

Clinical Policy: Endocrine Agents: Endometriosis

Reference Number: OH.PHAR.PPA.98

Effective Date: 01.01.2021

Last Review Date: 11.20

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 Endometriosis** requiring prior authorization:

NO PA REQUIRED "PREFERRED"	STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	DANAZOL DEPO-SUBQ PROVERA® 104 (medroxyprogesterone acetate) LUPANETA PACK® (leuprolide acetate and norethindrone acetate) LUPRON DEPOT® 3.75 MG, 11.25 MG (leuprolide acetate) ORLISSA® (elagolix) ZOLADEX® (goserelin acetate)	SYNAREL® (nafarelin acetate)

FDA Approved Indication(s)

Endocrine Agents requiring prior authorization are indicated for the treatment of:

- **Endometriosis**

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 [Brand name(s)] [is/are] **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

1. Prescribed indication is FDA-approved or supported by standard pharmacopeias;
2. Member must meet labeled age requirements for the medication;
3. If request is for a **step therapy medication**, member meets the following :
 - a. Therapeutic failure of ≥ 30 day trial with both a preferred NSAID and a preferred oral contraceptive, unless member meets one of the following (i, ii, or iii);
 - i. Allergy to medications not requiring prior approval;
 - ii. Contraindication to or drug interaction with medications not requiring prior approval;
 - iii. History of unacceptable/toxic side effects to medications not requiring prior approval;
4. If request is **for a non-preferred medication**, member meets all of the following (a, and b):
 - a. Therapeutic failure of ≥ 30 day trial with both a preferred NSAID and a preferred oral contraceptive, unless member meets one of the following (i, ii, or iii);
 - i. Allergy to medications not requiring prior approval;
 - ii. Contraindication to or drug interaction with medications not requiring prior approval;
 - iii. History of unacceptable/toxic side effects to medications not requiring prior approval;
 - b. Therapeutic failure of ≥ 90 days of at least one preferred step therapy product, unless member meets one of the following (i, ii, or iii);
 - i. Allergy to medications not requiring prior approval;
 - ii. Contraindication to or drug interaction with medications not requiring prior approval;
 - iii. History of unacceptable/toxic side effects to medications not requiring prior approval;

Approval duration: 12 months

II. 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.

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

IV. Product Availability: See package insert; clinical pharmacology or other appropriate clinical reference for product availability

V. References. Refer to package insert.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New policy created.	11.20	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.