JOHNS HOPKINS MEDICINE / JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS018
		Effective Date	01/01/2006
		Review Date	02/16/2023
	Subject **Lupron, Leuprolide Acetate subcutaneous: Self-administered leuprolide therapy**	*Revision Date*	11/08/2019
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This document applies to the following Participating Organizations:

Priority Partners

Keywords: leuprolide, Lupron subcutaneous

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I. POLICY

A. Self-administered Lupron and generic leuprolide acetate subcutaneous injection will require prior authorization to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.
   1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
   2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. **Leuprolide acetate subcutaneous** may be approved for patients who meet the following:
   1. Advanced prostate cancer
      a. Patient has a documented diagnosis of advanced prostate cancer AND one of the following:
         i. Patient has inoperable prostate tumor
         ii. Patient refuses to undergo orchiectomy
      b. Documentation has been provided showing leuprolide is being used as palliative treatment
   2. Precocious puberty
      a. Documentation has been provided showing a diagnosis of true (central) precocious puberty (defined as sexual maturation less than age 8 in girls and sexual maturation less than age 10 in boys) with support that tumors have been ruled out by laboratory tests, CT, MRI, or ultrasound.
   3. Hormone suppression of puberty
      a. Documentation has been provided showing the following:
         i. Patient has Tanner stage 2 or above development
         ii. Diagnosis of gender dysphoria through medical evaluation by a health professional in accordance with MDH guidance, and other applicable JHHC policies

B. **Leuprolide therapy for behavioral disorders**: Leuprolide acetate will be carved out for coverage consideration under fee-for-service when it is used for the treatment of adult males with certain diagnosed behavioral disorders. These PA requests will need to be submitted to the Maryland Department of Health for Priority Partners members.

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval for hormone suppression of puberty will be for 12 months.
   i. Approval for continuation of therapy can be extended in 12-month intervals with clinical documentation showing beneficial patient response to treatment
B. Initial approval for other diagnoses listed above, will be restricted to 6 months of therapy
   i. Approval for continuation of therapy can be extended for six month intervals for these diagnoses with clinical documentation showing continued beneficial patient response to treatment

IV. EXCLUSIONS

A. Lupron is not approved for the following:
   1. Polycystic ovarian disease
   2. Hypermenorrhea
   3. Pre-menstrual syndrome
   4. Endometrial cancer
   5. Paraphilia/hypersexuality
   6. Infertility
   7. Any indications that are not FDA-approved, or guideline-supported
B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. RECOMMENDED DOSAGE

All FDA approved dosage(s) and dosing interval(s) for the FDA approved indication(s).

VI. REFERENCES

1. Lupron [Prescribing Information]. North Chicago, IL: AbbVie, Inc.; December 2018
2. Endocrine Treatment of Transsexual Persons:An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab (2009) 94 (9): 3132-3154

VII. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
4/20/2016	Removed background information; Updated title with Leuprolide Acetate/Lupron Depot/Eligard; Clarified exclusions with specific guidance regarding Eligard per PI; Removed process of initiation of request
3/17/2017	Addition of criteria for hormone suppression therapy for patients diagnosed with gender dysphoria per DHMH guidance and applicable JHHC policies

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7/27/2017	Updated Exclusion section regarding physician samples
5/18/2018	Clarified the MDH carveout policy for Lupron
07/01/2018	Removed EHP Line of Business
09/18/2018	Clarified the coverage criteria for leuprolide and brand name products; Added additional product reference
06/05/2019	Converted from a MEDS policy to a MMDP policy
08/26/2019	Clarified applicable leuprolide products
11/08/2019	Reactivated MEDS018, and separated out the self-administered formulation of Leuprolide (MEDS018) from provider-administered Leuprolide (MMDP026)

Review Dates: 01/16/2008, 1/14/2009, 3/1/2014, 4/20/2016, 4/19/2017, 07/17/2019, 2/16/2023

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