	Johns Hopkins HealthCare LLC Pharmacy Public Medical Management Drug Policies	<i>Policy Number</i>	MMDP073
		<i>Effective Date</i>	06/01/2022
		<i>Review Date</i>	04/20/2022
	<i>Subject</i> Lupron Depot 1-Month 7.5 mg, 3-Month 22.5 mg, 4-Month 30 mg, and 6-Month 45 mg (Prostate Cancer, Ovarian Cancer, Gender Dysphoria & Salivary Gland Tumors)	<i>Revision Date</i>	04/20/2022
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This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Lupron Depot


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I. [POLICY](#)

- A. Lupron Depot 1-Month 7.5 mg, Lupron Depot 3-Month 22.5 mg, Lupron Depot 4-Month 30 mg, and Lupron Depot 6-Month 45 mg (leuprolide acetate for depot suspension) will require prior authorization for medical benefit coverage to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

II. [POLICY CRITERIA](#)

- A. Lupron Depot 1-Month 7.5 mg, Lupron Depot 3-Month 22.5 mg, Lupron Depot 4-Month 30 mg, or Lupron Depot 6-Month 45 mg may be approved for patients who meet the following:
1. Prostate cancer:
 - a. Documentation has been submitted showing the patient has a diagnosis of prostate cancer
 2. Gender dysphoria:
 - a. Documentation has been submitted showing one of the following:
 - I. Lupron Depot will be used for pubertal hormonal suppression in an adolescent patient meeting the following:
 - i. Patient has a diagnosis of gender dysphoria
 - ii. Patient has reached Tanner stage 2 of puberty or greater
 - II. Lupron Depot will be used for gender transition in a patient meeting the following:
 - i. Patient has a diagnosis of gender dysphoria
 - ii. Patient will receive Lupron Depot concomitantly with gender-affirming hormones
 3. Ovarian cancer
 - a. Documentation has been submitted showing the patient has been diagnosed with malignant sex cord-stromal tumors
 4. Salivary gland tumors
 - a. Documentation has been submitted showing the following:
 - I. Patient has a diagnosis of recurrent salivary gland tumors
 - II. Tumors are androgen receptor positive

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III. AUTHORIZATION PERIOD/LIMITATIONS

- A. Initial approval will be limited to 12 months of therapy
- B. Continuation of therapy will be based on indications:
 1. Salivary gland tumors and ovarian cancer:
 - a. Continuation may be provided in 12-month intervals with documentation showing the patient is continuing to tolerate the regimen and there has not been disease progression while on treatment
 2. Prostate cancer:
 - a. Continuation may be provided in 12-month intervals with documentation showing the patient is experiencing a clinical benefit from therapy (e.g., serum testosterone less than 50 ng/dL) without unacceptable toxicity
 3. Gender dysphoria:
 - a. Continuation may be provided in the same duration interval as the initial approval with evidence that the patient still meets the initial criteria noted above

IV. EXCLUSIONS

- A. Lupron Depot will not be covered for the following:
 1. Any indications or uses that are not FDA-approved, or guideline-supported

V. RECOMMENDED DOSAGE

Please refer to the FDA-approved prescribing information for indication-specific dosing details.

VI. CODES

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Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.


Medication	HCCPCS/CPT Code
Injection, leuprolide acetate (for depot suspension), 7.5 mg	J9217

VII. REFERENCES

1. Lupron Depot 7.5 mg, 22.5 mg, 30 mg, 45mg [prescribing information]. North Chicago, IL: AbbVie Inc.; March 2019
2. The NCCN Drugs & Biologics Compendium® © 2022 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed April 11, 2022.
3. Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine Treatment of Gender-Dysphoric/GenderIncongruent Persons: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2017;102(11):3869–3903.
4. Standards of care for the health of transsexual, transgender, and gender-nonconforming people, 7th version. ©2012 World Professional Association for Transgender Health. Available at <http://www.wpath.org>.

VIII. APPROVALS

Signature on file at JHHC

 JOHNS HOPKINS <small>M E D I C I N E</small> <small>JOHNS HOPKINS HEALTHCARE</small>	Johns Hopkins HealthCare LLC Pharmacy Public Medical Management Drug Policies	<i>Policy Number</i>	MMDP073
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DATE OF REVISION	SUMMARY OF CHANGE
04/20/2022	Policy creation

Review Dates: 04/20/2022

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