



## MEDICAL POLICY STATEMENT

Original Effective Date	Next Annual Review Date	Last Review / Revision Date
01/01/2014	11/10/2017	05/03/2016
Policy Name		Policy Number
Lupron DEPOT		SRx-0028
Policy Type		
<input checked="" type="checkbox"/> Medical	<input type="checkbox"/> Administrative	<input type="checkbox"/> Payment

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) apply to Medical health benefit plans administered by CSMG and its affiliates and are derived from literature based on and supported by applicable federal or state coverage mandates, clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any federal or state coverage mandate, Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

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### A. SUBJECT

Lupron DEPOT® (leuprolide acetate for depot suspension)

### B. BACKGROUND

The CareSource Medication Policies are therapy class policies that are used as a guide when determining health care coverage for our members with benefit plans covering prescription drugs. Medication Policies are written on selected prescription drugs requiring prior authorization or Step-Therapy. The Medication Policy is used as a tool to be interpreted in conjunction with the member's specific benefit plan.

The intent of the Lupron DEPOT® (leuprolide) medication (PA) Program is to encourage appropriate selection of patients for therapy according to product labeling and/or clinical guidelines and/or clinical studies, and also to encourage use of preferred agents.

### C. DEFINITIONS

N/A

### D. POLICY

- I. CareSource will approve the use of leuprolide (**Lupron DEPOT®**) and consider its use as medically necessary in the following clinical settings:
  - A. Diagnosis of advanced disease breast cancer and **ALL** of the following:
    1. Pre- **OR** Peri-menopausal women
    2. Palliation of signs and symptoms for locally advanced, recurrent, or metastatic disease
    3. Prescribed by an oncologist



- B. Diagnosis of prostate cancer and **ALL** of the following:
  - 1. Palliation of signs and symptoms of symptomatic locally advanced, recurrent, **OR** metastatic disease
  - 2. Intermediate to high risk of disease recurrence in clinically localized prostate cancer, as indicated by **1 (one) or more** of the following:
    - 2.1 Intermediate risk of recurrence:
      - a. T2a or lower, an aggressive histologic pattern (ie, Gleason score of 7)
      - b. T2a or lower, and PSA 10 to 20mg/mL (mcg/L)
      - c. T2b or T2c
    - 2.2 High risk of recurrence:
      - a. T2c or lower, and aggressive histologic pattern (ie, Gleason score of 8 to 10)
      - b. T2c or lower, and PSA greater than 20 ng/mL (mcg/L)
      - c. T3a
  - 3. Prescribed by an oncologist
- C. Diagnosis of central precocious puberty and the following:
  - 1. Boys aged 9 years or younger **OR** girls aged 8 years or younger
  - 2. Signs and symptoms associated with progression of pubertal development
  - 3. Female with **ALL** of the following:
    - 3.1 Breast development Tanner stage 2 or greater
    - 3.2 Increased uterine volume (longitudinal diameter 3.4 cm or greater) on pelvic ultrasound
    - 3.3 Menstrual bleeding or vaginal discharge
    - 3.4 No pregnancy currently
    - 3.5 No undiagnosed abnormal vaginal bleeding
  - OR**
  - Male with **ALL** of the following:
    - 3.6 Signs and symptoms as indicated by **1 (one) or more** of the following:
      - a. Acne
      - b. Erections
      - c. Nocturnal emissions
      - d. Oily skin
    - 3.7 Testicular volume 4mL or greater
  - 4. Confirmed diagnostic evaluation, including assessment of:
    - 5.1 Bone age and growth velocity
    - 5.2 Hormone levels (gonadal sex steroid levels)
    - 5.3 Hormone stimulation testing
    - 5.4 Central Nervous System imaging
  - 5. Prescribed by an endocrinologist
- D. Diagnosis of symptomatic endometriosis and **ALL** of the following:
  - 1. Age 18 and older
  - 2. Endometriosis symptoms, as indicated by **1 (one) or more** of the following:
    - 2.1 Dysmenorrhea
    - 2.2 Dyspareunia
    - 2.3 Pelvic pain
  - 3. Not currently breast feeding, pregnant, or planning to become pregnant
  - 4. Patients who have failed control of symptoms with **ALL**:
    - 4.1 NSAIDs
    - 4.2 Any contraceptives



5. No vaginal bleeding of unknown cause
6. Prescribed by an gynecologist or obstetrician
- E. Diagnosis of symptomatic uterine leiomyomas (fibroids) for the purpose of reducing size and/or associate bleeding indicated by **ALL** of the following:
  1. Age 18 or older
  2. Not currently breast feeding, pregnant, or planning to become pregnant
  3. Leiomyoma symptoms, as indicated by **1 (one) or more** of the following:
    - 3.1 Abnormal uterine bleeding
    - 3.2 Bulk-related symptoms (eg, pelvic pain or pressure, dyspareunia, urinary symptoms)
    - 3.3 Iron deficiency anemia
    - 3.4 Other causes of symptoms or bleeding ruled out (eg, by endometrial biopsy)
  4. Prescribed by an gynecologist or obstetrician
- F. Dysfunctional uterine bleeding, as indicated by **ALL** of the following:
  1. Prior planned endometrial ablation for definitive treatment
  2. No current breast-feeding
  3. No pregnancy currently or anticipated while receiving medication
  4. Other causes of symptoms or bleeding ruled out (e.g. by endometrial biopsy)
  5. Patients who have failed control of symptoms with:
    - 5.1 Oral estrogen or progesterone therapy (or combination)
  6. Prescribed by an gynecologist or obstetrician

**ALL other uses of leuprolide acetate are considered experimental/investigational and therefore, will follow CareSource's Off-Label policy.**

**NOTE:** Documented diagnosis must be confirmed by portions of the individual's medical record which will confirm the presence of disease and will need to be supplied with prior authorization request. These medical records may include, but are not limited to test reports, chart notes from provider's office or hospital admission notes.

**Refer to the product package insert for dosing, administration and safety guidelines.**

#### **CONDITIONS OF COVERAGE**

**Place of Service** Office, Home

**\*\*Must be administered under the supervision of a physician**

**NOTE:** CareSource supports administering injectable medications in various settings, as long as those services are furnished in the most appropriate and cost-effective setting that are supportive of the patient's medical condition(s) and unique needs and condition(s). The decision on the most appropriate setting for administration is based on the member's current medical condition(s) and any required monitoring or additional services that may coincide with the delivery of the specific medication.

**HCPCS** J1950 – leuprolide acetate injection (for depot suspension), per 3.75mg  
J9217 – leuprolide acetate (for depot suspension), per 7.5mg  
J9218 - Leuprolide acetate, per 1 mg

**CPT**



#### **AUTHORIZATION PERIOD**

Coverage may be approved for **up to** 12 months. Coverage may be approved for re-treatment, but requires meeting current initial diagnosis criteria only and evidence of a beneficial response.

#### **E. REVIEW/REVISION HISTORY**

Date Issued: 01/01/2014  
Date Reviewed: 01/01/2014, 09/25/2014, 11/10/2014  
Date Revised: 09/25/2014  
11/10/2014  
05/05/2015 – Placed into new template  
10/20/2015 – Add new criteria and specialist criteria  
05/03/2016 – Add Leuprolide acetate 1mg

#### **F. REFERENCES**

1. LUPRON DEPOT® [Prescribing Information]. North Chicago, IL; AbbVie, Inc.; June 2014.
2. LUPRON DEPOT-PED® [package insert]. North Chicago, IL; AbbVie, Inc.; June 2013.
3. Gonadotropin-releasing Hormone (GnRH) Agonists; Milliman ACG: A-0304 (AC) 20<sup>th</sup> edition, February 2016.

**The Medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.**

Independent Medical Review – 08/14/2014