**Trelstar® (triptorelin)**
(Intramuscular)

*Document Number: IC-0131*

**Last Review Date:** 02/06/2018  
**Date of Origin:** 11/28/2011  

I. **Length of Authorization**

- **Endometriosis/Uterine leiomyomata (fibroids):** Coverage will be provided for 6 months and medication is NOT eligible for renewal  
- **All other indications:** Coverage will be provided for 12 months and may be renewed

II. **Dosing Limits**

A. **Quantity Limit (max daily dose) [Pharmacy Benefit]:**
   - 3.75 mg injection – 1 injection every 28 days  
   - 11.25 mg injection – 1 injection every 84 days  
   - 22.5 mg injection – 1 injection every 168 days

B. **Max Units (per dose and over time) [Medical Benefit]:**
   - **Prostate Cancer** 6 units every 168 days  
   - **All Other Indications** 1 unit every 28 days

III. **Initial Approval Criteria**

Coverage is provided in the following conditions:

**Prostate cancer †**

**Central Precocious Puberty (CPP) ‡**

- Patient is less than 13 years old: **AND**
- Onset of secondary sexual characteristics earlier than age 8 for girls and 9 for boys associated with pubertal pituitary gonadotropin activation: **AND**
- Diagnosis is confirmed by a pubertal gonadal sex steroid levels and a pubertal LH response to stimulation by native GnRH: **AND**
- Bone age advanced greater than 2 standard deviations (SD) beyond chronological age; **AND**
- Tumor has been ruled out by lab tests such as diagnostic imaging of the brain (to rule out intracranial tumor), pelvic/testicular/adrenal ultrasound (to rule out steroid secreting tumors), and human chorionic gonadotropin levels (to rule out a chorionic gonadotropin secreting tumor)

**Endometriosis ‡**
- Patient older than 18; **AND**
- Documentation patient’s diagnosis has been confirmed by a workup/evaluation (versus presumptive treatment)

**Uterine leiomyomata (fibroids) ‡**
- Patient older than 18; **AND**
- Documentation patient’s diagnosis has been confirmed by a workup/evaluation (versus presumptive treatment): **AND**
- Documentation patient is receiving iron therapy

† FDA Approved Indication(s); ‡ Compendia recommended indication(s)

### IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

**Oncology Indications**
- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe implant site reactions, convulsions/seizures, development or worsening of psychiatric symptoms, etc.

**CPP**
- Patient continues to meet criteria identified in section III; **AND**
- Disease response as indicated by lack of progression or stabilization of secondary sexual characteristics, decrease in height velocity, and improvement in final height prediction; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include severe implant site reactions, convulsions/seizures, development or worsening of psychiatric symptoms, etc.

### V. Dosage/Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
</tr>
</thead>
</table>
Prostate Cancer | 3.75 mg intramuscularly (IM) once every 4 weeks, 11.25 mg IM once every 12 weeks, or 22.5 mg IM once every 24 weeks
---|---
All other indications | 3.75 mg every 4 weeks

VI. Billing Code/Availability Information

**Jcode:**
J3315– Injection, triptorelin 3.75 mg: 1 billable unit = 3.75 mg

**NDC:**
- Trelstar 3.75mg powder for injection and Mixject delivery system: 0023-5902-xx
- Trelstar 11.25mg powder for injection and Mixject delivery system: 0023-5904-xx
- Trelstar 22.5mg powder for injection and Mixject delivery system: 0023-5906-xx

VII. References

2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for triptorelin. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed January 2018.
7. Fuqua JS. Treatment and Outcomes of Precocious Puberty: An Update. The Journal of Clinical Endocrinology & Metabolism 2013 98:6, 2198-2207

Appendix 1 – Covered Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C61</td>
<td>Malignant neoplasm of prostate</td>
</tr>
<tr>
<td>D25.0</td>
<td>Submucous leiomyoma of uterus</td>
</tr>
<tr>
<td>D25.1</td>
<td>Intramural leiomyoma of uterus</td>
</tr>
<tr>
<td>D25.2</td>
<td>Subserosal leiomyoma of uterus</td>
</tr>
<tr>
<td>D25.9</td>
<td>Leiomyoma of uterus, unspecified</td>
</tr>
<tr>
<td>E30.1</td>
<td>Precocious puberty</td>
</tr>
<tr>
<td>E30.8</td>
<td>Other disorders of puberty</td>
</tr>
<tr>
<td>N80.0</td>
<td>Endometriosis of uterus</td>
</tr>
<tr>
<td>N80.1</td>
<td>Endometriosis of ovary</td>
</tr>
<tr>
<td>N80.2</td>
<td>Endometriosis of fallopian tube</td>
</tr>
<tr>
<td>N80.3</td>
<td>Endometriosis of pelvic peritoneum</td>
</tr>
<tr>
<td>N80.8</td>
<td>Other endometriosis</td>
</tr>
<tr>
<td>N80.9</td>
<td>Endometriosis, unspecified</td>
</tr>
<tr>
<td>Z85.46</td>
<td>Personal history of malignant neoplasm of prostate</td>
</tr>
</tbody>
</table>

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

| Jurisdiction(s): N | NCD/LCD Document(s): L33685 |
### Medicare Part B Administrative Contractor (MAC) Jurisdictions

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Applicable State/US Territory</th>
<th>Contractor</th>
</tr>
</thead>
<tbody>
<tr>
<td>E (1)</td>
<td>CA, HI, NV, AS, GU, CNMI</td>
<td>Noridian Healthcare Solutions, LLC</td>
</tr>
<tr>
<td>F (2 &amp; 3)</td>
<td>AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ</td>
<td>Noridian Healthcare Solutions, LLC</td>
</tr>
<tr>
<td>5</td>
<td>KS, NE, IA, MO</td>
<td>Wisconsin Physicians Service Insurance Corp (WPS)</td>
</tr>
<tr>
<td>6</td>
<td>MN, WI, IL</td>
<td>National Government Services, Inc. (NGS)</td>
</tr>
<tr>
<td>H (4 &amp; 7)</td>
<td>LA, AR, MS, TX, OK, CO, NM</td>
<td>Novitas Solutions, Inc.</td>
</tr>
<tr>
<td>8</td>
<td>MI, IN</td>
<td>Wisconsin Physicians Service Insurance Corp (WPS)</td>
</tr>
<tr>
<td>N (9)</td>
<td>FL, PR, VI</td>
<td>First Coast Service Options, Inc.</td>
</tr>
<tr>
<td>J (10)</td>
<td>TN, GA, AL</td>
<td>Palmetto GBA, LLC</td>
</tr>
<tr>
<td>M (11)</td>
<td>NC, SC, WV, VA (excluding below)</td>
<td>Palmetto GBA, LLC</td>
</tr>
<tr>
<td>L (12)</td>
<td>DE, MD, PA, NJ, DC (includes Arlington &amp; Fairfax counties and the city of Alexandria in VA)</td>
<td>Novitas Solutions, Inc.</td>
</tr>
<tr>
<td>K (13 &amp; 14)</td>
<td>NY, CT, MA, RI, VT, ME, NH</td>
<td>National Government Services, Inc. (NGS)</td>
</tr>
<tr>
<td>15</td>
<td>KY, OH</td>
<td>CGS Administrators, LLC</td>
</tr>
</tbody>
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**Jurisdiction(s):** 6, K  
**NCD/LCD Document(s):** A52453


**Jurisdiction(s):** H, L  
**NCD/LCD Document(s):** L34822