

GnRH Analogues
Camcevi (leuprolide)
Eligard (leuprolide)
Fensolvi (leuprolide)
Firmagon (degarelix)
Lupron (leuprolide)
Supprelin LA (histrelin)
Trelstar (triptorelin)
Triptodur (triptorelin)
Zoladex (goserelin)
Effective 10/01/2024

Plan	<input checked="" type="checkbox"/> MassHealth UPPL <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		
Specialty Limitations	N/A		
Contact Information	Medical and Specialty Medications		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
Contact Information	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Notes	Camcevi, Eligard, Firmagon, Lupron, Triptodur is also available on the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria. Additional agents from this class are available through the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria.		

Overview

The gonadotropin-releasing hormone (GnRH) analogues are used for multiple hormonal indications that include prostate cancer, breast cancer, endometriosis, uterine fibroids and central precocious puberty (CPP).

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for members when all the following criteria are met, and documentation is provided:

All Agents

Paraphilia (Off-Label)

1. Diagnosis of paraphilia

2. The member is under the care of a specialist (or being prescribed by specialist) to treat the disorder (psychiatrist, psychologist, etc.)

Camcevi (leuprolide)

ALL of the following:

1. Diagnosis of advanced prostate cancer
2. Prescriber is an oncologist/urologist
3. Appropriate dose and frequency

Eligard (leuprolide)

ONE of the following:

1. Diagnosis of advanced prostate cancer
 - a. Prescriber is an oncologist/urologist
 - b. Appropriate dose and frequency
2. Diagnosis of PMDD (*off-label*)
 - a. Appropriate dose and frequency
 - b. Inadequate response or adverse reaction to TWO or contraindication to ALL SSRIs
 - c. Inadequate response or adverse reaction to ONE or contraindication to ALL hormonal contraceptives
3. Diagnosis of **ONE** of the following (*off-label*): gender dysphoria, transgenderism, or therapy after gender reassignment surgery
 - a. Requests quantity is within quantity limits:
 - i. 7.5 mg syringe: ≤ 1 unit/28 days (1 month)
 - ii. 22.5 mg syringe: ≤ 1 unit/84 days (3 months)
 - iii. 30 mg syringe: ≤ 1 unit/112 days (4 months)
 - iv. 45 mg syringe: ≤ 1 unit/168 days (6 months)
4. Indication of ovarian suppression/preservation (*off-label*)
 - a. Member is currently being treated with a chemotherapeutic agent
 - a. Appropriate dosing and frequency
5. Severity of menstrual bleeding (e.g., anemia, hemoglobin levels, abdominal pain, interference with daily activities – off label)
 - a. Physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **BOTH** of the following:
 - i. Hormonal contraceptives (e.g., oral contraceptives, IUD, Depo-Provera)
 - ii. Non-contraceptive estrogen-progestin formulations
 - b. Physician attestation of inadequate response, adverse reaction, or contraindication to tranexamic acid
 - c. **ONE** of the following:
 - i. If member is a surgical candidate, expected date of surgery (can use for approval duration)
 - ii. If member is not a surgical candidate, **ONE** of the following:
 1. Paid claims or physician attestation that member is being treated with add-back therapy for bone loss
 2. Yearly BMD scan has been performed to indicate that the member does not need to be treated for osteoporosis



Fensolvi (leuprolide)

ONE of the following:

1. Diagnosis of central precocious puberty (CPP) with onset of secondary sex characteristics before age 8 years (female sex assigned at birth/biologic females) or 9 years (male sex assigned at birth/biologic males)
 - a. Prescriber is a pediatric endocrinologist or consult notes from a pediatric endocrinologist are provided
 - b. **ONE** of the following:
 - i. Member is currently less than 11 years of age (female sex assigned at birth/biologic females) or 12 years of age (male sex assigned at birth/biologic males)
 - ii. Member is ≥ 11 years of age and < 12 years of age (female sex assigned at birth/biologic females) or ≥ 12 years of age (male sex assigned at birth/biologic males) and < 13 years of age and requires one additional year of prolonged therapy due to developmental delay
 - c. Appropriate dose and frequency
2. Fensolvi (leuprolide) will be used for a stimulation test to diagnosis CPP
3. Diagnosis of **ONE** of the following (off-label): gender dysphoria, transgenderism, or therapy after gender reassignment surgery
 - a. Requests quantity is within quantity limits: 45 mg syringe kit - ≤ 1 unit/112 days (4 months)
4. Indication of ovarian suppression/preservation (off-label)
 - a. Member is currently being treated with a chemotherapeutic agent
 - b. Appropriate dosing and frequency
5. Severity of menstrual bleeding (e.g., anemia, hemoglobin levels, abdominal pain, interference with daily activities – off label)
 - a. Physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **BOTH** of the following:
 - iii. Hormonal contraceptives (e.g., oral contraceptives, IUD, Depo-Provera)
 - iv. Non-contraceptive estrogen-progestin formulations
 - b. Physician attestation of inadequate response, adverse reaction, or contraindication to tranexamic acid
 - c. **ONE** of the following:
 - i. If member is a surgical candidate, expected date of surgery (can use for approval duration)
 - ii. If member is not a surgical candidate, **ONE** of the following:
 1. Paid claims or physician attestation that member is being treated with add-back therapy for bone loss
 2. Yearly BMD scan has been performed to indicate that the member does not need to be treated for osteoporosis

Firmagon (degarelix)

ONE of the following:

1. Diagnosis of advanced prostate cancer
 - a. Prescriber is an oncologist/urologist
 - b. Appropriate dose and frequency

Lupron (leuprolide)

ONE of the following:

1. Diagnosis of advanced prostate cancer
 - a. Prescriber is an oncologist/urologist



- b. Appropriate dose and frequency
- 2. Diagnosis of endometriosis
 - a. Appropriate dose and frequency
 - b. Physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** NSAIDs
 - c. Physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** hormonal contraceptives
- 3. Diagnosis of CPP with onset of secondary sex characteristics before age 8 years (female sex assigned at birth/biologic females) or 9 years (male sex assigned at birth/biologic males)
 - a. Prescriber is a pediatric endocrinologist or consult notes from a pediatric endocrinologist are provided
 - b. **ONE** of the following:
 - i. Member is currently less than 11 years of age (female sex assigned at birth/biologic females) or 12 years of age (male sex assigned at birth/biologic males)
 - ii. Member is ≥ 11 years of age and < 12 years of age (female sex assigned at birth/biologic females) or ≥ 12 years of age (male sex assigned at birth/biologic males) and < 13 years of age and requires one additional year of prolonged therapy due to developmental delay
 - c. Appropriate dose and frequency
- 4. Diagnosis of uterine leiomyomata
 - a. Appropriate dose and frequency
 - b. **ONE** of the following
 - i. Anticipated surgery date (or notation on PA that surgery is planned once fibroids shrink)
 - ii. Clinical rationale why surgical intervention is not appropriate
 - c. Physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** hormonal contraceptives (*if request states fibroid shrinkage prior to surgery is a goal, trial may be bypassed*)
- 5. Diagnosis of endometriosis – extended duration of therapy (off-label)
 - a. Anticipated duration of therapy
 - b. **ONE** of the following:
 - i. Paid claims or physician attestation that member is being treated with add-back therapy for bone loss
 - ii. Yearly bone mineral density (BMD) scan has been performed to indicate that the member does not need to be treated for osteoporosis
- 6. Diagnosis of uterine leiomyomata – extended duration of therapy (off-label)
 - a. **ONE** of the following:
 - i. Updated surgery date
 - ii. **ALL** of the following:
 - 1. Clinical rationale why surgery is not an option (i.e., underlying medical conditions)
 - 2. **ONE** of the following:
 - a. Paid claims or physician attestation that member is being treated with add-back therapy for bone loss
 - b. Yearly BMD scan has been performed to indicate that the member does not need to be treated for osteoporosis
- 7. Lupron will be used for a stimulation test to diagnosis CPP
- 8. Diagnosis of **ONE** of the following (off-label): gender dysphoria, transgenderism, or therapy after gender reassignment surgery
 - a. Requested quantity is within quantity limits:



- i. 3.75 mg kit, 7.5 mg 1-month pediatric kit 11.25 mg 1-month pediatric kit 15 mg pediatric kit: ≤ 1 unit/28 days (1 month)
 - ii. 11.25 mg 3-month kit 11.25 mg 3-month pediatric kit 22.5 mg pediatric kit 30 mg pediatric kit: ≤ 1 unit/84 days (3 months)
 - iii. 45 mg pediatric kit: ≤ 1 unit/168 days (6 months)
 - iv. 7.5 mg adult kit: ≤ 1 unit/28 days (1 month)
 - v. 22.5 mg adult kit: ≤ 1 unit/84 days (3 months)
 - vi. 30 mg adult kit: ≤ 1 unit/112 days (4 months)
 - vii. 45 mg adult kit: ≤ 1 unit/168 days (6 months)
- 9. Indication of ovarian suppression in breast cancer (off-label)
 - a. Member is currently being treated with **ONE** of the following:
 - i. anastrozole
 - ii. exemestane
 - iii. letrozole
 - iv. tamoxifen
- 10. Severity of menstrual bleeding (e.g., anemia, hemoglobin levels, abdominal pain, interference with daily activities – off label)
 - a. Physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **BOTH** of the following:
 - i. Hormonal contraceptives (e.g., oral contraceptives, IUD, Depo-Provera)
 - ii. Non-contraceptive estrogen-progestin formulations
 - b. Physician attestation of inadequate response, adverse reaction, or contraindication to tranexamic acid
 - c. **ONE** of the following:
 - i. If member is a surgical candidate, expected date of surgery (can use for approval duration)
 - ii. If member is not a surgical candidate, **ONE** of the following:
 - 1. Paid claims or physician attestation that member is being treated with add-back therapy for bone loss
 - 2. BMD scan has been performed to indicate that the member does not need to be treated for osteoporosis
- 11. Diagnosis of PMDD
 - a. Appropriate dose and frequency
 - b. Inadequate response or adverse reaction to TWO or contraindication to ALL SSRIs
 - c. Inadequate response or adverse reaction to ONE or contraindication to ALL hormonal contraceptives

Supprelin LA (histrelin)

ONE of the following:

- 1. Diagnosis of CPP with onset of secondary sex characteristics before age 8 years (female sex assigned at birth/biologic females) or 9 years (male sex assigned at birth/biologic males)
 - a. Prescriber is a pediatric endocrinologist or consult notes from a pediatric endocrinologist are provided
 - b. **ONE** of the following:
 - i. Member is currently less than 11 years of age (female sex assigned at birth/biologic females) or 12 years of age (male sex assigned at birth/biologic males)



- ii. Member is ≥ 11 years of age and < 12 years of age (female sex assigned at birth/biologic females) or ≥ 12 years of age (male sex assigned at birth/biologic males) and < 13 years of age and requires one additional year of prolonged therapy due to developmental delay
 - c. Appropriate dose and frequency
- 2. Supprelin LA will be used for a stimulation test to diagnosis CPP
- 3. Diagnosis of **ONE** of the following (off-label): gender dysphoria, transgenderism, or therapy after gender reassignment surgery
 - a. Requested quantity is within quantity limits: 50 mg implant - ≤ 1 unit/365 days (1 year)

Trelstar (triptorelin)

ONE of the following:

- 1. Diagnosis of advanced prostate cancer
 - a. Prescriber is an oncologist/urologist
 - b. Appropriate dose and frequency
- 2. Diagnosis of catamenial epilepsy
 - a. Prescriber is a neurologist or endocrinologist or consult notes from a neurologist or endocrinologist are provided
 - b. Physician attestation of inadequate response or adverse reaction to **TWO** anticonvulsants
 - c. Physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** progesterone therapy or synthetic progestin therapy
 - d. Requested dose is 3.75 mg every 4 weeks

Triptodur (triptorelin)

ONE of the following:

- 1. Diagnosis of CPP with onset of secondary sex characteristics before age 8 years (female sex assigned at birth/biologic females) or 9 years (male sex assigned at birth/biologic males)
 - a. Prescriber is a pediatric endocrinologist or consult notes from a pediatric endocrinologist are provided
 - b. **ONE** of the following:
 - i. Member is currently less than 11 years of age (female sex assigned at birth/biologic females) or 12 years of age (male sex assigned at birth/biologic males)
 - ii. Member is ≥ 11 years of age and < 12 years of age (female sex assigned at birth/biologic females) or ≥ 12 years of age (male sex assigned at birth/biologic males) and < 13 years of age and requires one additional year of prolonged therapy due to developmental delay
 - c. Appropriate dose and frequency (refer to dosing table)
- 2. Triptodur (triptorelin) will be used for a stimulation test to diagnosis CPP
- 3. Diagnosis of **ONE** of the following (off-label): gender dysphoria, transgenderism, or therapy after gender reassignment surgery
 - a. Requested quantity is within quantity limits: 22.5 mg vial kit - ≤ 1 unit/112 days (4 months)
- 4. Severity of menstrual bleeding (e.g., anemia, hemoglobin levels, abdominal pain, interference with daily activities – off label)
 - a. Physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **BOTH** of the following:
 - i. Hormonal contraceptives (e.g., oral contraceptives, IUD, Depo-Provera)
 - ii. Non-contraceptive estrogen-progestin formulations
 - b. Physician attestation of inadequate response, adverse reaction, or contraindication to tranexamic acid
 - c. **ONE** of the following:



- i. If member is a surgical candidate, expected date of surgery (can use for approval duration)
- ii. If member is not a surgical candidate, **ONE** of the following:
 - 1. Paid claims or physician attestation that member is being treated with add-back therapy for bone loss
 - 2. BMD scan has been performed to indicate that the member does not need to be treated for osteoporosis

Zoladex (goserelin)

ONE of the following:

1. Diagnosis of advanced breast cancer
 - a. Appropriate dose and frequency
2. Diagnosis of advanced prostate cancer
 - b. Prescriber is an oncologist/urologist
 - c. Appropriate dose and frequency
 - d. Prescriber must submit documentation of trials of alternatives with rebate or clinical rationale for use of non-rebate product (as per the non-FDA approved and non-rebate medications guideline)
3. Diagnosis of abnormal uterine bleeding
 - a. Appropriate dose and frequency
 - b. Anticipated surgery date
4. Diagnosis of endometriosis
 - a. Appropriate dose and frequency
 - b. Physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** NSAIDs
 - c. Physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** hormonal contraceptives
 - d. Prescriber must also submit documentation of trials of alternatives with rebate or clinical rationale for use of non-rebate product (as per the non-FDA approved and non-rebate medications guideline)
5. Diagnosis of endometriosis – extended duration of therapy (off-label)
 - a. Anticipated duration of therapy
 - b. **ONE** of the following:
 - i. Paid claims or physician attestation that member is being treated with add-back therapy for bone loss
 - ii. Yearly bone mineral density (BMD) scan has been performed to indicate that the member does not need to be treated for osteoporosis
 - c. Prescriber must also submit documentation of trials of alternatives with rebate or clinical rationale for use of non-rebate product (as per the non-FDA approved and non-rebate medications guideline.)
6. Indication of ovarian suppression/preservation (off-label)
 - a. Member is currently being treated with a chemotherapeutic agent
 - b. Appropriate dose and frequency
7. Diagnosis of advanced breast cancer (off-label)
 - a. Requested dose is 10.8 mg every 3 months
8. Severity of menstrual bleeding (e.g., anemia, hemoglobin levels, abdominal pain, interference with daily activities – off label)



- a. Physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **BOTH** of the following:
 - i. Hormonal contraceptives (e.g., oral contraceptives, IUD, Depo-Provera)
 - ii. Non-contraceptive estrogen-progestin formulations
 - b. Physician attestation of inadequate response, adverse reaction, or contraindication to tranexamic acid
 - c. **ONE** of the following:
 - i. If member is a surgical candidate, expected date of surgery (can use for approval duration)
 - ii. If member is not a surgical candidate, **ONE** of the following:
 - 1. Paid claims or physician attestation that member is being treated with add-back therapy for bone loss
 - 2. Yearly BMD scan has been performed to indicate that the member does not need to be treated for osteoporosis
 - d. Prescriber must also submit documentation of trials of alternatives with rebate or clinical rationale for use of non-rebate product (as per the non-FDA approved and non-rebate medications guideline)
9. Diagnosis of PMDD
- a. Appropriate dose and frequency
 - b. Inadequate response or adverse reaction to TWO or contraindication to ALL SSRIs
 - c. Inadequate response or adverse reaction to ONE or contraindication to ALL hormonal contraceptives
 - d. Prescriber must also submit documentation of trials of alternatives with rebate or clinical rationale for use of non-rebate product (as per the non-FDA approved and non-rebate medications guideline)

Continuation of Therapy

Reauthorization infers positive response to therapy.

Limitations

1. Initial approvals will be granted based on diagnosis:
 - a. Advanced breast and prostate cancer: 1 year
 - b. Catamenial epilepsy (for Trelstar only): 1 year
 - c. CPP: 1 year until member reaches age 11 (biological female) or 12 (biological male)
 - d. Endometriosis
 - i. Lupron: 6 months (alone or with add-back therapy)
 - ii. Zoladex*: 6 months
 - e. Gender dysphoria: 1 year
 - f. GnRH stimulation test for CPP diagnosis: 1 dose only
 - g. Paraphilia: 1 year
 - h. PMDD: 1 year
 - i. Uterine leiomyomata (fibroids)/endometrial thinning prior to endometrial ablation
 - i. Lupron and Zoladex: 1 month or until time of surgery documented
2. Reauthorizations will be granted based on diagnosis:
 - a. Advanced breast and prostate cancer: 1 year
 - b. Catamenial epilepsy (for Trelstar only): 1 year
 - c. CPP: 1 year until the member reaches age 11 (biological female) or 12 (biological male). For request for use beyond the specified ages documenting that the member has a developmental



disability that requires extended treatment, an additional year may be approved (through age 12 for biologic female or age 13 for biologic male).

- d. Endometriosis
 - i. Lupron: 6 additional months with add-back therapy (max total duration of 1 year)
- e. Gender dysphoria: 1 year
- f. Paraphilia: 1 year
- g. PMDD: 1 year
- h. Uterine leiomyomata (fibroids)/endometrial thinning prior to endometrial ablation
 - i. Lupron and Zoladex: 1 additional month or until time of surgery documented

*Approvals for Zoladex (for no dyspareunia or moderate hepatic impairment) will only be granted for 6 months max.

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Review History

02/20/2019 – Reviewed

09/16/2020 – Reviewed and Updated; added new medication Oriahnn, references updated; added QL to program for Orilissa and Oriahnn; Maximum approval included in limitations. Effective 11/01/20.

09/22/2021 – Reviewed and Updated; added new medication Myfembree; references updated. Effective 11/01/2021

11/16/2022 – Reviewed and updated for Nov P&T. Separated out Comm/Exch vs MH. Matched MH UPPL criteria. Effective 2/1/23

02/08/2023 - Reviewed and updated for Feb P&T. Matched MH UPPL criteria. New drug Camcevi added to guideline with criteria matching other advanced prostate cancer agents. The following drugs were added to criteria requiring PA: Eligard, Fensolvi, Firmagon, Lupaneta Pack, Lupron, Orgovyx, Supprelin LA, Synarel, Trelstar, Triptodur, Vantas, Zoladex. Expanded indication for Myfembree in endometriosis added with criteria



matching Orilissa. Criteria for Lupron and generic leuprolide vial for advanced prostate cancer updated to require use of 1 less costly leuprolide agent (Camcevi, Eligard, Supprelin LA or Trelstar). Off-label indications added to criteria per NCQA standards. Clarification added for approval of oral agents when needle-phobia is cited. Clarification that hormonal contraceptives do not decrease fibroid size. Clarification for duration of therapy/recertification duration and criteria for extended duration beyond recommended limits. Clarification for appropriate breast cancer regimens and ovarian suppression. Effective 4/1/23.

06/14/23 – Reviewed and updated for P&T. Removed preferred product requirement from Fensolvi and Triptodur criteria for requests through MB. Added language that Zoladex only available through MB. Effective 6/30/23.

09/11/24 – Reviewed and updated for P&T. Separated out MB agents from GnRH policy. Clarification added that in extended therapy for endometriosis or fibroids that BMD would be required yearly for continued use. Clarification that GnRH agents can be utilized to preserve ovarian function in patients undergoing chemotherapy for a wide range of treatments/diagnoses. Fensolvi®, Supprelin LA® and Zoladex® were updated to be managed through medical. Wording updated to utilize the preferred verbiage gender dysphoria and transgenderism. Clarified that the following will be dual benefit: Camcevi, Eligard, Firmagon, Lupron, Triptodur. Effective 10/1/24.

