JOHNS HOPKINS MEDICINE / JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP046
		Effective Date	06/01/2022
		Review Date	04/20/2022
	Subject **Eligard**	*Revision Date*	04/20/2022
		Page	1 of 2

This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Eligard

Table of Contents		Page Number
I.	POLICY	1
II.	POLICY CRITERIA	1
III.	AUTHORIZATION PERIOD/LIMITATIONS	1
IV.	EXCLUSIONS	2
V.	RECOMMENDED DOSAGE	2
VI.	CODES	2
VII.	REFERENCES	2
VIII.	APPROVALS	2

I. POLICY

A. Eligard (leuprolide acetate) 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. Eligard may be approved for patients who meet the following:
   1. Prostate cancer
      a. Documentation has been submitted supporting a diagnosis of prostate cancer.
   2. Salivary gland tumor
      a. Documentation has been submitted supporting a diagnosis of recurrent salivary gland tumors that are androgen receptor positive.
   3. Hormone Suppression
      a. Patient is an adolescent
      b. Documentation has been submitted showing the following:
         I. Patient has a diagnosis of gender dysphoria
         II. Patient has reached Tanner stage 2 of puberty or greater
   4. Gender Transition
      a. Documentation has been submitted showing the following:
         I. Patient has a diagnosis of gender dysphoria
         II. Patient will be receiving concurrent treatment with gender-affirming hormones

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be limited to 12 months of therapy
B. Continuation of therapy may be approved in 12-month intervals with documentation showing a beneficial response to treatment and no evidence of unacceptable toxicity.

1. Additionally, for prostate cancer patients: evidence supporting a clinical benefit is required (e.g.serum testosterone less than 50 ng/dL)

IV. EXCLUSIONS

A. Eligard will not be covered for the following:
   1. Any indications 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
Leuprolide acetate (for depot suspension), 7.5 mg	J9217

VII. REFERENCES

1. Eligard [prescribing information]. Fort Collins, CO: Tolmar Pharmaceuticals; April 2019.
2. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed March 1, 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

DATE OF REVISION	SUMMARY OF CHANGE
04/20/2022	Policy Creation

Review Dates: 04/20/2022

Revision Dates: