SPECIALTY GUIDELINE MANAGEMENT

LUPANETA PACK-1 Month 3.75 mg
LUPANETA PACK-3 Month 11.25 mg
(leuprolide acetate for depot suspension/norethindrone acetate)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Lupaneta Pack is indicated for initial management of the painful symptoms of endometriosis and for management of recurrence of symptoms.

Limitations 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.

All other indications are considered experimental/investigational and are not a covered benefit.

II. EXCLUSIONS

Coverage will not be provided for members with any of the following exclusions:

A. Pregnancy
B. Breastfeeding
C. Undiagnosed abnormal uterine bleeding

III. CRITERIA FOR INITIAL APPROVAL

A. Endometriosis

Authorization of up to 6 months (one treatment course) may be granted to adult members who are prescribed Lupaneta Pack for initial treatment of endometriosis.

IV. CONTINUATION OF THERAPY

A. Endometriosis

Authorization of up to 6 months (for a lifetime maximum of 12 months total) may be granted to adult members who are prescribed Lupaneta Pack for retreatment of endometriosis when both of the following criteria are met:

1. Member has had a recurrence of symptoms
2. Member has a bone mineral density within normal limits

V. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

VI. REFERENCES

1. Lupaneta Pack [package insert]. North Chicago, IL: AbbVie Inc.; June 2015.