Updated: 02/2018
DMMA Approved: 04/2018

Request for Prior Authorization for Lupron®, Lupron Depot® (leuprolide acetate)
Website Form – www.highmarkhealthoptions.com
Submit request via: Fax - 1-855-476-4158

All requests for Lupron (leuprolide acetate) require prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

*** Note: please reference the Highmark Health Options Gender Transition Services (MP-033-MD-DE) policy for all gender dysphoria requests. Diagnosis specific form below.**

Lupron®, Lupron Depot® (leuprolide acetate) Prior Authorization Criteria:
For all requests for Interleukin-5 Inhibitors all of the following criteria must be met:

- The requested dose and frequency should be appropriate based on treatment guidelines and within FDA approved or compendia supported dosing recommendations

Coverage may be provided with a diagnosis of advanced prostate cancer and the following criteria is met:

- The member is receiving palliative treatment for advanced prostatic cancer
- **Intial Duration of Approval:** 12 months
- **Reauthorization Criteria**
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of endometriosis and the following criteria is met:

- The member is 18 years of age or older
- The diagnosis has been confirmed by laprascopy OR
- The diagnosis has NOT been confirmed by laprascopy but:
    - An evaluation to exclude other causes of pelvic pain, such as irritable bowel syndrome (IBS), interstitial cystitis, fibromyalgia and musculoskeletal disorders (e.g. trigger point pain and pelvic floor dysfunction) should be pursued prior to therapy for endometriosis
    - Abnormalities of the urinary, gastrointestinal, neurologic and musculoskeletal systems as well as manifestations of psychological or psychiatric disorders have been ruled out as sources of pelvic pain
- The member has tried and failed or had an inadequate response to conventional treatment (e.g. oral contraceptives, NSAIDs)
- Add back therapy with norethindrone acetate 5mg while on Lupron to help prevent bone density loss and/or hot flash side effects will be recommended
- **Initial Duration of Approval:** 6 months
- **Reauthorization Criteria**
    - Documentation of the reason for retreatment when a second course of treatment is requested
    - When criteria is met, coverage will be approved for 6 months (one additional treatment course; maximum of 2 courses total)

- **Reauthorization Duration of Approval**: 6 months

Coverage may be provided with a diagnosis of Uterine leiomyomata (fibroids) resistant to conventional treatment and the following criteria is met:

- The female member is 18 years of age or older
- The member has failed a one month trial of iron therapy if presence of anemia
- Preoperative use to shrink fibroid(s) to allow a less invasive surgical approach other than abdominal hysterectomy
- **Initial Duration of Approval:** 3 months (one treatment course)
- **Reauthorization Criteria**
    - If a second course of treatment is requested, documentation of the reason for delay in surgery is required
- **Reauthorization Duration of Approval:** 3 months (one additional treatment course; maximum of 2 courses total)

Coverage may be provided with a diagnosis of Central Precocious Puberty (CPP) and the following criteria is met:

- Prior to initiation of treatment, a clinical diagnosis of CPP should be confirmed by: baseline LH and FSH measurements in the pubertal range, a pubertal response to a GnRH/Lupron stimulation test performed by a pediatric endocrinologist, and advanced bone age (defined as >/= 2 standard deviations above the gender/age related mean)
- Baseline evaluation including height, weight, sex steroid levels, and adrenal steroid level
- Neuro-imaging (CT or MRI) of the brain and pituitary/hypothalamic area to rule out CNS lesions
- If a male child, beta human chorionic gonadotropin level to rule out a chorionic gonadotropin secreting tumor
- Documentation of the age of onset of secondary sexual characteristics occurred (< 8 years of age in a female child or < 9 years of age in a male child)
- Documentation of current age (< 11 years of age for female, < 12 years of age for male)
- **Initial Duration of Approval:** 12 months
- **Reauthorization Criteira**
    - Documentation the member has had a physical exam in the prescriber's office within the past year
    - Documentation of current age (< 11 years of age for female, < 12 years of age for male), evaluation of pubertal development and bone age
- **Reauthorization Duration of Approval:** 12 months

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LUPRON, LUPRON DEPOT, LUPRON DEPOT-PED (leuprolide acetate)
*****Advanced Prostate Cancer, Endometriosis, Uterine Leiomyomata (Fibroids), Central Precocious Puberty (CPP)*****
PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Health Options Pharmacy Services. **FAX:** (855) 476-4158
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (844) 325-6253 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Health Options ID:	Member weight: _____pounds or _____kg

REQUESTED DRUG INFORMATION

Medication:	Strength:
Frequency:	Duration:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:

Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? ☐ Yes ☐ No

Billing Information

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis:

☐ **Advanced Prostate Cancer**

- Is the member receiving palliative treatment for advanced prostatic cancer? ☐ Yes ☐ No

☐ **Endometriosis**

- Please select all that apply to the member:
  ☐ Confirmed by laparoscopy
  ☐ Must complete an evaluation to exclude other causes of pelvic pain, such as irritable bowel syndrome (IBS), interstitial cystitis, fibromyalgia, and musculoskeletal disorders (e.g. trigger point pain and pelvic floor dysfunction) and abnormalities of the urinary, gastrointestinal, neurologic and musculoskeletal systems as well as manifestations of psychological or psychiatric disorders have been ruled out as a source of pain
- Has the member tried and failed or had an intolerance to conventional treatment? ☐ Yes ☐ No
  Please documents agents tried and failed
- Has add back therapy with norethindrone acetate 5mg while on Lupron been recommended to help prevent bone density loss and/or hot flash side effects? ☐ Yes ☐ No

☐ **Uterine Leiomyomata (fibroids)**

- Is the medication being used preoperatively to shrink fibroid(s) to allow a less invasive surgical approach?
  ☐ Yes ☐ No
- Does the member have anemia? ☐ Yes ☐ No
  - If yes, has a one month trial of iron therapy been tried? ☐ Yes ☐ No

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*****Advanced Prostate Cancer, Endometriosis, Uterine Leiomyomata (Fibroids), Central Precocious Puberty (CPP)*****
PRIOR AUTHORIZATION FORM (CONTINUED) – PAGE 2 OF 2

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Health Options Pharmacy Services. **FAX:** (855) 476-4158
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MEMBER INFORMATION

Member Name:	DOB:
Health Options ID:	Member weight: _____pounds or _____kg

MEDICAL HISTORY (Complete for ALL requests) - continued

☐ **Central Precocious Puberty (CPP)**

- Is the baseline LH and FSH in pubertal range? ☐ Yes ☐ No
- Was a pubertal response to a GnRH/Lupron stimulation test performed by a pediatric endocrinologist?
  ☐ Yes ☐ No
- Is the member's bone age considered advanced (≥2 standard deviations above the gender/age related mean)?
  ☐ Yes ☐ No
- Has neuro-imaging (CT or MRI) of the brain and pituitary/hypothalamic area been conducted to rule out CNS lesions?
  ☐ Yes ☐ No
- If a male, has the beta human chorionic gonadotropin level to rule out a chorionic gonadotropin secreting tumor?
  ☐ Yes ☐ No
- At what age did the onset of secondary sexual characteristics occur?:_____
- Baseline Height: _____ Baseline Weight: _____
- Baseline Sex Steroid Level: _____ Baseline Adrenal Steroid Level: _____

☐ **Other: _____ ICD-10 Code: _____**

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

☐ **Advanced Prostate Cancer**
Has the member experienced a clinical benefit from Lupron? ☐ Yes ☐ No

☐ **Endometriosis**
Please provide rationale for re-treatment: _____

☐ **Uterine Leiomyomata (fibroids)**
Please provide rationale for delay in surgery: _____

☐ **Central Precocious Puberty (CPP)**
Date of last physical exam with evaluation of pubertal development: _____
Please attach documentation of evaluation.
Current Bone age: _____ Date of collection:_____

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date

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LUPRON, LUPRON DEPOT, LUPRON DEPOT-PED (leuprolide acetate)
*****Gender Dysphoria*****
PRIOR AUTHORIZATION FORM

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PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Health Options ID:	Member weight: _____pounds or _____kg

REQUESTED DRUG INFORMATION

Medication:	Strength:
Frequency:	Duration:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:

Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? ☐ Yes ☐ No

Billing Information

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis:

☐ **Gender Dysphoria**

- Has the member been through a thorough evaluation by a qualified mental health professional followed by a period of psychotherapy of a duration specified by a qualified mental health professional (minimum of three months, though longer periods may be recommended. Psychotherapy may run concurrently)? ☐ Yes ☐ No
- Has the member had a documented real-life experience (living as the other gender) of at least three months prior to the administration of hormones? ☐ Yes ☐ No
- Has the member provided informed consent for medical, psychological, and socio-cultural factors? ☐ Yes ☐ No

Please select all that apply to the member:

ADULTS AND ADOLESCENTS	CHILDREN
☐A marked incongruence, lasting at least 6 months in duration, between one's experienced/expressed gender and primary and/or secondary sex characteristics (or in young adolescents, the anticipated secondary sex characteristics) ☐A strong desire, lasting at least 6 months in duration, to be rid of one's primary and/or secondary sex characteristics because of marked incongruence with one's experienced/expressed gender (or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics)	☐A strong desire, lasting at least 6 months in duration, to be of the other gender or an insistence that one is the other gender (or some alternative gender different from one's assigned gender) ☐In boys (assigned gender), a strong preference for cross-dressing or simulating female attire; or in girls (assigned gender), a strong preference for wearing only typical masculine clothing and a strong resistance to the wearing of typical feminine clothing

*Please continue to next page.**

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*****Gender Dysphoria*****
PRIOR AUTHORIZATION FORM (CONTINUED) – PAGE 2 OF 2

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MEMBER INFORMATION

Member Name:	DOB:
Health Options ID:	Member weight: _____pounds or _____kg

MEDICAL HISTORY (Complete for ALL requests) - continued

☐ **Gender Dysphoria – continued**

Please select all that apply to the member:

ADULTS AND ADOLESCENTS	CHILDREN
☐A strong desire, lasting at least 6 months in duration, for the primary and/or secondary sex characteristics of the other gender ☐A strong desire, lasting at least 6 months in duration, to be of the other gender (or some alternative gender different from one's assigned gender) ☐A strong desire, lasting at least 6 months in duration, to be treated as the other gender (or some alternative gender different from one's assigned gender) ☐A strong conviction, lasting at least 6 months in duration, that one has the typical feelings and reactions to the other gender (or some alternative gender different from one's assigned gender)	☐A strong preference for cross-gender roles in make-believe play or fantasy play ☐A strong preference for the toys, games, or activities stereotypically used or engaged in by the other gender ☐A strong preference for playmates of the other gender ☐In boys (assigned gender), a strong rejection of typically masculine toys, games and activities, and a strong avoidance of rough and tumble play; or in girls (assigned gender), a strong rejection of typically feminine toys, games, and activities ☐A strong dislike of ones' sexual anatomy ☐A strong desire for the primary and/or secondary sex characteristics that match one's experienced gender

☐ **Other: _____ ICD-10 Code: _____**

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

Diagnosis:

☐ **Gender Dysphoria**

- Has the member experienced stability or improvement in gender dysphoria? ☐ Yes ☐ No
- *Please attach documentation of stability or improvement.*

☐ **Other: _____ ICD-10 Code: _____**

- Has the member experienced a significant improvement with treatment? ☐ Yes ☐ No
- Please describe: _____

_____

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date