

Trelstar® (triptorelin) (Intramuscular)

Document Number: IC-0131

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I. Length of Authorization

- Endometriosis/Uterine Leiomyomata (fibroids): Coverage will be provided for 6 months and 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]:

- Trelstar 3.75 mg injection single-dose delivery system – 1 injection every 28 days
- Trelstar 11.25 mg injection single-dose delivery system – 1 injection every 84 days
- Trelstar 22.5 mg injection single-dose delivery system – 1 injection every 168 days

B. Max Units (per dose and over time) [HCPCS Unit]:

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 †^{1,2}

- Patient is at least 18 years of age

Central Precocious Puberty (CPP) ‡^{9-12,16}

- Patient is less than 13 years of age; **AND**
- Onset of secondary sexual characteristics earlier than age 8 for females and 9 for males associated with pubertal pituitary gonadotropin activation; **AND**
- Diagnosis is confirmed by pubertal gonadal sex steroid levels and a pubertal luteinizing hormone (LH) response to stimulation by native gonadotropin-releasing hormone (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

Gender Dysphoria (formerly Gender Identity Disorder) ‡^{13,17,18}

- Patient has a diagnosis of gender dysphoria as confirmed by a qualified mental health professional (MHP)** OR the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-V) Criteria §; **AND**
- A qualified MHP** has confirmed all of the following:
 - Patient has demonstrated a long-lasting and intense pattern of gender nonconformity or gender dysphoria (whether suppressed or expressed); **AND**
 - Gender dysphoria worsened with the onset of puberty; **AND**
 - Any coexisting psychological, medical, or social problems that could interfere with treatment (e.g., that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start treatment; **AND**
 - Patient has sufficient mental capacity to give informed consent to this (reversible) treatment; **AND**
- Patient has been informed of the effects and side effects of treatment (including potential loss of fertility if the individual subsequently continues with sex hormone treatment) and options to preserve fertility; **AND**
- Patient has given informed consent and (particularly when the adolescent has not reached the age of legal medical consent, depending on applicable legislation) the parents or other caretakers or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process; **AND**
- A pediatric endocrinologist or other clinician experienced in pubertal assessment has confirmed all of the following:
 - Agreement in the indication for treatment; **AND**
 - Puberty has started in the adolescent (e.g., Tanner stage \geq G2/B2); **AND**
 - There are no medical contraindications to treatment

**** Definition of a qualified mental health professional¹⁸**

- Are licensed by their statutory body and hold, at a minimum, a master's degree or equivalent training in a clinical field relevant to this role and granted by a nationally accredited statutory institution; **AND**
- For countries requiring a diagnosis for access to care, the health care professional should be competent using the latest edition of the World Health Organization's International Classification of Diseases (ICD) for diagnosis. In countries that have not implemented the latest ICD, other taxonomies may be used; efforts should be undertaken to utilize the latest ICD as soon as practicable; **AND**
- Are able to identify co-existing mental health or other psychosocial concerns and distinguish these from gender dysphoria, incongruence, and diversity; **AND**
- Are able to assess capacity to consent for treatment; **AND**
- Have experience or be qualified to assess clinical aspects of gender dysphoria, incongruence, and diversity; **AND**
- Undergo continuing education in health care relating to gender dysphoria, incongruence, and diversity

§ DSM-V Criteria for Gender Dysphoria ^{13,17}

- A marked incongruence between one's experienced/expressed gender and natal gender of at least 6mo in duration, as manifested by at least TWO of the following:
 - A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics (or in young adolescents, the anticipated secondary sex characteristics)
 - A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender (or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics)
 - A strong desire for the primary and/or secondary sex characteristics of the other gender
 - A strong desire to be of the other gender (or some alternative gender different from one's designated gender)
 - A strong desire to be treated as the other gender (or some alternative gender different from one's designated gender)
 - A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's designated gender); **AND**
- The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning; **AND**
- Specify one of the following:
 - The condition exists with a disorder of sex development; **OR**
 - The condition is posttransitional, in that the individual has transitioned to full-time living in the desired gender (with or without legalization of gender change) and has undergone (or is preparing to have) at least one sex-related medical procedure or treatment regimen—namely, regular sex hormone treatment or gender reassignment surgery confirming the desired gender (e.g., penectomy, vaginoplasty in natal males; mastectomy or phalloplasty in natal females).

Endometriosis ‡ ^{3,4}

- Patient is at least 18 years of age; **AND**

- Documentation patient’s diagnosis has been confirmed by a workup/evaluation (versus presumptive treatment)

Uterine Leiomyomata (fibroids) † 8

- Patient is at least 18 years of age; **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); Φ Orphan Drug

IV. Renewal Criteria 1

Coverage may 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 diseases (e.g., myocardial infarction, stroke, etc.), metastatic vertebral lesions, spinal cord compression etc.; **AND**

Prostate Cancer 1,2

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

Central Precocious Puberty (CPP) 9-12,16

- Disease response as indicated by lack of progression or stabilization of secondary sexual characteristics, decrease in height velocity, and a decrease in the ratio of bone age to chronological age (BA:CA), and improvement in final height prediction

Gender Dysphoria 13,17

- Patient has shown a beneficial response to treatment as evidenced by routine monitoring of clinical pubertal development and applicable laboratory parameters

Endometriosis/Uterine Leiomyomata (fibroids) 8

- Coverage may not be renewed.

V. Dosage/Administration

Indication	Dose
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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
Gender Dysphoria	3.75 mg intramuscularly (IM) at weeks 0, 2, 4 and every 4 weeks thereafter
All other indications	3.75 mg intramuscularly (IM) every 4 weeks

VI. Billing Code/Availability Information

HCPCS Code:

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

NDC(s):

- Trelstar 3.75mg for injection with MIXJECT single-dose delivery system: 74676-5902-xx
- Trelstar 11.25mg for injection with MIXJECT single-dose delivery system: 74676-5904-xx
- Trelstar 22.5mg for injection with MIXJECT single-dose delivery system: 74676-5906-xx

VII. References

1. Trelstar [package insert]. Ewing, NJ; Verity Pharmaceuticals, Inc; March 2023. Accessed March 2023.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for triptorelin. National Comprehensive Cancer Network, 2023. 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 2023.
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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
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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
F64.0	Transsexualism
F64.1	Dual role transvestism
F64.2	Gender identity disorder of childhood
F64.8	Other gender identity disorders
F64.9	Gender identity disorder, unspecified
N80.00	Endometriosis of the uterus, unspecified
N80.01	Superficial endometriosis of the uterus
N80.02	Deep endometriosis of the uterus
N80.03	Adenomyosis of the uterus
N80.101	Endometriosis of right ovary, unspecified depth
N80.102	Endometriosis of left ovary, unspecified depth
N80.103	Endometriosis of bilateral ovaries, unspecified depth
N80.109	Endometriosis of ovary, unspecified side, unspecified depth
N80.111	Superficial endometriosis of right ovary
N80.112	Superficial endometriosis of left ovary
N80.113	Superficial endometriosis of bilateral ovaries
N80.119	Superficial endometriosis of ovary, unspecified ovary
N80.121	Deep endometriosis of right ovary
N80.122	Deep endometriosis of left ovary
N80.123	Deep endometriosis of bilateral ovaries
N80.129	Deep endometriosis of ovary, unspecified ovary
N80.201	Endometriosis of right fallopian tube, unspecified depth
N80.202	Endometriosis of left fallopian tube, unspecified depth
N80.203	Endometriosis of bilateral fallopian tubes, unspecified depth
N80.209	Endometriosis of unspecified fallopian tube, unspecified depth
N80.211	Superficial endometriosis of right fallopian tube
N80.212	Superficial endometriosis of left fallopian tube

N80.213	Superficial endometriosis of bilateral fallopian tubes
N80.219	Superficial endometriosis of unspecified fallopian tube
N80.221	Deep endometriosis of right fallopian tube
N80.222	Deep endometriosis of left fallopian tube
N80.223	Deep endometriosis of bilateral fallopian tubes
N80.229	Deep endometriosis of unspecified fallopian tube
N80.30	Endometriosis of pelvic peritoneum, unspecified
N80.311	Superficial endometriosis of the anterior cul-de-sac
N80.312	Deep endometriosis of the anterior cul-de-sac
N80.319	Endometriosis of the anterior cul-de-sac, unspecified depth
N80.321	Superficial endometriosis of the posterior cul-de-sac
N80.322	Deep endometriosis of the posterior cul-de-sac
N80.329	Endometriosis of the posterior cul-de-sac, unspecified depth
N80.331	Superficial endometriosis of the right pelvic sidewall
N80.332	Superficial endometriosis of the left pelvic sidewall
N80.333	Superficial endometriosis of bilateral pelvic sidewall
N80.339	Superficial endometriosis of pelvic sidewall, unspecified side
N80.341	Deep endometriosis of the right pelvic sidewall
N80.342	Deep endometriosis of the left pelvic sidewall
N80.343	Deep endometriosis of the bilateral pelvic sidewall
N80.349	Deep endometriosis of the pelvic sidewall, unspecified side
N80.351	Endometriosis of the right pelvic sidewall, unspecified depth
N80.352	Endometriosis of the left pelvic sidewall, unspecified depth
N80.353	Endometriosis of bilateral pelvic sidewall, unspecified depth
N80.359	Endometriosis of pelvic sidewall, unspecified side, unspecified depth
N80.361	Superficial endometriosis of the right pelvic brim
N80.362	Superficial endometriosis of the left pelvic brim
N80.363	Superficial endometriosis of bilateral pelvic brim
N80.369	Superficial endometriosis of the pelvic brim, unspecified side
N80.371	Deep endometriosis of the right pelvic brim
N80.372	Deep endometriosis of the left pelvic brim
N80.373	Deep endometriosis of bilateral pelvic brim
N80.379	Deep endometriosis of the pelvic brim, unspecified side
N80.381	Endometriosis of the right pelvic brim, unspecified depth

N80.382	Endometriosis of the left pelvic brim, unspecified depth
N80.383	Endometriosis of bilateral pelvic brim, unspecified depth
N80.389	Endometriosis of the pelvic brim, unspecified side, unspecified depth
N80.3A1	Superficial endometriosis of the right uterosacral ligament
N80.3A2	Superficial endometriosis of the left uterosacral ligament
N80.3A3	Superficial endometriosis of the bilateral uterosacral ligament(s)
N80.3A9	Superficial endometriosis of the uterosacral ligament(s), unspecified side
N80.3B1	Deep endometriosis of the right uterosacral ligament
N80.3B2	Deep endometriosis of the left uterosacral ligament
N80.3B3	Deep endometriosis of bilateral uterosacral ligament(s)
N80.3B9	Deep endometriosis of the uterosacral ligament(s), unspecified side
N80.3C1	Endometriosis of the right uterosacral ligament, unspecified depth
N80.3C2	Endometriosis of the left uterosacral ligament, unspecified depth
N80.3C3	Endometriosis of bilateral uterosacral ligament(s), unspecified depth
N80.3C9	Endometriosis of the uterosacral ligament(s), unspecified side, unspecified depth
N80.391	Superficial endometriosis of the pelvic peritoneum, other specified sites
N80.392	Deep endometriosis of the pelvic peritoneum, other specified sites
N80.399	Endometriosis of the pelvic peritoneum, other specified sites, unspecified depth
N80.40	Endometriosis of rectovaginal septum, unspecified involvement of vagina
N80.41	Endometriosis of rectovaginal septum without involvement of vagina
N80.42	Endometriosis of rectovaginal septum with involvement of vagina
N80.50	Endometriosis of intestine, unspecified
N80.511	Superficial endometriosis of the rectum
N80.512	Deep endometriosis of the rectum
N80.519	Endometriosis of the rectum, unspecified depth
N80.521	Superficial endometriosis of the sigmoid colon
N80.522	Deep endometriosis of the sigmoid colon
N80.529	Endometriosis of the sigmoid colon, unspecified depth
N80.531	Superficial endometriosis of the cecum
N80.532	Deep endometriosis of the cecum
N80.539	Endometriosis of the cecum, unspecified depth
N80.541	Superficial endometriosis of the appendix
N80.542	Deep endometriosis of the appendix
N80.549	Endometriosis of the appendix, unspecified depth

N80.551	Superficial endometriosis of other parts of the colon
N80.552	Deep endometriosis of other parts of the colon
N80.559	Endometriosis of other parts of the colon, unspecified depth
N80.561	Superficial endometriosis of the small intestine
N80.562	Deep endometriosis of the small intestine
N80.569	Endometriosis of the small intestine, unspecified depth
N80.A0	Endometriosis in cutaneous scar
N80.A1	Endometriosis of bladder, unspecified depth
N80.A2	Superficial endometriosis of bladder
N80.A41	Deep endometriosis of bladder
N80.A42	Superficial endometriosis of right ureter
N80.A43	Superficial endometriosis of left ureter
N80.A49	Superficial endometriosis of bilateral ureters
N80.A51	Superficial endometriosis of unspecified ureter
N80.A52	Deep endometriosis of right ureter
N80.A53	Deep endometriosis of left ureter
N80.A59	Deep endometriosis of bilateral ureters
N80.A61	Deep endometriosis of unspecified ureter
N80.A62	Endometriosis of right ureter, unspecified depth
N80.A63	Endometriosis of left ureter, unspecified depth
N80.A69	Endometriosis of bilateral ureters, unspecified depth
N80.B1	Endometriosis of unspecified ureter, unspecified depth
N80.B2	Endometriosis of pleura
N80.B31	Endometriosis of lung
N80.B32	Superficial endometriosis of diaphragm
N80.B39	Deep endometriosis of diaphragm
N80.B4	Endometriosis of diaphragm, unspecified depth
N80.B5	Endometriosis of the pericardial space
N80.B6	Endometriosis of the mediastinal space
N80.C0	Endometriosis of cardiothoracic space
N80.C10	Endometriosis of the abdomen, unspecified
N80.C11	Endometriosis of the anterior abdominal wall, subcutaneous tissue
N80.C19	Endometriosis of the anterior abdominal wall, fascia and muscular layers
N80.C2	Endometriosis of the anterior abdominal wall, unspecified depth

N80.C3	Endometriosis of the umbilicus
N80.C4	Endometriosis of the inguinal canal
N80.C9	Endometriosis of extra-pelvic abdominal peritoneum
N80.D0	Endometriosis of other site of abdomen
N80.D1	Endometriosis of the pelvic nerves, unspecified
N80.D2	Endometriosis of the sacral splanchnic nerves
N80.D3	Endometriosis of the sacral nerve roots
N80.D4	Endometriosis of the obturator nerve
N80.D5	Endometriosis of the sciatic nerve
N80.D6	Endometriosis of the pudendal nerve
N80.D9	Endometriosis of the femoral nerve
N80.9	Endometriosis, unspecified
Z85.46	Personal history of malignant neoplasm of prostate
Z87.890	Personal history of sex reassignment

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: <https://www.cms.gov/medicare-coverage-database/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):

Jurisdiction(s): 6, K	NCD/LCD Document (s): A52453
https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a52453&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMD%2C6%2C3%2C5%2C1%2CF%2CP	

Jurisdiction(s): J, M	NCD/LCD Document (s): A59160
https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a59160&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMD%2C6%2C3%2C5%2C1%2CF%2CP	

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.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC