

**GnRH Analogues**  
**Effective 06/30/2023**

<b>Plan</b>	<input checked="" type="checkbox"/> MassHealth UPPL <input type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX)		
<b>Specialty Limitations</b>	These medications have been designated specialty and must be filled at a contracted specialty pharmacy.		
<b>Contact Information</b>	<b>Specialty Medications</b>		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	<b>Non-Specialty Medications</b>		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	<b>Medical Specialty Medications (NLX)</b>		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
<b>Exceptions</b>	Trelstar and Zoladex are available through the medical benefit only.		

### Overview

Drugs that require PA	
Camcevi® (leuprolide) <sup>DUAL</sup>	Orilissa® (elagolix)
Eligard® (leuprolide)	Orgovyx® (relugolix)
Fensolvi® (leuprolide) <sup>DUAL</sup>	Supprelin LA® (histrelin) <sup>DUAL</sup>
Firmagon® (degarelix)	Synarel® (nafarelin)
Lupaneta Pack® (leuprolide/norethindrone) <sup>DUAL</sup>	Trelstar® (triptorelin) <sup>MB</sup>
Lupron® (leuprolide) <sup>DUAL</sup>	Triptodur® (triptorelin) <sup>DUAL</sup>
Myfembree® (relugolix/estradiol/norethindrone)	Vantas® (histrelin)
Oriahnn® (elagolix/estradiol/norethindrone)	Zoladex® (goserelin) ‡ <sup>MB</sup>

‡This product does not participate in the federal rebate program.

DUAL – Drugs available through both pharmacy and medical benefits.

MB – Medical Benefit

### 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:

### 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 **ONE** of the following (off-label): gender identity disorder, gender dysphoria, transsexualism, or therapy after gender reassignment surgery
  - a. **ONE** of the following:
    - i. For the 7.5 mg syringe, requested quantity is  $\leq 1$  unit/28 days (1 month)
    - ii. For the 22.5 mg syringe, requested quantity is  $\leq 1$  unit/84 days (3 months)
    - iii. For the 30 mg syringe, requested quantity is  $\leq 1$  unit/112 days (4 months)

### Fensolvi® (leuprolide)

**ONE** of the following:

1. Diagnosis of central precocious puberty (CPP) with onset of secondary sex characteristics before age 8 years (biologic females) or 9 years (biologic males)
  - a. Prescriber is a pediatric endocrinologist or consult notes from a pediatric endocrinologist are provided
  - b. Member is currently less than 11 years of age (biologic females) or 12 years of age (biologic males)
  - c. Appropriate dose and frequency
  - d. **If reviewing under Pharmacy Benefit:** Physician attestation of inadequate response, adverse reaction, or contraindication to Lupron® (leuprolide)
2. Fensolvi (leuprolide) will be used for a stimulation test to diagnosis CPP
3. Diagnosis of **ONE** of the following (off-label): gender identity disorder, gender dysphoria, transsexualism, or therapy after gender reassignment surgery
  - a. Requests quantity is  $\leq 1$  unit/112 days (4 months)
4. 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
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. BMD scan has been performed to indicate that the member does not need to be treated for osteoporosis
- d. **If reviewing under Pharmacy Benefit:** Physician attestation of inadequate response, adverse reaction, or contraindication to Lupron (leuprolide)

**Firmagon® (degarelix)**

**ALL** of the following:

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

**Lupaneta® Pack (leuprolide/ norethindrone)**

**ONE** of the following:

- 1. 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
- 2. Diagnosis of endometriosis – extended duration of therapy (off-label)
  - a. Anticipated duration of therapy
- 3. 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

**Lupron® (leuprolide)**

**ONE** of the following:

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



- c. **If reviewing under Pharmacy Benefit:** Physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** of the following:
      - i. Camcevi® (leuprolide)
      - ii. Eligard® (leuprolide)
      - iii. Supprelin LA® (histrelin)
      - iv. Trelstar® (triptorelin)
- 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 (biologic females) or 9 years (biologic males)
  - a. Prescriber is a pediatric endocrinologist or consult notes from a pediatric endocrinologist are provided
  - b. Member is currently less than 11 years of age (biologic females) or 12 years of age (biologic males)
  - 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. 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)
  - 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. 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 identity disorder, gender dysphoria, transsexualism, or therapy after gender reassignment surgery



- a. **ONE** of the following:
  - i. For the 3.75 mg kit and 7.5 mg kit, requested quantity is  $\leq 1$  unit/28 days (1 month)
  - ii. For the 11.25 mg kit, 22.5 mg kit, and 30 mg pediatric kit, requested quantity is  $\leq 1$  unit/84 days (3 months)
  - iii. For the 30 mg adult kit, requested quantity is  $\leq 1$  unit/112 days (4 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

**Myfembree® (relugolix/estradiol/ norethindrone)**

**ONE** of the following:

- 1. 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. **BOTH** of the following:
    - i. Physician attestation of inadequate response, adverse reaction, or contraindication to Lupron® (leuprolide) unless there is documentation of needle-phobia
    - ii. Requested quantity is  $\leq 1$  tablet/day
- 2. Diagnosis of uterine leiomyomata
  - a. Appropriate dose and frequency
  - b. Anticipated surgery date or clinical rationale why surgical intervention is not appropriate
  - c. Physician attestation of inadequate response or adverse reaction to one hormonal contraceptive, or contraindication to all hormonal contraceptives
  - d. **BOTH** of the following:
    - i. Physician attestation of inadequate response, adverse reaction, or contraindication to **BOTH** of the following:



1. Lupron (leuprolide) *(if documentation of needle-phobia, Lupron trial may be bypassed)*
  2. Oriahnn (elagolix/estradiol/norethindrone)
    - ii. Requested quantity is  $\leq 1$  unit/day
3. Diagnosis of endometriosis – extended duration of therapy (off-label)
  - a. Anticipated duration of therapy
4. Diagnosis of uterine leiomyomata – extended duration of therapy (off-label)
  - a. **ONE** of the following:
    - i. Updated surgery date
    - ii. Clinical rationale why surgery is not an option (i.e., underlying medical conditions)
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. BMD scan has been performed to indicate that the member does not need to be treated for osteoporosis
  - d. Physician attestation of inadequate response, adverse reaction, or contraindication to Lupron (leuprolide) unless there is documentation of needle-phobia

#### **Oriahnn (elagolix/estradiol/norethindrone)**

**ONE** of the following:

1. Diagnosis of uterine leiomyomata
  - a. Appropriate dose and frequency
  - b. Anticipated surgery date or 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
  - d. **BOTH** of the following:
    - i. Physician attestation of inadequate response, adverse reaction, or contraindication to Lupron unless there is documentation of needle-phobia
    - ii. Requested quantity is  $\leq 2$  units/day
2. Diagnosis of uterine leiomyomata – extended duration of therapy (off-label)
  - a. **ONE** of the following:
    - i. Updated surgery date
    - ii. Clinical rationale why surgery is not an option (i.e., underlying medical conditions)

#### **Orilissa (elagolix)**

**ONE** of the following:

1. Diagnosis of endometriosis



- a. Physician documentation of inadequate response or adverse reaction to one NSAID, or contraindication to all NSAIDs
  - b. Physician documentation of inadequate response or adverse reaction to one hormonal contraceptive, or contraindication to all hormonal contraceptives
  - c. Physician documentation of inadequate response, adverse reaction, or contraindication to Lupron (leuprolide) unless there is documentation of needle-phobia
  - d. Appropriate dose and frequency
2. 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. Bone mineral density (BMD) scan has been performed to indicate that the member does not need to be treated for osteoporosis
3. 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
  - d. Physician attestation of inadequate response, adverse reaction, or contraindication to Lupron® (leuprolide) unless there is documentation of needle-phobia

#### **Orgovyx® (relugolix)**

**ALL** of the following:

- 1. Diagnosis of advanced prostate cancer
- 2. Prescriber is an oncologist/urologist
- 3. Appropriate dose and frequency
- 4. **BOTH** of the following (*trials of low cost alternatives may be bypassed if needle-phobia*):
  - a. Physician attestation of inadequate response, adverse reaction, or contraindication to Firmagon® (degarelix)
  - b. Physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** of the following:
    - i. Lupron® Depot (leuprolide)
    - ii. Supprelin LA® (histrelin)
    - iii. Trelstar® (triptorelin)

#### **Supprelin LA® (histrelin)**



**ONE** of the following:

1. Diagnosis of CPP with onset of secondary sex characteristics before age 8 years (biologic females) or 9 years (biologic males)
  - a. Prescriber is a pediatric endocrinologist or consult notes from a pediatric endocrinologist are provided
  - b. Member is currently less than 11 years of age (biologic females) or 12 years of age (biologic males)
  - 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 identity disorder, gender dysphoria, transsexualism, or therapy after gender reassignment surgery
  - a. Requested quantity is  $\leq$  1 unit/365 days (1 year)

**Synarel® (nafarelin)**

**ONE** of the following:

1. 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
2. Diagnosis of CPP with onset of secondary sex characteristics before age 8 years (biologic females) or 9 years (biologic males)
  - a. Prescriber is a pediatric endocrinologist or consult notes from a pediatric endocrinologist are provided
  - b. Member is currently less than 11 years of age (biologic females) or 12 years of age (biologic males)
  - c. Appropriate dose and frequency
3. Diagnosis of endometriosis – extended duration of therapy (off-label)
  - a. Anticipated duration of therapy
  - b. **ONE** of the following:
    - i. Physician attestation that member is being treated with add-back therapy for bone loss
    - ii. Bone mineral density (BMD) scan has been performed to indicate that the member does not need to be treated for osteoporosis
4. Synarel (nafarelin) will be used for a stimulation test to diagnosis CPP
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. BMD scan has been performed to indicate that the member does not need to be treated for osteoporosis

**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 (biologic females) or 9 years (biologic males)
  - a. Prescriber is a pediatric endocrinologist or consult notes from a pediatric endocrinologist are provided
  - b. Member is currently less than 11 years of age (biologic females) or 12 years of age (biologic males)
  - c. Appropriate dose and frequency (refer to dosing table)
  - d. **If reviewing under Pharmacy Benefit:** Physician attestation of inadequate response, adverse reaction, or contraindication to Lupron (leuprolide)
2. Triptodur (triptorelin) will be used for a stimulation test to diagnosis CPP
3. Diagnosis of **ONE** of the following (off-label): gender identity disorder, gender dysphoria, transsexualism, or therapy after gender reassignment surgery
  - a. Requested quantity is  $\leq 1$  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
- d. **If reviewing under Pharmacy Benefit:** Physician attestation of inadequate response, adverse reaction, or contraindication to Lupron® (leuprolide)

**Vantas® (histrelin)**

**ALL** of the following:

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

**Zoladex® (goserelin)**

**ONE** of the following:

1. Diagnosis of advanced breast cancer
  - a. Appropriate dose and frequency
2. Diagnosis of advanced prostate cancer
  - a. Prescriber is an oncologist/urologist
  - b. Appropriate dose and frequency
  - c. 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. 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 in breast cancer (off-label)
  - a. Member is currently being treated with **ONE** of the following:
    - i. anastrozole
    - ii. exemestane
    - iii. letrozole



- iv. tamoxifen
- 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. 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)

### **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. Lupaneta Pack, Synarel\*, Zoladex\*: 6 months
    - iii. Myfembree: 1 year
    - iv. Orilissa\*: 1 year (no dyspareunia), 6 months (dyspareunia or moderate hepatic impairment; max total duration of 6 months)
  - e. Gender identity disorder: 1 year
  - f. GnRH stimulation test for CPP diagnosis: 1 dose only
  - g. Paraphilia: 1 year
  - h. Uterine leiomyomata (fibroids)/endometrial thinning prior to endometrial ablation
    - i. Lupron and Zoladex: 1 month or until time of surgery documented
    - ii. Oriahnn and Myfembree: 6 months
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)
  - d. Endometriosis



- i. Lupron: 6 additional months with add-back therapy (max total duration of 1 year)
  - ii. Lupaneta Pack: 6 additional months with add-back therapy
  - iii. Myfembree: 1 year (max total duration of 24 months)
  - iv. Orilissa: 1 year for dyspareunia only (max total duration of 24 months)
- e. Gender identity disorder: 1 year
- f. Paraphilia: 1 year
- g. Uterine leiomyomata (fibroids)/endometrial thinning prior to endometrial ablation
  - i. Lupron and Zoladex: 1 additional month or until time of surgery documented
  - ii. Oriahnn and Myfembree: 6 months (Total therapy duration should not exceed 24 months)

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

## References

1. Eligard® [package insert]. Fort Collins, CO: Tolmar Therapeutics Inc.; 2019 April.
2. Fensolvi® [package insert]. Fort Collins, CO: Tolmar Therapeutics Inc.; 2022 April.
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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 NCOA 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.

