Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 204.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Triptodur (triptorelin)

Applicable line of business:

Commercial	X	Medicaid	
Medicare	X	ACA	X
CHIP	X		

I. Policy:
Triptodur (triptorelin)

II. Purpose/Objective:
To provide a policy of coverage regarding Triptodur (triptorelin)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

DESCRIPTION:
Triptodur (triptorelin) is an agonist analog of gonadotropin releasing hormone (GnRH) and causes suppression of ovarian and testicular steroidogenesis due to decreased levels of LH and FSH with subsequent decrease in testosterone (male) and estrogen (female) levels. After chronic and continuous administration, usually 2 to 4 weeks after initiation, a sustained decrease in LH and FSH secretion occurs. When used for assisted reproductive technologies (ART), prevents premature LH surge in women undergoing controlled ovarian hyperstimulation.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Triptodur (triptorelin) will be considered medically necessary for the commercial, exchange, and CHIP lines of business when ALL of the following criteria are met:

- Medical record documentation of a diagnosis of central precocious puberty **AND**
- Prescription written by or in consultation with an endocrinologist **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to Lupron Depot-Ped

Triptodur will be considered medically necessary for Gender Confirmation Treatment when all of the following criteria are met:

- Psychological evaluation for gender dysphoria by a behavioral health professional with a minimum of a master's degree or equivalent who is capable of evaluating the member in accordance with WPATH Guidelines:
    - 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 have documented credentials from a relevant licensing board or equivalent for that country.
    - Competence in using the *Diagnostic Statistical Manual of Mental Disorders* and/or the *International Classification of Diseases* for diagnostic purposes.
    - Ability to recognize and diagnose co-existing mental health concerns and to distinguish these from gender dysphoria.
    - Documented supervised training and competence in psychotherapy or counseling.
    - Knowledgeable about gender nonconforming identities and expressions, and the assessment and treatment of gender dysphoria.
    - 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.
- The use of medical intervention for gender dysphoria is age dependent. For use of a gonadotropin-releasing hormone (GnRH) analogs, the member must be peri-pubertal and a minimum of Tanner Stage 2, as documented by the provider. GnRH analogs are not medically necessary once the individual is post-pubertal.

QUANTITY LIMITS: (For Navitus auths only): 1 vial per 168 days; minimum day supply: 168; maximum day supply: 180

AUTHORIZATION DURATION: Approve with no end date.

Triptodur (triptorelin) will be considered medically necessary for the Medicare line of business when ALL of the following criteria are met:

- Medical record documentation of a diagnosis of central precocious puberty **AND**
- Prescription written by or in consultation with an endocrinologist

Triptodur will be considered medically necessary for Gender Confirmation Treatment when all of the following criteria are met:

- Psychological evaluation for gender dysphoria by a behavioral health professional with a minimum of a master's degree or equivalent who is capable of evaluating the member in accordance with WPATH Guidelines:
    - 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 have documented credentials from a relevant licensing board or equivalent for that country.
    - Competence in using the *Diagnostic Statistical Manual of Mental Disorders* and/or the *International Classification of Diseases* for diagnostic purposes.
    - Ability to recognize and diagnose co-existing mental health concerns and to distinguish these from gender dysphoria.
    - Documented supervised training and competence in psychotherapy or counseling.
    - Knowledgeable about gender nonconforming identities and expressions, and the assessment and treatment of gender dysphoria.
    - 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.
- The use of medical intervention for gender dysphoria is age dependent. For use of a gonadotropin-releasing hormone (GnRH) analogs, the member must be peri-pubertal and a minimum of Tanner Stage 2, as documented by the provider. GnRH analogs are not medically necessary once the individual is post-pubertal.

AUTHORIZATION DURATION: Approve with no end date.

INFORMATIONAL ONLY:

- Pre-pubertal - no medical treatment
- Peri-pubertal – gonadotropin-releasing hormone (GnRH) analogs to achieve suppression of pubertal hormones may be considered once the member reaches Tanner Stage* 2
    - *The Tanner Scale is measurement of physical development in children, adolescents and adults. http://www.childgrowthfoundation.org/CMS/FILES/Puberty_and_the_Tanner_Stages.pdf
    - Between 14 – 16 yrs of age –pubertal development of the desired opposite sex can be using a
    - gradually increasing dose schedule of cross-gender hormone.
    - Adolescents should be treated with GnRH analogues, progestins (e.g., medroxyprogesterone) or other medications that block and/or neutralize testosterone, estrogens and progesterone secretion.
- Post-pubertal – continuous hormone replacement therapy
    - Female to male: IM testosterone or topical testosterone
    - Male to female: Anti-androgen therapy (e.g., Spironolactone, GnRH agonists, plus estrogen) Age 40 yrs or older – estrogen cream, patch or injectable

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Triptodur [prescribing information]. Atlanta, GA: Arbor Pharmaceuticals LLC; December 2022.
2. Coleman EA, Radix AE, Bouman WP, et al. Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. World Professional Association of Transgender Health. International Journal of Transgender Health. 2022 Sep 15. 23(1): S1-S259 [cited 2023 Dec 26]. Avialable from: https://www.wpath.org/soc8

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 11/19/19

Revised: 10/4/22 (LOB carve out), 10/2/23 (Medicaid business segment), 12/29/23 (references added), 10/1/24 (LOB table, taglines, Darwin to Navitus)

Reviewed: 11/16/20, 10/4/21

MA UM Committee approval: 12/31/23