Clinical Policy: Endocrine Agents: Uterine Fibroids

Reference Number: OH.PHAR.PPA.99
Effective Date: 01.01.2021
Last Review Date: 01.22
Line of Business: Medicaid

Coding Implications
remove if no codes added
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

The following are **Endocrine Agents for treatment of Uterine Fibroids** requiring prior authorization: **leuprolide acetate (Lupron Depot 3.75 mg, 11.25 mg); elagolix and estradiol and norethindrone (Oriahnn); relugolix and estradiol and norethindrone (Myfembree).**

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
LUPRON DEPOT® 3.75 MG, 11.25 MG (leuprolide acetate) ORIAHNN® (elagolix and estradiol and norethindrone)	MYFEMBREE® (relugolix and estradiol and norethindrone)

FDA Approved Indication(s)

Endocrine Agents Lupron Depot or Oriahnn are indicated for the treatment of:

- **Uterine leiomyomas (fibroids)**

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Buckeye Health Plan® that **Lupron Depot, Oriahnn, or Myfembree are medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Uterine Leiomyomas (fibroids) (must meet all)**:**

1. Diagnosis of uterine leiomyomas (fibroids);
2. Member must meet labeled age requirements for requested medication;
3. Therapeutic failure of ≥ 90-day trial of at least one preferred oral contraceptive;
4. For Myfembree requests, documentation that the member cannot be changed to a preferred medication. Acceptable reasons include:
   - Allergies to all medications that are preferred.
   - Contraindication to or drug-to-drug interaction with medications that are preferred.
   - History of unacceptable/toxic side effects to medications that are preferred.
5. Dose does not exceed the FDA-approved maximum recommended dose for the relevant indication.

PLEASE NOTE:

- Members who have been treated with **Oriahnn or Myfembree for 24 months or more are not eligible for additional authorizations.**
- Members who have been treated with **Lupron Depot for 6 months or more are not eligible for additional authorizations.**

Approval duration: 6 months

B. Diagnoses/Indications for which coverage is NOT authorized:
Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 for Medicaid or evidence of coverage documents.

II. Dosage and Administration: varies by drug product. See package insert; clinical pharmacology or other appropriate clinical reference for FDA approved dosing and administration.

III. Product Availability:

Drug Name	Availability
Lupron Depot	Powder for injection: 3.75 mg, 11.25 mg
Oriahnn	Capsule: 300 mg/1 mg/0.5 mg and 300 mg
Myfembree	Tablet: 40 mg/1 mg/0.5 mg

IV. References. Refer to package insert.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New policy created.	11.20	N/A
Annual review. Added diagnosis requirement, age requirements, and FDA-approved maximum recommended dose requirements to initial approval criteria for uterine leiomyomas. Added Lupron Depot and Oriahnn to product availability chart.	10.21	N/A
ODM Q4 P&T update. Added Myfembree to list of non-preferred medications. Added criteria that preferred medications must be tried before non-preferred medications under "Initial Approval Criteria." Added Myfembree to product availability list.	01.22	N/A

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.