JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP074
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	Subject **Lupron Depot-PED**	*Revision Date*	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-PED (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-PED may be approved for patients who meet the following
   1. Central precocious puberty (CPP):
      a. Documentation has been submitted showing the following:
         I. Patient's diagnosis of CPP has been confirmed by a pubertal response to a gonadotropin releasing hormone (GnRH) agonist test or a pubertal level of a third-generation luteinizing hormone (LH) assay
         II. An intracranial tumor evaluation has been completed with appropriate lab tests and diagnostic imaging, such as computed tomography (CT scan), magnetic resonance imaging (MRI), or ultrasound
         III. An assessment of the patient's bone age versus chronological age supports the diagnosis of CPP
         IV. Patient meets one of the following age onsets of secondary sexual characteristics:
            i. Female patients: less than 8 years of age at the onset
            ii. Male patients: less than 9 years of age at the onset
   2. Gender dysphoria:
      a. Documentation has been submitted showing one of the following:
         I. Lupron Depot-PED 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-PED 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-PED concurrently with gender-affirming hormones

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be limited to 12 months of therapy

B. Continuation of therapy will be based on indication:
   1. Central precocious puberty (CPP):
      a. Continuation may be provided in 12-month intervals with documentation showing the following:
         I. Patient has not experienced treatment failure such as clinical pubertal progression, lack of growth deceleration, and continued excessive bone age advancement
         II. Patient meets one of the following age specifications:
            i. Female patients: Patient is currently less than 12 years of age
            ii. Male patients: Patient is currently less than 13 years of age
   2. 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-PED 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

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), per 3.75 mg	J1950

VII. REFERENCES

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VIII. APPROVALS

Signature on file at JHHC

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