Triptodur® (triptorelin)
(Intramuscular)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 12 months.
- Renewal: Prior authorization validity may be renewed every 12 months thereafter.

II. Dosing Limits

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

- 6 billable units (22.5 mg) per 168 days

III. Initial Approval Criteria

Coverage is provided in the following conditions:

Universal Criteria [1]

- Patient does not have a hypersensitivity to gonadotropin releasing hormone (GnRH) or GnRH analog type medications; **AND**

Central Precocious Puberty (CPP) † Φ [1,3,4,6,10,11]

- Patient is between the ages of 2 and less than 13 years; **AND**
- Will not be used in combination with growth hormone; **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 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)

Gender Dysphoria (formerly Gender Identity Disorder) ‡ [12,14,16]

- Patient has experienced puberty development to at least Tanner stage 2 (*Note: this applies only to patients <18 years of age);* **AND**

- 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, Text Revision (DSM-5-TR) 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 patient'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**
- For adolescent patients, a pediatric endocrinologist or other clinician experienced in pubertal assessment has confirmed all of the following:
    - Agreement in the indication for treatment; **AND**
    - There are no medical contraindications to treatment

**** Definition of a qualified mental health professional** [16]

- 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-5-TR Criteria for Gender Dysphoria in Adolescents and Adults [14]

• 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

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1]

Coverage can be renewed based on the following criteria:

- Patient continues to meet the universal criteria and indication-specific relevant criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: psychiatric events (e.g., emotional lability including crying, irritability, impatience, anger, and aggression), convulsions, signs and symptoms of pseudotumor cerebri idiopathic intracranial hypertension (e.g., headaches, papilledema, blurred vision, diplopia, vision loss, eye pain, tinnitus, dizziness, and nausea), etc.; **AND**

Central Precocious Puberty (CPP) [4,10,11]

- Patient is less than 13 years of age; **AND**
- 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

Gender Dysphoria [12,14,16]

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

V. Dosage/Administration [1,15]

Indication	Dose

CPP and Gender Dysphoria	22.5 mg administered by a healthcare provider as a single intramuscular injection once every 24 weeks.

VI. Billing Code/Availability Information

HCPCS Code:

- J3316 – Injection, triptorelin, extended-release, 3.75 mg; 1 billable unit = 3.75 mg

NDC:

- Triptodur 22.5 mg single-use kit: 24338-0150-xx

VII. References

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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
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

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

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes		
Jurisdiction	**NCD/LCA/LCD Document (s)**	**Contractor**
6, K	A52453	National Government Services, Inc

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
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
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