



## Trelstar® (triptorelin) (Intramuscular)

Document Number: IC-0131

Last Review Date: 04/01/2020

Date of Origin: 11/28/2011

Dates Reviewed: 12/2011, 03/2012, 06/19/2012, 09/2012, 12/2012, 03/2013, 06/2013, 09/2013, 12/2013, 03/2014, 06/2014, 09/2014, 12/2014, 3/2015, 05/2015, 8/2015, 11/2015, 2/2016, 5/2016, 8/2016, 11/2016, 02/2017, 5/2017, 8/2017, 11/2017, 02/2018, 05/2018, 04/2019, 04/2020

### 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) [NDC Unit]:

- 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) [HCPCS Unit]:

- |                              |                        |
|------------------------------|------------------------|
| <b>Prostate Cancer</b>       | 6 units every 168 days |
| <b>All Other Indications</b> | 1 unit every 28 days   |

### III. Initial Approval Criteria

Coverage is provided in the following conditions:

#### Prostate cancer <sup>1,2</sup> †

- Patient is 18 years or older

#### Central Precocious Puberty (CPP) <sup>5,6,7,9,10,11</sup> ‡

- 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) ; **AND**
- Will not be used in combination with growth hormone

#### **Endometriosis** <sup>3,4</sup> †

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

#### **Uterine leiomyomata (fibroids)** <sup>8</sup> †

- Patient is 18 years or older; **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:

- Patient continues to meet the indication-specific relevant criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: hypersensitivity reactions, urinary tract obstruction, severe QT/QTc interval prolongation, severe hyperglycemia/diabetes, cardiovascular toxicity, metastatic vertebral lesions, spinal cord compression etc.; **AND**

#### **Prostate Cancer** <sup>1,2</sup>

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

#### **CPP** <sup>5,6,7,9,10,11</sup>

- Disease response as indicated by lack of progression or stabilization of secondary sexual characteristics, decrease in growth velocity and bone age advancement, and improvement in final height prediction

#### **Endometriosis/Uterine leiomyomata (fibroids)**

- Coverage may not be renewed.

## V. Dosage/Administration

Indication	Dose
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 intramuscularly (IM) every 4 weeks

## VI. Billing Code/Availability Information

### HCPCS code:

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

### NDC:

- Trelstar 3.75mg powder for injection with Mixject delivery system: 00023-5902-xx
- Trelstar 11.25mg powder for injection with Mixject delivery system : 00023-5904-xx
- Trelstar 22.5mg powder for injection with Mixject delivery system: 00023-5906-xx

## VII. References

1. Trelstar [package insert]. Madison, NJ; Allergan USA, Inc; December 2018. Accessed March 2020.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for triptorelin. National Comprehensive Cancer Network, 2020. 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 March 2020.
3. Bergqvist A, Bergh T, Hogström L, et al. Effects of triptorelin versus placebo on the symptoms of endometriosis. *Fertil Steril*. 1998 Apr;69(4):702-8.
4. Donnez J, Dewart PJ, Hedon B, et al. Equivalence of the 3-month and 28-day formulations of triptorelin with regard to achievement and maintenance of medical castration in women with endometriosis. *Fertil Steril*. 2004 Feb;81(2):297-304.
5. Swaenepoel C, Chaussain JL, & Roger M: Long-term results of long-acting luteinizing-hormone-releasing hormone agonist in central precocious puberty. *Horm Res* 1991; 36:126-130.
6. Oostdijk W, Hummelink R, Odink RJH, et al: Treatment of children with central precocious puberty by a slow-release gonadotropin-releasing hormone agonist. *Eur J Pediatr* 1990; 149:308-313.
7. Fuqua JS. Treatment and Outcomes of Precocious Puberty: An Update. *The Journal of Clinical Endocrinology & Metabolism* 2013 98:6, 2198-2207
8. van Leusden HAIM: Symptom-free interval after triptorelin treatment of uterine fibroids: long-term results. *Gynecol Endocrinol* 1992; 6:189-198.

9. Beccuti G, Ghizzoni L. Normal and Abnormal Puberty. Endotext. De Groot LJ, Chrousos G, Dungan K, et al., editors, South Dartmouth (MA): MDText.com, Inc.; 2000-. Accessed at: <https://www.ncbi.nlm.nih.gov/books/NBK279024/>.
10. Brito VN, Spinola-Castro AM, Kochi C, et al. Central precocious puberty: revisiting the diagnosis and therapeutic management. Arch Endocrinol Metab. 2016 Apr;60(2):163-72.
11. Carel JC, Eugster E, Rogol A, et al. Consensus statement on the use of gonadotropin-releasing hormone analogs in children. Pediatrics. 2009 Apr;123(4):e752-62. doi: 10.1542/peds.2008-1783. Epub 2009 Mar 30.
12. First Coast Service Options, Inc. Local Coverage Article: Billing and Coding: Luteinizing Hormone-Releasing Hormone (LHRH) Analogs (A57655). Centers for Medicare & Medicaid Services, Inc. Updated on 11/21/2019 with effective date 10/03/2018. Accessed March 2020.
13. National Government Services, Inc. Local Coverage Article: Billing and Coding: Luteinizing Hormone-Releasing Hormone (LHRH) Analogs (A52453). Centers for Medicare & Medicaid Services, Inc. Updated on 11/01/2019 with effective date 11/07/2019. Accessed March 2020.
14. Novitas Solutions, Inc. Local Coverage Article: Billing and Coding: Luteinizing Hormone-Releasing Hormone (LHRH) Analogs (A56776). Centers for Medicare & Medicaid Services, Inc. Updated on 11/08/2019 with effective date 11/14/2019. Accessed March 2020.
15. CGS Administrators, LLC. Local Coverage Article: Billing and Coding: Triptorelin Pamoate -J3315 (A57297). Centers for Medicare & Medicaid Services, Inc. Updated on 9/19/2019 with effective date 9/26/2019. Accessed March 2020.

## Appendix 1 – Covered Diagnosis Codes

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

## 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), Local Coverage Determinations (LCDs) and Local Coverage Articles (LCAs) 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/LCA):

<b>Jurisdiction(s):</b> N	<b>NCD/LCD Document (s):</b> A57655
<a href="https://www.cms.gov/medicare-coverage-database/search/document-id-search-results.aspx?DocID=A57655&amp;bc=gAAAAAAAAAAAA&amp;">https://www.cms.gov/medicare-coverage-database/search/document-id-search-results.aspx?DocID=A57655&amp;bc=gAAAAAAAAAAAA&amp;</a>	
<b>Jurisdiction(s):</b> 6, K	<b>NCD/LCD Document (s):</b> A52453
<a href="https://www.cms.gov/medicare-coverage-database/search/document-id-search-results.aspx?DocID=A52453&amp;bc=gAAAAAAAAAAAA%3d%3d&amp;">https://www.cms.gov/medicare-coverage-database/search/document-id-search-results.aspx?DocID=A52453&amp;bc=gAAAAAAAAAAAA%3d%3d&amp;</a>	
<b>Jurisdiction(s):</b> H	<b>NCD/LCD Document (s):</b> A56776
<a href="https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A56776&amp;bc=gAAAAAAAAAAAA">https://www.cms.gov/medicare-coverage-database/search/article-date-search.aspx?DocID=A56776&amp;bc=gAAAAAAAAAAAA</a>	
<b>Jurisdiction(s):</b> 15	<b>NCD/LCD Document (s):</b> A57297
<a href="https://www.cms.gov/medicare-coverage-database/search/document-id-search-results.aspx?DocID=A57297&amp;bc=gAAAAAAAAAAAA&amp;">https://www.cms.gov/medicare-coverage-database/search/document-id-search-results.aspx?DocID=A57297&amp;bc=gAAAAAAAAAAAA&amp;</a>	

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.

### Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC