Clinical Policy: Leuprolide Acetate and Norethindrone Acetate (Lupaneta Pack)

Reference Number: HIM.PA.SP51
Effective Date: 12.01.17
Last Review Date:
Line of Business: Health Insurance Marketplace

Revision Log

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

Description
Leuprolide acetate for depot suspension and norethindrone acetate tablets (Lupaneta Pack®) are a gonadotropin-releasing hormone (GnRH) receptor agonist and progestin respectively.

FDA Approved Indication(s)
Lupaneta Pack (3.75 mg; 11.25 mg) is indicated for initial management of the painful symptoms of endometriosis and for management of recurrence of symptoms.

Limitation(s) of use: Duration of use is limited due to concerns about adverse impact on bone mineral density. The initial treatment course of Lupaneta Pack is limited to six months. A single retreatment course of not more than six months may be administered after the initial course of treatment if symptoms recur. Use of Lupaneta Pack for longer than a total of 12 months is not recommended.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Endometriosis (must meet all):

1. Diagnosis of endometriosis;
2. Prescribed by or in consultation with a gynecologist;
3. Age ≥ 18 years;
4. Endometriosis as a cause of pain is (a or b):
   a. Surgically confirmed;
   b. Clinically suspected and member has failed a 3-month trial of one of the following agents within the last year or has a documented intolerance or contraindication to the agent (i, ii, or iii):
      i. A nonsteroidal anti-inflammatory drug;
      ii. An oral or depot contraceptive;
      iii. A progestin;
5. At the time of request, member is not pregnant;
6. Dose does not exceed leuprolide acetate depot 3.75 mg/month or 11.25 mg/3 months (either depot formulation in addition to oral norethindrone acetate 5 mg daily).

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Endometriosis (must meet all):

1. Previously received medication via Centene benefit or member has previously met initial approval criteria;
2. Patient has not received ≥ 12 months of therapy;
3. Member is responding positively to therapy (e.g., improvement in dysmenorrhea, dyspareunia, pelvic pain/induration/tenderness, or size of endometrial lesions);
7. If request is for a dose increase, new dose does not exceed leuprolide acetate depot 3.75 mg/month or 11.25 mg/3 months (either depot formulation in addition to oral norethindrone acetate 5 mg daily).

Approval duration: 6 months

Total duration of therapy should not exceed 12 months.

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to HIM.PA.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. 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 policy – HIM.PHAR.21 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

V. References

1. Lupaneta Pack 3.75 Prescribing Information. North Chicago, IL: AbbVie Inc.; June 2015. http://rxabbvie.com/pdf/lupaneta_3_75_pi.pdf. Accessed July 13 2017.
2. Lupaneta Pack 11.25 Prescribing Information. North Chicago, IL: AbbVie Inc.; June 2015. http://rxabbvie.com/pdf/lupaneta_11_25_pi.pdf. Accessed July 13 2017.
3. Committee on Practice Bulletins - Gynecology. Management of endometriosis. July 2010 (reaffirmed 2016); 116(1): 223-236.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	09.01.17	11.17

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.

 Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members

and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.