Medical Policy

Trelstar® (triptorelin)	
MEDICAL POLICY NUMBER	MED_Clin_Ops-125
CURRENT VERSION EFFECTIVE DATE	01/01/2024
APPLICABLE PRODUCT AND MARKET	*Individual Family Plan*: ALL *Small Group:* ALL *Medicare Advantage*: ALL

PURPOSE

The purpose of this policy is to establish the clinical review criteria that support the determination of medical necessity Trelstar® (triptorelin) therapy.

POLICY

Prior Authorization and Medical Review is required.

Coverage for Trelstar:

- Endometriosis/Uterine Leiomyomata (fibroids): 6 months and is NOT eligible for renewal
- All other indications: 12 months and may be renewed
- Max Units (per dose and over time):
    - Prostate Cancer: 6 units every 168 days
    - All Other Indications: 1 unit every 28 days

Initial

Prostate Cancer

A. Patient is at least 18 years of age; **AND**
B. Patient has a diagnosis of advanced prostate cancer; **AND**
C. Trelstar will be used as palliative therapy.

Central Precocious Puberty (CPP)

A. Patient is between the ages of 2 and less than 13 years; **AND**
B. Trelstar will not be used in combination with growth hormone; **AND**
C. Onset of secondary sexual characteristics earlier than age 8 for females and 9 for males associated with pubertal pituitary gonadotropin activation; **AND**
D. Diagnosis is confirmed by pubertal gonadal sex steroid levels and a pubertal luteinizing hormone (LH) response to stimulation by native GnRH; **AND**
E. Bone age advanced greater than 2 standard deviations (SD) beyond chronological age; **AND**
F. 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)

Gender Dysphoria (formerly Gender Identity Disorder)

A. 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**
B. A qualified MHP* has confirmed all of the following:
    a. Patient has demonstrated a long-lasting and intense pattern of gender nonconformity or gender dysphoria (whether suppressed or expressed); **AND**
    b. Gender dysphoria worsened with the onset of puberty; **AND**
    c. 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**
    d. Patient has sufficient mental capacity to give informed consent to this (reversible) treatment; **AND**
C. 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**
D. 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**
E. A pediatric endocrinologist or other clinician experienced in pubertal assessment has confirmed all of the following:
    a. Agreement in the indication for treatment; **AND**
    b. Puberty has started in the adolescent (e.g., Tanner stage ≥G2/B2); **AND**
    c. There are no medical contraindications to treatment

***Definition of a qualified mental health professional**

- A master's degree or its equivalent in a clinical behavioral science field. This degree or a more advanced one should be granted by an institution accredited by the appropriate national or regional accrediting board. The mental health professional should also have documented credentials from the relevant licensing board or equivalent; **AND**
- Competence in using the Diagnostic Statistical Manual of Mental Disorders and/or the International Classification of Diseases for diagnostic purposes; **AND**
- Ability to recognize and diagnose co-existing mental health concerns and to distinguish these from gender dysphoria; **AND**
- Knowledgeable about gender nonconforming identities and expressions, and the assessment and treatment of gender dysphoria; **AND**
- Continuing education in the assessment and treatment of gender dysphoria. This may include attending relevant professional meetings, workshops, or seminars; obtaining supervision from a mental health professional with relevant experience; or participating in research related to gender nonconformity and gender dysphoria

****DSM-V Criteria for Gender Dysphoria**

- 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 post-transitional, 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

A. Patient is at least 18 years of age; **AND**
B. Documentation patient's diagnosis has been confirmed by a workup/evaluation (versus presumptive treatment)

Uterine Leiomyomata

A. Patient is at least 18 years of age; **AND**
B. Documentation patient's diagnosis has been confirmed by a workup/evaluation (versus presumptive treatment); **AND**
C. Documentation patient is receiving iron therapy.

Renewal

A. Patient continues to meet initial criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc.; **AND**
B. 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

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

Central Precocious Puberty (CPP)

A. Patient is less than 13 years of age; **AND**
B. Disease response as indicated by lack of progression or stabilization of secondary sexual characteristics, decrease in height velocity, a decrease in the ratio of bone age to chronological age (BA:CA), and improvement in final height prediction; **AND**
C. Will not be used in combination with growth hormone.

Gender Dysphoria

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

Endometriosis/Uterine Leiomyomata

A. Coverage may NOT be renewed

LIMITATIONS/EXCLUSIONS

1) Any indication other than those listed above due to insufficient evidence of therapeutic value

DEFINITIONS

A. TRELSTAR (triptorelin pamoate for injectable suspension), for intramuscular use. Initial U.S. Approval: 2000
    a. TRELSTAR is supplied in the TRELSTAR MIXJECT single-dose delivery system consisting of a vial with a Flip-Off seal containing sterile lyophilized triptorelin pamoate microgranules incorporated in a biodegradable copolymer of lactic and glycolic acids, a MIXJECT vial adapter, and a pre-filled syringe containing sterile water for injection, USP, 2 mL, pH 6 to 8.5.

CODING

Applicable NDC Codes	
00023-5902-xx	Trelstar 3.75mg for injection with MIXJECT single-dose delivery system
00023-5904-xx	Trelstar 11.25mg for injection with MIXJECT single-dose delivery system
00023-5906-xx	Trelstar 22.5mg for injection with MIXJECT single-dose delivery system

Applicable Procedure Code	
J3315	Injection, triptorelin 3.75 mg: 1 billable unit = 3.75 mg

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
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
N80.0	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

EVIDENCE BASED REFERENCES

1. Trelstar [package insert]. Ewing, NJ; Verity Pharmaceuticals, Inc; December 2021. Accessed July 2022.

Policy History
This policy has been approved by the approval body listed below or has received other necessary approval pursuant to Brand New Day/Central Health Medicare Plan Care's policies on clinical criteria and policy development.

Approval Body	Pharmacy and Therapeutics Committee
Original Effective Date	July 26, 2022
Version Date	V1 – July 26, 2022 V2 – March 1, 2023 – Adopted by MA UMC V3 – January 1, 2024 - Updated to Brand New Day/Central Health Medicare Plan/Central Health Medicare Plan