JOHNS HOPKINS MEDICINE / JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP072
		Effective Date	06/01/2022
		Review Date	04/20/2022
	Subject **Lupron Depot 3.75mg and Lupron Depot-3 Month 11.25mg (Endometriosis & Fibroids)**	*Revision Date*	04/20/2022
		Page	1 of 3

This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Lupron Depot

Table of Contents	Page Number

I. POLICY

A. Lupron Depot 3.75mg and Lupron Depot-3 Month 11.25mg (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 or Lupron Depot -3 Month may be approved for patients who meet the following:
  1. Endometriosis
     a. Documentation has been submitted showing the patient has a diagnosis of endometriosis
  2. Uterine leiomyomata (fibroids)
     a. Documentation has been submitted showing the patient has a diagnosis of uterine leiomyomata, and either of the following:
        I. Patient has anemia due to uterine leiomyomata
        II. Lupron Depot will be used prior to surgery for uterine leiomyomata
  3. Breast cancer
     1. Documentation has been submitted showing the patient has a diagnosis of hormone receptor-positive breast cancer
  4. Ovarian cancer
     a. Documentation has been submitted showing the following:
        I. Patient has a diagnosis of persistent disease or recurrence of epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer
        II. Lupron Depot will be used as monotherapy
  5. 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 concurrently with gender-affirming hormones

6. Preservation of ovarian function
   a. Documentation has been submitted showing the preservation of ovarian function is being requested for a patient that is premenopausal and undergoing chemotherapy
7. Prevention of recurrent menstrual related attacks in acute porphyria
   a. Documentation has been submitted showing the following:
      I. Patient has been diagnosed with acute porphyria
      II. Prescriber is, or has consulted with, a physician experienced in the management of porphyrias

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be limited to 12 months of therapy
   1. Caveats:
      a. Initial approval will be limited to 3 months for treatment of uterine leiomyomata, and preservation of ovarian function
      b. Initial approval will be limited to 6 months of therapy for endometriosis

B. Continuation of therapy will be based on indication:
   1. Endometriosis:
      a. Continuation may be provided for retreatment of endometriosis for up to 6 months (lifetime maximum of 12 months total) with documentation showing the following:
         I. Patient has had a recurrence of symptoms
         II. Patient has a bone mineral density within normal limits
   2. Uterine leiomyomata (fibroids):
      a. Continuation may be provided for up to 3 months (lifetime maximum of 6 months total) with documentation showing the following:
         I. Patient has anemia due to uterine leiomyomata
         II. Lupron Depot will be used prior to surgery for uterine leiomyomata
   3. Breast cancer 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
   4. Preservation of ovarian function, prevention of recurrent menstrual related attacks in acute porphyria, and 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

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

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

Review Dates: 04/20/2022

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