Mass General Brigham
Health Plan

GnRH Analogues
Effective 06/30/2023

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	These medications have been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical and Specialty Medications**		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Exceptions	Trelstar and Zoladex are available through the medical benefit only.		

Overview

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

‡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 ≤ 1 unit/28 days (1 month)
        ii. For the 22.5 mg syringe, requested quantity is ≤ 1 unit/84 days (3 months)
        iii. For the 30 mg syringe, requested quantity is ≤ 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 ≤ 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® (triprorelin)

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 ≤ 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 ≤ 1 unit/84 days (3 months)
iii. For the 30 mg adult kit, requested quantity is ≤ 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 ≤ 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 ≤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 ≤ 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 ≤ 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 ≤ 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. anastrazole
        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.
3. Firmagon®[package insert]. Parsippany, NJ: Ferring Pharmaceuticals Inc.; 2020 February.
4. Lupaneta®Pack [package insert]. North Chicago, IL: Abbvie, Inc.; 2013 October.
5. Lupron® Depot 1 month [package insert]. North Chicago, IL: Abbvie, Inc.; 2022 July.
6. Lupron® Depot 3 month [package insert]. North Chicago, IL: Abbvie, Inc.; 2020 March.
7. Lupron® Depot Ped [package insert]. North Chicago, IL: Abbvie, Inc.; 2022 April.
8. Lupron® Depot [package insert]. North Chicago, IL: Abbvie, Inc.; 2022 April.
9. Leuprolide acetate injection [package insert]. Princeton, NJ: Sandoz Inc.; 2021 June.
10. Myfembree® [package insert]. Mississauga, ON: Pantheon, Inc.; 2022 August
11. Oriahnn® [package insert]. North Chicago, IL: Abbvie, Inc.; 2021 August.
12. Orgovyx® [package insert]. Brisbane, CA: Myovant Sciences, Inc.; 2020 December.
13. Orilissa® [package insert]. North Chicago, IL: Abbvie, Inc.; 2021 February.
14. Supprelin® LA [package insert]. Malvern, PA: Endo Pharmaceuticals, Inc.; 2022 April.
15. Synarel® [package insert]. New York, NY: Pfizer Inc.; 2022 April.
16. Trelstar® [package insert]. Ewing, NJ: Verity Pharmaceuticals, Inc.; 2021 December.
17. Triptodur® [package insert]. Atlanta, GA: Arbor Pharmaceuticals, LLC; 2022 April.
18. Zoladex® 10.8 mg [package insert]. Deerfield, IL: Tersera therapeutics, LLC; 2020 December.
19. Zoladex 3.6 mg [package insert]. Deerfield, IL: Tersera therapeutics, LLC; 2020 December.
20. Camcevi® [package insert]. Durham, NC: Accord Biopharma Inc.; 2021 May.
21. Welt CK. Physiology of gonadotropin-releasing hormone. In: Post TW (Ed). UptoDate [database on the Internet]. Waltham (MA): UptoDate; 2022 [cited 2022 August 9]. Available from: https://www.uptodate.com/contents/physiology-of-gonadotropin-releasing-hormone
22. Aragon-Ching J, Williams K. Impact of androgen-deprivation therapy on the immune system: implications for combination therapy of prostate cancer. Frontiers in Bioscience. 2007 Sept 1; 4957-71.
23. Martin TJ, Gaddy D. Bone loss goes beyond estrogen. Nature Medicine 2006 (12); 612-13. Available from: http://www.nature.com/nm/journal/v12/n6/pdf/nm0606-612.pdf
24. Hornstein M, Gibbons W. Gonadotropin releasing hormone agonists for long term treatment of endometriosis. In: Basow DS (Ed). UptoDate [database on the Internet]. Waltham (MA): UptoDate; 2017 [cited 2017 Nov 27]. Available from: http://www.utdol.com/utd/index.do.
25. Lee RJ, Smith MR. Initial systemic therapy for advanced, recurrent, and metastatic noncastrate (castration-sensitive) prostate cancer. In: Post TW (Ed.). UptoDate [database on the Internet]. Waltham (MA): UptoDate; 2022 [cited 2022 August 9]. Available from: https://www.uptodate.com/contents/initial-systemic-therapy-for-advanced-recurrent-and-metastatic-noncastrate-castration-sensitive-prostate-cancer

26. Harrington J, Palmert MR. Treatment of precocious puberty. In: Post TW (Ed.). UptoDate [database on the Internet]. Waltham (MA): UptoDate; 2022 [cited 2022 Aug 18]. Available from: https://www.uptodate.com/contents/treatment-of-precocious-puberty
27. Schenken RS. Endometriosis: treatment of pelvic pain. In: Post TW (Ed.). UptoDate [database on the Internet]. Waltham (MA): UptoDate; 2022 [cited 2022 Aug 18]. Available from: https://www.uptodate.com/contents/endometriosis-treatment-of-pelvic-pain
28. Garcia FD, Thibaut F. Current Concepts in the Pharmacotherapy of Paraphilias. Drugs. 2011; 71 (6):771-90.
29. Saernger P. Definition, etiology, and evaluation of precocious puberty. In: Basow DS (Ed). UptoDate [database on the Internet]. Waltham (MA): UptoDate; 2017 [cited 2017 Nov 27]. Available from: http://www.utdol.com/utd/index.do.
30. Carel JC, Leger J. Precocious puberty. N Engl J Med. 2008.358:2366-77.
31. Carel JC, Eugster EA, Rogol A, Ghizzoni L, Palmert MR. Consensus statement on the use of gonadotropin-releasing hormone analogs in children. Pediatrics. 2009 Apr;123(4):e752-62.
32. American Medical Association. Removing financial barriers to care for transgender patients. Policy H-185.950
33. [cited 20
34. Hembree WC, Cohen-Kettenis P, Delemarre-van de Waal HA, Gooren LJ, Meyer WJ, Spack NP, Tangpricha V, et al. Endocrine treatment of transsexual persons: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab 2009; 94:3132-3154.
35. Gooren LJ. Care of transsexual persons. N Engl J Med. 2011 Mar 31;364(13): 1251-1257.
36. American Psychological Association. Position statement on access to care for transgender and gender variant individuals [position statement on the internet]. 2012 [cited 2017 Nov 27]. Available from: http://www.psychiatry.org/advocacy—newsroom/positions-statements.
37. Olson-Kennedy J, Forcier M. Management of transgender and gender diverse children and adolescents. In: Post TW (Ed.). UptoDate [database on the Internet]. Waltham (MA): UptoDate; 2022 [cited 2022 Aug 26]. Available from: https://www.uptodate.com/contents/management-of-transgender-and-gender-diverse-children-and-adolescents.
38. NCCN Practice Guidelines in Oncology. Breast cancer [guideline on the Internet]. Version 4.2022. 2022 June 21 [cited 2022 Aug 9]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf
39. Masuda N, Iwata H, Anan K, Takeuchi T, Kohno N, Takei H et al. Monthly versus 3-monthly goserelin acetate treatment in pre-menopausal patients with estrogen receptor-positive early breast cancer. Breast Cancer Res Treat. 2011 Apr;126(2):443-51.
40. Aydiner A, Kilic L, Yildiz I, Keskin S, Sen F, Kucucuk S et al. Two different formulations with equivalent effect? Comparison of serum estradiol suppression with monthly goserelin and trimonthly leuprolide in breast cancer patients. Med Oncol. 2013 Mar;30(1):354.
41. Kauntiz AM. Abnormal uterine bleeding: Management in premenopausal patients. In: Basow DS (Ed). UptoDate [database on the Internet]. Waltham (MA): UptoDate; 2020 [cited 2020 Aug 19]. Available from: http://www.utdol.com/utd/index.do.
42. American College of Obstetricians and Gynecologists. ACOG committee opinion no. 557: Management of acute abnormal uterine bleeding in nonpregnant reproductive-aged women. Obstet Gynecol. 2013;121(4):891-896.
43. Crinò A, Di Giorgio G et al. Central precocious puberty and growth hormone deficiency in a boy with Prader-Willi syndrome. Eur J Pediatr. 2008 Dec;167(12):1455-8. Epub 2008 Feb 27.
44. Stewart EA. Uterine fibroids (leiomyomas): treatment overview. In: Post TW (Ed.). UptoDate [database on the Internet]. Waltham (MA): UptoDate; 2022 [cited 2022 Aug 18]. Available from: https://www.uptodate.com/contents/uterine-fibroids-leiomyomas-treatment-overview

45. American College of Obstetricians and Gynecologists' Committee on Practice Bulletins–Gynecology. Management of Symptomatic Uterine Leiomyomas: ACOG Practice Bulletin, Number 228. Obstet Gynecol. 2021 Jun 1;137(6):e100-e115. doi: 10.1097/AOG.0000000000004401. PMID: 34011888.
46. Thompson IM. Flare Associated with LHRH-Agonist Therapy. Rev Urol. 2001;3 Suppl 3(Suppl 3):S10-4. PMID: 16986003; PMCID: PMC1476081.
47. Eastham JA, Auffenberg GB, Barocas DA, Chou R, Crispino T, Davis JW, Eggener S, Horwitz EM, Kane CJ, Kirkby E, Lin DW, McBride SM, Morgans AK, Pierorazio PM, Rodrigues G, Wong WW, Boorjian SA. Clinically Localized Prostate Cancer: AUA/ASTRO Guideline, Part I: Introduction, Risk Assessment, Staging, and Risk-Based Management. J Urol. 2022 Jul;208(1):10-18. doi: 10.1097/JU.0000000000002757. Epub 2022 May 10. PMID: 35536144.
48. Virgo KS, Rumble RB, de Wit R, Mendelson DS, Smith TJ, Taplin ME, Wade JL 3rd, Bennett CL, Scher HI, Nguyen PL, Gleave M, Morgan SC, Loblaw A, Sachdev S, Graham DL, Vapiwala N, Sion AM, Simons VH, Talcott J. Initial Management of Noncastrate Advanced, Recurrent, or Metastatic Prostate Cancer: ASCO Guideline Update. J Clin Oncol. 2021 Apr 10;39(11):1274-1305. doi: 10.1200/JCO.20.03256. Epub 2021 Jan 26. PMID: 33497248.
49. Choi E, Buie J, Camacho J, Sharma P, de Riese WTW. Evolution of Androgen Deprivation Therapy (ADT) and Its New Emerging Modalities in Prostate Cancer: An Update for Practicing Urologists, Clinicians and Medical Providers. Res Rep Urol. 2022 Mar 30;14:87-108. doi: 10.2147/RRU.S303215. PMID: 35386270; PMCID: PMC8977476.
    Foresee Pharmaceuticals Co, Ltd. Safety, Efficacy, and Pharmacokinetic Behavior of Leuprolide Mesylate in Subjects With Advanced Prostate Carcinoma. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000- [cited 2022 Aug 24]. Available from: https://clinicaltrials.gov/ct2/show/NCT02234115 NLM Identifier: NCT02234115.
50. Leuprolide Injection Emulsion Now Available in the US for the Treatment of Advanced Prostate Cancer [press release on the Internet]. Targeted Oncology: 2022 April 6 [cited 2022 Aug 24]. Available from: 12 Dec 17]. Available from: www.tgender.net/taw/ama_resolutions.pdf.
51. https://www.targetedonc.com/view/leuprolide-injection-emulsion-now-available-in-the-us-for-the-treatment-of-advanced-prostate-cancer
52. Lexicomp Online, Lexi-Drugs Online. Waltham, MA: UpToDate, Inc.; August 4, 2022. https://online.lexi.com. Accessed August 24, 2022.
53. AbbVie: A Clinical Study to Evaluate the Safety and Efficacy of Elagolix in Participants With Moderate to Severe Endometriosis-Associated Pain. In: ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000-[cited 2022 Sept 1]. Available from https://clinicaltrials.gov/ct2/show/NCT03213457 NLM Identifier: NCT03213457.
54. Shumer DE, Nokoff NJ, Spack NP. Advances in the Care of Transgender Children and Adolescents. Adv Pediatr. 2016;63(1):79-102.
55. Maybin JA, Critchley HO. Medical management of heavy menstrual bleeding. Womens Health (Lond). 2016;12(1):27-34.
56. Myovant Sciences Announces FDA Approval of ORGOVYX™ (relugolix), the First and Only Oral Gonadotropin-Releasing Hormone (GnRH) Receptor Antagonist for Advanced Prostate Cancer [press release on the internet]. Pipeline Review; 2020 Dec 19 [cited 2021 May 7]. Available from: https://pipelinereview.com/index.php/2020121976955/Small-Molecules/Myovant-Sciences-Announces-FDA-Approval-of-ORGOVYX-relugolix-the-First-and-Only-Oral-Gonadotropin-Releasing-Hormone-GnRH-Receptor-Antagonist-for-Advanced-Prostate-Cancer.html.
57. Shore ND, Saad F, Cookson MS, George DJ, Saltzstein DR, Tutrone R, et al. Oral Relugolix for Androgen-Deprivation Therapy in Advanced Prostate Cancer. N Engl J Med. 2020 Jun 4;382(23):2187-2196. doi: 10.1056/NEJMoa2004325. Epub 2020 May 29.

58. Herzog AG. Reproductive endocrine considerations and hormonal therapy for women with epilepsy. Epilepsia. 1991;32 Suppl 6:S27-33.
59. Herzog AG. Catamenial epilepsy: definition, prevalence pathophysiology and treatment. Seizure. 2008 Mar;17(2):151-9.
60. Bauer J, Wildt L, Flugel D, Stefan H. The effect of a synthetic GnRH analogue on catamenial epilepsy: a study in ten patients. J Neurol 1992;239:284-6.

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.