

<b>Reference number(s)</b>
1994-A

## 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.