Eligard 22.5 mg		3	84
	Lupron Depot 4-Month & Eligard 30 mg		4	112
	Lupron Depot 6-Month & Eligard 45 mg		6	168
	Camcevi 6-Month 42 mg	J1952	42	168
	Camcevi ETM 3-Month 21 mg	J1952	21	84
Endometriosis, Uterine Fibroids	Lupron Depot 1-Month 3.75 mg	J1950	1	28
	Lupron Depot 3-Month 11.25 mg		3	84
Central Precocious Puberty	Leuprolide acetate, per 1 mg	J9218	14	14
	Lupron Depot-Ped 7.5 mg	J1950	2	28
	Lupron Depot-Ped 11.25 mg		3	28
	Lupron Depot-Ped 15 mg		4	28
	Lupron Depot-Ped 30 mg		8	84
	Lupron Depot-Ped 45 mg		12	168
	Fensolvi 45 mg kit	J1951	12	168
	Vobrig	Pending	Pending	Pending
Breast Cancer	Lupron Depot 1-Month 3.75 mg	J1950	1	28
	Lupron Depot 3-Month 11.25 mg		3	84
	Lupron Depot 1-Month & Eligard 7.5 mg	J9217	1	28
	Lupron Depot 3-Month & Eligard 22.5 mg		3	84
	Eligard 4-month 30 mg		4	112
	Eligard 6-month 45 mg		6	168
Ovarian Cancer	Lupron Depot 1-Month 3.75 mg	J1950	1	28
	Lupron Depot 3-Month 11.25 mg		3	84
Salivary Gland Tumors	Lupron Depot 1-Month & Eligard 7.5 mg	J9217	1	28
	Lupron Depot 3-Month & Eligard 22.5 mg		3	84
	Camcevi 6-Month 42 mg	J1952	42	168
	Camcevi ETM 3-Month 21 mg	J1952	21	84

NA – not available

Appendix F: States with Regulations against Redirections in Cancer

State	Step Therapy Prohibited?	Notes
FL	Yes	For stage 4 metastatic cancer and associated conditions
GA	Yes	For stage 4 metastatic cancer. Redirection does not refer to review of medical necessity or clinical appropriateness
IA	Yes	For standard of care stage 4 cancer drug use, supported by peer-reviewed, evidence-based literature, and approved by FDA
IN	Yes	For advanced, metastatic cancer and associated conditions
LA	Yes≠	For stage 4 advanced, metastatic cancer or associated conditions. ≠Exception if clinically equivalent therapy, contains identical active ingredient(s), and proven to have same efficacy
MS	Yes	For advanced metastatic cancer and associated conditions
NV	Yes	Stage 3 and stage 4 cancer patients for a prescription drug to treat the cancer or any symptom thereof of the covered person
OH	Yes	For stage 4 metastatic cancer and associated conditions
OK	Yes	For advanced metastatic cancer and associated conditions
PA	Yes	For stage 4 advanced, metastatic cancer
TN	Yes^	For cancer and associated conditions ^Exception if step therapy is for AB-rated generic equivalent, interchangeable biological product, or biosimilar product to the equivalent brand drug
TX	Yes	For stage 4 advanced, metastatic cancer and associated conditions

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Leuprolide acetate injection Leuprolide acetate (Lupron Depot 7.5, 22.5, 30, 45) Leuprolide acetate (Eligard 7.5, 22.5, 30, 45) Leuprolide mesylate (Camcevi, Camcevi ETM)	Prostate cancer	Camcevi (SC) – 42 mg every 6 months	See regimen
		Camcevi ETM (SC) – 21 mg every 3 months	See regimen
		Leuprolide acetate injection (SC): 1 mg per day	See regimen
		Lupron Depot (IM) – 7.5 mg per month; 22.5 mg per 3 months; 30 mg per 4 months; 45 mg per 6 months	See regimen
		Eligard (SC) – 7.5 mg per month; 22.5 mg per 3 months; 30 mg per 4 months; 45 mg per 6 months	See regimen
		Vabrinty (SC) – 7.5 mg per month; 22.5 mg per 3 months; 30 mg per 4 months; 45 mg per 6 months	See regimen
Leuprolide acetate (Lupron Depot 3.75, 11.25)	Endometriosis	Lupron Depot - 3.75 mg per month; 11.25 mg per 3 months	See regimen

Drug Name	Indication	Dosing Regimen	Maximum Dose
Leuprolide acetate (Lupron Depot 3.75)	Uterine fibroids	Lupron Depot (IM) - 3.75 mg/month, 11.25 mg per 3 months	See regimen
Leuprolide acetate injection Leuprolide acetate (Lupron Depot-Ped 7.5, 11.25, 15 [1 mo]; 11.25, 30 [3 mo]); 45 [6 mo] Fensolvi (leuprolide acetate) Vobrig (leuprolide acetate)	CPP	Leuprolide acetate (SC): • Diagnostic: 20 mcg/kg or as needed; • Treatment: Initial: 50 mcg/kg/day; titrate dose upward by 10 mcg/kg/day if down-regulation is not achieved (higher mg/kg doses may be required in younger children).	See regimen
		Lupron Depot-Ped (IM): Monthly administration weight-based starting dose: 7.5 mg (≤ 25 kg), 11.25 mg (> 25 to 37.5 kg), 15 mg (> 37.5 kg) (increase as needed up to 15 mg/month); 3-month administration: 11.25 mg or 30 mg; 6-month administration: 45 mg	See regimen
		Fensolvi (SC): 45 mg once every six months	See regimen
		Vobrig (SC): Daily administration weight-based starting dose: 0.8 mg (≤ 16 kg), 1.2 mg (> 16 kg to 24 kg), 1.6 mg (> 24 kg to 32 kg), 2.0 mg (> 32 kg to 40 kg), 2.4 mg (> 40 kg to 48 kg), 2.8 mg (> 48 kg) Increase daily dosage by 0.4 mg increments if total down regulation is not achieved with the starting dosage	See regimen
Leuprolide acetate (Lupron Depot 3.75) Leuprolide acetate (Eligard 7.5, 22.5, 30, 45)	Breast cancer **(off-label)**	Lupron Depot (IM) 3.75 mg per month, 11.25 mg per 3 months Eligard (SC) - 7.5 mg per month; 22.5 mg per 3 months; 30 mg per 4 months; 45 mg per 6 months Vabrinty (SC) - 7.5 mg per month; 22.5 mg per 3 months; 30 mg per 4 months; 45 mg per 6 months	See regimen
Leuprolide acetate (Lupron Depot 3.75, 11.25)	Ovarian cancer **(off-label)**	Lupron Depot (IM) 3.75 mg per month, 11.25 mg per 3 months	See regimen

Drug Name	Indication	Dosing Regimen	Maximum Dose
Leuprolide acetate (Lupron Depot 7.5, 22.5) Leuprolide acetate (Eligard 7.5, 22.5, 30, 45) Leuprolide mesylate (Camcevi, Camcevi ETM)	Salivary gland tumors **(off-label)**	Lupron Depot (IM) - 7.5 mg per month; 22.5 mg per 3 months. Eligard (SC) - 7.5 mg per month; 22.5 mg per 3 months; 30 mg per 4 months; 45 mg per 6 months Camcevi (SC) – 42 mg every 6 months Camcevi ETM (SC) – 21 mg every 3 months Vabrinty (SC) - 7.5 mg per month; 22.5 mg per 3 months; 30 mg per 4 months; 45 mg per 6 months	See regimen

VI. Product Availability

Drug Name	Availability
Leuprolide acetate injection	Kit: 2.8 mL multi-dose vial (1 mg/0.2 mL)
Leuprolide acetate (Eligard)	Kit: 7.5 mg (1 month), 22.5 mg (3 month), 30 mg (4 month), 45 mg (6 month)
Leuprolide acetate (Lupron Depot)	Prefilled syringe: 7.5 mg (1 month), 22.5 mg (3 month), 30 mg (4 month), 45 mg (6 month)
Leuprolide acetate (Lupron Depot 3.75)	Prefilled syringe: 3.75 mg (1 month)
Leuprolide acetate (Lupron Depot 11.25)	Prefilled syringe: 11.25 mg (3 month)
Leuprolide acetate (Lupron Depot-Ped)	Prefilled syringe: 7.5 mg (1 month), 11.25 mg (1 month), 15 mg (1 month) Prefilled syringe: 11.25 mg (3 month), 30 mg (3 month) Prefilled syringe: 45 mg (6 month)
Leuprolide acetate (Fensolvi)	Kit: syringe A: prefilled with diluent for reconstitution and syringe B: prefilled with 45 mg lyophilized leuprolide acetate powder
Leuprolide acetate (Vabrinty)	Kit: 7.5 mg (1 month), 22.5 mg (3 month), 30 mg (4 month), 45 mg (6 month)
Leuprolide acetate (Vobrig)	Prefilled pen for single-patient-use: 28 mg/2.8 mL
Leuprolide mesylate (Camcevi)	Injection emulsion: 42 mg
Leuprolide mesylate (Camcevi ETM)	Injection emulsion: 21 mg

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Coding Implications*

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J1950	Injection, leuprolide acetate (for depot suspension), per 3.75 mg

HCPCS Codes	Description
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
J9003	Leuprolide injectable (camcevi etm), 1 mg
J9217	Leuprolide acetate (for depot suspension), 7.5 mg
J9218	Leuprolide acetate, per 1 mg
J9219	Leuprolide acetate implant, 65 mg
S9560	Home injectable therapy; hormonal therapy (e.g.; leuprolide, goserelin), including administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

**See Appendix E: Additional Information on Diagnosis-specific HCPCS Codes, Billable Units, and Day Supply*

Reviews, Revisions, and Approvals	Date	P&T Approval Date
4Q 2022 annual review: modified Commercial approval duration to 6 months or to member's renewal date, whichever is longer; added HCPCS codes for Fensolvi and Camcevi; for Lupron Depot (7.5, 22.5, 30, 45) updated FDA-approved indication to include non-palliative treatment of advanced prostate cancer; references reviewed and updated. Template changes applied to other diagnoses/indications and continued therapy section.	07.21.22	11.22
For oncology indications, removed references to specific Lupron Depot strengths.	01.05.23	
For breast cancer maximum dosing added option for 11.25 mg per 3 months.	03.21.23	
RT4: added new dosage form (45 mg) for 6-month dosing regimen for Lupron Depot-Ped	04.19.23	
4Q 2023 annual review: for uterine fibroids added requirement that Lupron Depot is prescribed concurrently with iron therapy per FDA indication and revised Commercial approval duration to 3 months as treatment per label is limited to three months; for gender dysphoria continuation of therapy added example of positive response to therapy; references reviewed and updated. RT4: updated Eligard FDA-approved indication per prescribing information for use in the treatment of advanced prostate cancer.	06.30.23	11.23
Corrected units for basal luteinizing hormone level from mIU/L to mIU/mL for CPP.	02.08.24	
4Q 2024 annual review: no significant changes; removed Lupaneta Pack as product is discontinued; added HCPCS code J1954; references reviewed and updated. Per September SDC, removed Commercial and HIM lines of business (separate policy will be created); for prostate cancer added	09.25.24	11.24

Reviews, Revisions, and Approvals	Date	P&T Approval Date
redirection to Eligard for Lupron Depot requests through the pharmacy benefit. Added Appendix F for states with regulations against redirections in cancer.		
For gender dysphoria and gender transition, added requirement for provider attestation of understanding current State regulations regarding transgender-related health care and such care is coverable under the State regulations, added to Appendix D link and notation that the Movement Advancement Project can be referenced to confirm transgender-related health care is coverable under the State regulations.	02.12.25	
For endometriosis and uterine leiomyomata (fibroids), added allowance for age < 18 years when member is postpubertal per prescribing information.	03.10.25	
4Q 2025 annual review: per NCCN for ovarian cancer added supported uses in malignant sex cord-stromal tumors, carcinosarcoma (malignant mixed Müllerian tumors), low-grade serous carcinoma, endometrioid carcinoma, mucinous neoplasms of the ovary; added Eligard as a product that can be used for breast cancer; added Camcevi as a product that can be used for salivary gland tumors; added criteria set for uterine sarcoma; RT4: added new strength, Camcevi ETM (21 mg); references reviewed and updated.	09.10.25	11.25
Added Vabrinty to policy per SDC request.	12.18.25	02.26
HCPCS code added [J9003].	02.18.26	
For Appendix F, added states IN, MS, OH, and OK.	03.26.26	
Added off-label use for female infertility per plan request.	05.05.26	08.26
4Q 2026 annual review: added requirement for age ≥ 18 years for salivary gland tumors and uterine sarcoma; per NCCN compendium for breast cancer added requirement that member is premenopausal or male and prescribed in combination with endocrine therapy; updated Appendix E with revised language for Tennessee; added S9560 HCPCS code; references reviewed and updated. RT4: added Vobrig to criteria.	09.14.26	11.26

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health

plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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