

PHARMACY POLICY STATEMENT

Georgia Medicaid

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 “ Dosage allowed ” below
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

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.

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.

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Revised date: 10/08/2020