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

Reference Number: CP.PCH.53
Effective Date: 12.01.24
Last Review Date: 08.26
Line of Business: Commercial, HIM

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™) 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)

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, and Vabrinty 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. 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:
HIM – 12 months
Commercial – 6 months or to member's renewal date, whichever is longer

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):*
**For Illinois HIM requests, the step therapy requirements below do not apply as of 1/1/2026 per IL HB 5395*
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:
HIM – 6 months
Commercial – 6 months or to member's renewal date, whichever is longer

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, or c):
   a. Fensolvi;
   b. Leuprolide acetate;
   c. Lupron Depot-Ped: 7.5 mg, 11.25 mg, 15 mg, 30 mg, 45 mg;

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, or d):
   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).

Approval duration:
HIM – 12 months
Commercial – 6 months or to member's renewal date, whichever is longer

E. Breast and Ovarian Cancer (off-label) (must meet all)**:**
1. Diagnosis of hormone receptor-positive breast cancer or ovarian cancer (including 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. 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:
HIM – 12 months
Commercial – 6 months or to member's renewal date, whichever is longer

F. Gender Dysphoria, Gender Transition (off-label) (must meet all)**:**
1. For HIM, request is for a member in a state other than the following, where gender dysphoria and gender transition treatment is not a covered benefit: AL, AZ, AR, FL, GA, IN, IA, KS, KY, LA, MS, MO, NE, NH, NC, OH, OK, SC, and TN;

2. Diagnosis of gender dysphoria or request is for gender transition;
3. 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*);
4. 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;
5. Member demonstrates understanding of expected GnRH analogue treatment outcomes and has given consent for such treatment;
6. If member has a psychiatric comorbidity, member is followed by mental health provider;
7. Psychosocial support will be provided during treatment;
8. Provider attestation of understanding current State regulations regarding transgender-related health care and such care is coverable under the State regulations (see *Appendix D*);
9. 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:
HIM – 12 months
Commercial – 6 months or to member's renewal date, whichever is longer

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. Request is for one of the following (a, b, c, or d):
   a. Eligard;
   b. Lupron Depot;
   c. Camcevi/Camcevi ETM;
   d. Vabrinty;
5. 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:
HIM – 12 months
Commercial – 6 months or to member's renewal date, whichever is longer

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. Member has endometrial stromal sarcoma or adenosarcoma without sarcomatous overgrowth;
5. Member is premenopausal;
6. Prescribed in combination with anastrozole, letrozole or exemestane;
7. 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:
HIM – 12 months
Commercial – 6 months or to member's renewal date, whichever is longer

I. Infertility and Fertility Preservation, Female* (off-label) (must meet all)**:**
** **California Commercial Plans** should not be approved using these criteria; refer to criteria HNCA.CP.PHAR.131 Infertility and Fertility Preservation*
1. Member must have infertility/fertility preservation coverage (optional pharmacy benefit – see *Appendix D*);
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.CPA.190 for commercial and HIM.PA.33 for health insurance marketplace; 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.CPA.190 for commercial and HIM.PA.103 for health insurance marketplace; 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.CPA.09 for commercial and HIM.PA.154 for health insurance marketplace.

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:
HIM – 12 months
Commercial – 6 months or to member's renewal date, whichever is longer

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 any 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:
HIM – up to a total treatment duration of 12 months
Commercial – 6 months or to member's renewal date, whichever is longer

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, or c):
   a. Fensolvi;
   b. Leuprolide acetate;
   c. Lupron Depot-Ped: 7.5 mg, 11.25 mg, 15 mg, 30 mg, 45 mg;
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, or c):
   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.

Approval duration:
HIM – 12 months
Commercial – 6 months or to member's renewal date, whichever is longer

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:
HIM – 12 months
Commercial – 6 months or to member's renewal date, whichever is longer

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. For HIM, request is for a member in a state other than the following, where gender dysphoria and gender transition treatment is not a covered benefit: AL, AZ, AR, FL, GA, IN, IA, KS, KY, LA, MS, MO, NE, NH, NC, OH, OK, SC, and TN;
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:
HIM – 12 months
Commercial – 6 months or to member's renewal date, whichever is longer

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:
HIM – 12 months
Commercial – 6 months or to member's renewal date, whichever is longer

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:
HIM – 12 months
Commercial – 6 months or to member's renewal date, whichever is longer

I. Infertility and Fertility Preservation, Female* (must meet all)**:**
** **California Commercial Plans** should not be approved using these criteria; refer to criteria HNCA.CP.PHAR.131 Infertility and Fertility Preservation*

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 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.CPA.190 for commercial and HIM.PA.33 for health insurance marketplace; 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.CPA.190 for commercial and HIM.PA.103 for health insurance marketplace; 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.CPA.09 for commercial and HIM.PA.154 for health insurance marketplace.

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.CPA.09 for commercial and HIM.PA.154 for health insurance marketplace, 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 women desiring pregnancy (labeled):** Initial: 50 mg PO once daily for 5 days. Begin on or about the fifth day of cycle if	150 mg/day per expert review Durations: 5 to 7 days per expert review

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	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.	

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.
- HIM line of business: : Infertility/Fertility Preservation
    - **AR**: In vitro fertilization are covered when: 1) The patient is the policyholder or the spouse of the policyholder and a covered dependent member under the policy, and the member's oocytes are fertilized with the sperm of the patient's spouse, and the patient and the patient's spouse have a history of unexplained infertility of at least two years' duration; OR 2) The infertility is associated with one or more of the following medical conditions: endometriosis; exposure in utero to diethylstilbestrol, commonly known as DES; Blockage of or removal of one or both fallopian tubes (lateral or

bilateral salpingectomy) not a result of voluntary sterilization; or abnormal male factors contributing to the infertility.

- **AZ**: Infertility - limited to diagnostic rendered for infertility evaluation; Fertility Preservation - medically necessary services and supplies for standard fertility preservation treatments are covered when a cancer treatment may directly or indirectly cause iatrogenic infertility. Iatrogenic infertility is infertility that is caused by a medical intervention, including reactions from prescribed drugs or from medical or surgical procedures that may be provided for cancer treatment.
- **CA**: Fertility Preservation – covers medically necessary services and supplies for established fertility preservation treatments in connection with iatrogenic Infertility; Infertility - with the exception of covered fertility preservation services, services or supplies that are intended to impregnate a woman are not covered. Excluded procedures include, but are not limited to:
  - Conception by medical procedures, such as artificial insemination, in-vitro fertilization (IVF), gamete intrafallopian transfer (GIFT), zygote intrafallopian transfer (ZIFT), or any process that involves harvesting, transplanting, or manipulating a human ovum. Also not covered are services and supplies (including injections and injectable medications) which prepare the covered person to receive these services;
  - Services and supplies for the purpose of diagnosing the cause of infertility.
- **DE:** Fertility/Infertility Preservation - For individuals who qualify under Delaware law, covered services include fertility care services, including in vitro fertilization services, identified in 18 Del. C. § 3342 for individuals who suffer from a disease or condition that results in the inability to procreate or to carry a pregnancy to live birth and standard fertility preservation services for individuals who must undergo medically necessary treatment that may cause iatrogenic infertility. Experimental fertility care services, monetary payments to gestational carriers or surrogates, and reversals of voluntary sterilization are not covered services.
- **GA:** Chapter 24 of Title 33 of the Official Code of Georgia:"Every health benefit policy renewed or issued after January 1, 2026, shall include coverage for expenses for standard fertility preservation services when a medically necessary treatment may directly or indirectly cause iatrogenic infertility in any covered person. Such coverage shall include evaluation expenses, laboratory assessments, medications, and treatments associated with standard fertility preservation services, including storage of gametes for up to one year."
- **IL:** Fertility Preservation Services – Coverage for medically necessary expenses for standard fertility preservation services when a necessary medical treatment may directly or indirectly cause iatrogenic infertility to a member; Infertility Expense Benefits – Infertility coverage for the diagnosis and treatment of infertility including, but not limited to, in vitro fertilization, uterine embryo lavage, embryo transfer, artificial insemination, gamete intrafallopian tube transfer, zygote intrafallopian tube transfer, low tubal ovum transfer, oocyte retrieval and intracytoplasmic sperm injection, to the extent the treatment is legal under applicable law.

- **IN:** Infertility Services - Covered services under this benefit are limited to medically necessary diagnostic tests to determine infertility and treatment of the underlying medical conditions that may cause infertility (e.g., endometriosis, obstructed fallopian tubes and hormone deficiency).
- **KS:** Infertility Services - Covered services for infertility treatment are limited to diagnostic testing to find the cause of infertility, such as diagnostic laparoscopy, endometrial biopsy, and semen analysis. Benefits are included to treat the underlying medical conditions that cause infertility (such as endometriosis, obstructed fallopian tubes and hormone deficiency).
- **KY:** Infertility Benefits - Covered services under this benefit are provided for medically necessary diagnostic and exploratory procedures to determine infertility including surgical procedures to correct a medically diagnosed disease or condition of the reproductive organs including, but not limited to, treatment of the following:1. Endometriosis;2. Collapsed/clogged fallopian tubes; or 3. Testicular failure.
- **LA**: Fertility Preservation – Medically necessary fertility preservation services for enrollees when a medical treatment will directly or indirectly result in "iatrogenic infertility," which is an impairment of fertility by surgery, radiation, chemotherapy, or other medical treatment affecting reproductive organs or processes. Cost-sharing such as deductibles, copayments, and coinsurance may be imposed on fertility preservation services if the cost-sharing is consistent with other benefits in the contract and place of service. Services include the collecting, freezing, preserving of ova or sperm, and other standard services that are not experimental or investigational. Coverage includes up to three (3) years of storage costs associated with oocytes and sperm during the enrollee's membership. Infertility – Covered services under this benefit are provided for medically necessary diagnostic and exploratory procedures to determine infertility and surgical procedures to correct a medically diagnosed disease or condition of the reproductive organs including, but not limited to, treatment of the following: 1. Endometriosis; 2. Collapsed/clogged fallopian tubes; or 3. Testicular failure.
- **MI**: Infertility Services - Covered service expenses under this benefit are provided for medically necessary diagnostic and exploratory procedures to determine infertility, including surgical procedures and prescription drugs, to correct a medically diagnosed disease or condition of the reproductive organs including, but not limited to, treatment of the following: 1. Endometriosis; 2. Collapsed/clogged fallopian tubes; or 3. Testicular failure
- **MO:** Infertility Services **-** Covered services for infertility treatment are limited to diagnostic testing to find the cause of infertility, such as diagnostic laparoscopy, endometrial biopsy, and semen analysis. Benefits are included to treat the underlying medical conditions that cause infertility (such as endometriosis, obstructed fallopian tubes and hormone deficiency).
- **NE:** For the treatment of infertility. Note: Coverage is available for diagnosis and services required to correct underlying medical causes of infertility.

- **NV:** Limited diagnostic and therapeutic infertility services determined to be medically necessary and requires prior authorization. Covered services do not include those services specifically excluded herein, but do include limited: a. Laboratory studies; b. Diagnostic procedures; and c. Artificial insemination services, up to six (6) cycles per member per lifetime.
- **NJ**: Subject to pre-approval, covered charges include: artificial insemination; and standard dosages, lengths of treatment and cycles of therapy of prescription drugs used to stimulate ovulation for artificial insemination or for unassisted conception
- **NC**: Limited to diagnostic testing to find the cause of infertility, such as diagnostic laparoscopy, endometrial biopsy, and semen analysis. Treatment of the underlying medical conditions that cause infertility (such as endometriosis, obstructed fallopian tubes and hormone deficiency) are considered a separate benefit. Treatment for infertility is limited to a lifetime benefit maximum, per member, of three medical ovulation induction cycles.
- **NY**: Infertility Treatment - We cover services for the diagnosis and treatment (surgical and medical) of infertility "Infertility" is a disease or condition characterized by the incapacity to impregnate another person or to conceive, defined by the failure to establish a clinical pregnancy after 12 months of regular, unprotected sexual intercourse or therapeutic donor insemination, or after six (6) months of regular, unprotected sexual intercourse or therapeutic donor insemination for a female 35 years of age or older. Earlier evaluation and treatment may be warranted based on a Member's medical history or physical findings. Basic Infertility Services, Comprehensive Infertility Services, Fertility Preservation Services
- **NH**: Infertility Services - Covered services for infertility treatment are limited to diagnostic testing to find the cause of infertility, such as diagnostic laparoscopy, endometrial biopsy, and semen analysis. Benefits are included to treat the underlying medical conditions that cause infertility (such as endometriosis, obstructed fallopian tubes and hormone deficiency). Benefits are only available to the extent the covered fertility services are legal under applicable law
- **OH**: Infertility - Covered service expenses under this benefit are provided for medically necessary diagnostic and exploratory procedures to determine infertility including surgical procedures to correct a medically diagnosed disease or condition of the reproductive organs including, but not limited to, treatment of the following:1. Endometriosis;2. Collapsed/clogged fallopian tubes; or 3. Testicular failure. This benefit is subject to deductible and coinsurance amount/copayment. No benefits will be payable for charges related to artificial insemination services, in vitro fertilization (IVF), gamete intrafallopian transfer (GIFT), and zygote intrafallopian transfer (ZIFT).
- **OK**: Infertility - Covered service expenses under this benefit are provided for medically necessary diagnostic and exploratory procedures to determine infertility including surgical procedures to correct a medically diagnosed disease or condition of the reproductive organs including, but not limited to, treatment of the following:1. Endometriosis;2. Collapsed/clogged fallopian tubes; or3. Testicular failure. This benefit is subject to deductible and coinsurance amount/copayment No benefits will be payable for charges related to artificial insemination services, in vitro fertilization

(IVF), gamete intrafallopian transfer (GIFT), and zygote intrafallopian transfer (ZIFT). Fertility Preservation -We cover standard medically necessary fertility preservation services for enrollees within reproductive age, diagnosed with cancer, when a medical treatment will directly or indirectly result in "iatrogenic infertility," which is an impairment of fertility by surgery, radiation, chemotherapy, or other medical treatment affecting reproductive organs or processes. Cost-sharing such as deductibles, copayments, and coinsurance may be imposed on fertility preservation services if the cost-sharing is consistent with other benefits in the contract and place of service.

- **PA:** Infertility - Covered services under this benefit are provided for medically necessary diagnostic and exploratory procedures to determine infertility. Coverage is also provided for artificial insemination, as well as for surgical procedures to correct a medically diagnosed disease or condition of the reproductive organs including, but not limited to, treatment of the following: 1. Endometriosis; 2. Collapsed/clogged fallopian tubes; or 3. Testicular failure. This benefit is subject to deductible and coinsurance/copayment. No benefits will be payable for charges related to in vitro fertilization (IVF), embryo transplant, gamete intrafallopian transfer (GIFT), and zygote intrafallopian transfer (ZIFT).
- **SC**: Infertility - Infertility treatment is limited to medical services provided to the member which are medically necessary for the diagnosis of infertility and services required to correct underlying medical conditions that may cause infertility (e.g., endometriosis). This does not include treatment for infertility, including artificial insemination, in vitro fertilization, and other types of artificial or surgical means of conception nor drugs administered in connection with these procedures
- **TN**: Infertility Services - Covered services for infertility treatment are limited to diagnostic testing to find the cause of infertility, such as diagnostic laparoscopy, endometrial biopsy, and semen analysis. Benefits are included to treat the underlying medical conditions that cause infertility (such as endometriosis, obstructed fallopian tubes and hormone deficiency).
- **TX**: Infertility - Infertility treatment is a covered service expense when medical services are provided to the enrollee which are medically necessary for the diagnosis of infertility such as diagnostic laparoscopy, endometrial biopsy, and semen analysis. Benefits are included to treat the underlying medical conditions that cause infertility (such as endometriosis, obstructed fallopian tubes and hormone deficiency). This does not cover treatment or surgical procedures for infertility including artificial insemination, in vitro fertilization, medically assisted reproduction (MAR), and other types of artificial or surgical means of contraception including drugs administered in connection with these procedures. Fertility Preservation - Medically necessary fertility preservation services for enrollees when a medical treatment will directly or indirectly result in "iatrogenic infertility," which is an impairment of fertility by surgery, radiation, chemotherapy, or other medical treatment affecting reproductive organs or processes. Cost-sharing such as deductibles, copayments, and coinsurance may be imposed on fertility preservation services if the cost-sharing is consistent with other benefits in the contract and place of service. Services include the collecting, freezing, preserving of ova or sperm, and other standard services that are not

experimental or investigational. (Storage is an exclusion.). Coverage may be limited to in-network providers for fertility preservation services unless the issuer does not have an in-network provider with the appropriate training and expertise to meet the needs of the enrollee. Prior authorization and/or referrals may be required.

- **All other states**: No benefits will be paid under this benefit provision for services provided or expenses incurred for infertility drugs, unless otherwise listed on the formulary.

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
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

Diagnosis	Requested Product	HCPCS Code	Billable Units	Day Supply
	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

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
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)	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)	See regimen

Drug Name	Indication	Dosing Regimen	Maximum Dose
		(increase as needed up to 15 mg/month); 3-month administration: 11.25 mg or 30 mg; 6-month administration: 45 mg	
		Fensolvi (SC): 45 mg once every six months	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
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)

Drug Name	Availability
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 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
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

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

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created (adapted from CP.PHAR.173) per September SDC and prior clinical guidance.	09.25.24	11.24
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	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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; for endometriosis and uterine leiomyomata (fibroids), added allowance for age < 18 years when member is postpubertal per prescribing information; added step therapy bypass for IL HIM per IL HB 5395; 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
For gender dysphoria and gender transition, as a result of the Marketplace Integrity and Affordability rule, added requirement for HIM, request is for a member in a state other than the following, where gender dysphoria and gender transition treatment is not a covered benefit: AL, AZ, AR, FL, GA, IN, IA, KS, KY, LA, MS, MO, NE, NH, NC, OH, OK, SC, and TN. HCPCS code added [J9003].	02.24.26	
Added off-label use for female infertility per plan request.	05.05.26	08.26

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.