Reference number(s)
C11969-A

SPECIALTY GUIDELINE MANAGEMENT

North Carolina State Health Plan:
Lupron Depot 3.75mg (leuprolide acetate for depot suspension)
Lupron Depot-3 Month 11.25mg (leuprolide acetate for depot suspension)

PROGRAM RATIONALE

Client Requested: The intent of the criteria is to ensure that patients follow selection elements established by North Carolina State Health Plan's Commercial Prior Authorization Approval policy.

PRIOR AUTHORIZATION CRITERIA[1]

Coverage is provided for:

- Endometriosis
- Uterine Leiomyomata (fibroids)

FDA-APPROVED INDICATIONS[2,3]

1. Endometriosis
   - Lupron Depot 3.75mg and Lupron Depot-3 Month 11.25mg is indicated for management of endometriosis, including pain relief and reduction of endometriotic lesions. Lupron Depot with norethindrone acetate 5 mg daily is also indicated for initial management of endometriosis and for management of recurrence of symptoms. Duration of initial treatment and retreatment should be limited to six months.
2. Uterine Leiomyomata (Fibroids)
   - Lupron Depot 3.75mg and Lupron Depot-3 Month11.25mg, concomitantly with iron therapy, is indicated for the preoperative hematologic improvement of patients with anemia caused by uterine leiomyomata. The clinician may wish to consider a one-month trial period on iron alone inasmuch as some of the patients will respond to iron alone. Lupron may be added if the response to iron alone is considered inadequate. Recommended duration of therapy with Lupron Depot 3.75 mg and 11.25 mg is up to 3 months. (The 11.25 mg dosage form is indicated only for women for whom three months of hormonal suppression is deemed necessary.)

CRITERIA FOR APPROVAL

1. What is the diagnosis?
   a. Endometriosis → Go to #6
   b. Uterine Leiomyomata (fibroids) → Go to #2
   c. Gender Dysphoria→ *Deny*
   d. Other → *Deny*

Uterine fibroids

2. Has the patient received previous therapy with Lupron Depot or Lupaneta Pack?
   a. Yes → *Go to #3*
   b. No → *Go to #4*

3. How long has the patient received previous therapy with Lupron Depot and Lupaneta Pack?
   a. <3 months → *Go to #4*
   b. ≥3months to <6 months → *Go to #4*
   a. ≥6 months → *Deny*

4. Does the patient have a diagnosis of anemia? (e.g., Hct ≤30% and/or Hgb ≤10 g/dL)
   a. Yes → *Approve up to 3 months (equivalent to one treatment course; maximum 6 months of therapy)*
   b. No → *Go to #5*

5. Will Lupron Depot be used prior to surgery for uterine fibroids?
   a. Yes → *Approve up to 3 months (equivalent to one treatment course; maximum 6 months of therapy)*

b. No → *Deny*

Endometriosis

6. Has the patient received previous therapy with Lupron Depot or Lupaneta Pack?
   a. Yes → *Go to #7*
   b. No → *Approve for 6 months (equivalent to one treatment course)*

7. How long has the patient received previous therapy with Lupron Depot and Lupaneta Pack?
   a. <6 months → *Approve up to 6 months (equivalent to one treatment course) for a lifetime maximum of 12 months of therapy*
   b. ≥6 months to <12 months → *Approve up to 6 months (equivalent to one treatment course) for a lifetime maximum of 12 months of therapy*
   c. ≥12 months → *Deny*

REFERENCES

1. North Carolina State Health Plan Commercial Prior Authorization Approval Policy.
2. Lupron Depot 3.75 mg [package insert]. North Chicago, IL: AbbVie Inc.; April 2018.
3. Lupron Depot-3 Month 11.25 mg [package insert]. North Chicago, IL: AbbVie Inc.; April 2018.

DOCUMENT HISTORY

Written:	Specialty Clinical Development (ST) 06/2016
Revised:	ST 12/2016 (added gender dysphoria), TE 12/2017 (removed gender dysphoria), TE 12/2018
Reviewed:	CDPR/LCB 06/2016, ME 02/2017, ME 12/2018

The Participating Group signed below hereby accepts and adopts as its own the criteria for use with Specialty Guideline Management, as administered by CVS/Caremark.

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Signature Date

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Client Name