

## PHARMACY POLICY STATEMENT

### Marketplace

DRUG NAME	Lupaneta Pack (leuprolide acetate, norethindrone acetate)
BILLING CODE	Must use a valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home/Office
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— see “ <b>Dosage allowed</b> ” below
LIST OF DIAGNOSES CONSIDERED <b>NOT</b> MEDICALLY NECESSARY	<a href="#">Click Here</a>

Lupaneta Pack (leuprolide acetate, norethindrone acetate) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

### ENDOMETRIOSIS

For **initial** authorization:

1. Member is premenopausal and 18 years of age or older; AND
2. Member is having painful symptoms (e.g., pelvic pain, dysmenorrhea, etc.) associated with endometriosis (documentation required); AND
3. Medication must be prescribed by or in consultation with a gynecologist; AND
4. Member has tried and failed to control symptoms after trials with **both** of the following, unless not tolerated or contraindicated:
  - a) 30 days of an NSAID;
  - b) 3 months of a hormonal contraceptive; AND
5. Member does **not** have any of the following:
  - a) Pregnancy or plan to become pregnant while taking medication;
  - b) Undiagnosed abnormal uterine bleeding.
6. **Dosage allowed:** 3.75 mg (IM injection) monthly or 11.25 mg every 3 months together with norethindrone acetate 5 mg tablet taken orally once per day for up to 6 months.

***If member meets all the requirements listed above, the medication will be approved for 6 months.***

For **reauthorization**:

1. Member has recurrence of endometriosis symptoms after the first course of treatment; AND
2. Duration of treatment has not exceeded 12 months.

***If member meets all the reauthorization requirements above, the medication will be approved for an additional 6 months. Reauthorization will not be allowed after 12 months of therapy.***

**CareSource considers Lupaneta Pack (leuprolide acetate, norethindrone acetate) not medically necessary for the treatment of the diseases that are not listed in this document.**

DATE	ACTION/DESCRIPTION
10/08/2020	New policy for Lupaneta Pack created.
09/16/2021	Annual review, no changes

References:

1. Lupaneta Pack [package insert]. North Chicago, IL: AbbVie Inc.; June, 2015.
2. Schrager S, Falleroni J, Edgoose J. Evaluation and treatment of endometriosis. *Am Fam Physician*. 2013 Jan 15;87(2):107-13.
3. Hewitt GD, Gerancher KR. Dysmenorrhea and endometriosis in the adolescent. *Obstet Gynecol*. 2018 Dec;132(6):e249-e258.
4. DiVasta AD, Feldman HA, Sadler Gallagher J, et al. Hormonal Add-Back Therapy for Females Treated With Gonadotropin-Releasing Hormone Agonist for Endometriosis: A Randomized Controlled Trial. *Obstet Gynecol*. 2015;126(3):617-627.
5. Armstrong C. ACOG updates guideline on diagnosis and treatment of endometriosis. *Am Fam Physician*. 2011 Jan 1;83(1):84-85.

Effective date: 01/01/2022

Revised date: 09/16/2021