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 Indication

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 not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Endometriosis

Authorization of up to 6 months (one treatment course) may be granted to members for initial treatment of endometriosis.

III. CONTINUATION OF THERAPY

Endometriosis

Authorization of up to 6 months (for a lifetime maximum of 12 months total) may be granted for retreatment of endometriosis when all of the following criteria are met:

- A. The member has had a recurrence of symptoms
- B. The member has a bone mineral density within normal limits

IV. REFERENCES

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

Lupaneta Pack 1994-A SGM P2021.docx

© 2021 Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

