Draft Revision Policy: Do Not Implement

Triptorelin (Triptodur®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

The proposal is to add text/statements in red and to delete text/statements with strikethrough:

POLICY

INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Triptodur is indicated for the treatment of pediatric patients 2 years of age and older with central precocious puberty (CPP).

Compendial Uses

- Gender dysphoria (also known as transgender and gender diverse [TGD] persons)
- Preservation of ovarian function
- Prevention of recurrent menstrual related attacks in acute porphyria

All other indications are considered experimental/investigational and not medically necessary.

DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: For central precocious puberty initial requests, laboratory report or medical record documentation of a pubertal response to a gonadotropin releasing hormone (GnRH) agonist test or a pubertal basal level of luteinizing hormone (LH) on a third-generation ~~luteinizing hormone (~~LH~~)~~ assay.

PRESCRIBER SPECIALTIES

Gender Dysphoria
The medication must be prescribed by or in consultation with a provider specialized in the care of transgender youth (e.g., pediatric endocrinologist, family or internal medicine physician, obstetrician-gynecologist) that has collaborated care with a mental health provider for members less than 18 years of age.

Prevention of Recurrent Menstrual-Related Attacks in Acute Porphyria
The medication must be prescribed by or in consultation with a provider experienced in the management of porphyrias.

COVERAGE CRITERIA

Central Precocious Puberty (CPP)

Authorization of 12 months may be granted for treatment of CPP when all of the following criteria are met:

- ~~The diagnosis of CPP has been confirmed by a pubertal response to a gonadotropin releasing hormone (GnRH) agonist test or a pubertal level of a third-generation luteinizing hormone (LH) assay.~~
- The diagnosis of CPP has been confirmed by either of the following criteria based on laboratory reference range:
  - A pubertal response to a gonadotropin releasing hormone (GnRH) agonist test
  - A pubertal basal level of luteinizing hormone (LH) on a third-generation LH assay
- The assessment of bone age versus chronological age supports the diagnosis of CPP.
- The member meets either of the following criteria:
  - The member is a female and was less than 8 years of age at the onset of secondary sexual characteristics.
  - The member is a male and was less than 9 years of age at the onset of secondary sexual characteristics.
- The pathologic cause of CPP has been assessed (e.g., imaging screening for intracranial tumors, genetic testing for familial CPP [e.g., MKRN3 or DLK1 ~~mutations~~ variants]).

Gender Dysphoria

*Individual is age 18 or older or the individual is less than age 18 as permissive under applicable law
Authorization of 12 months may be granted for pubertal hormonal suppression in an adolescent member when all of the following criteria are met:

- The member has a diagnosis of gender dysphoria.
- The member is able to make an informed decision to engage in treatment.
- The member has reached Tanner stage 2 of puberty or greater.
- The member's comorbid conditions are reasonably controlled.
- The member has been educated on any contraindications and side effects to therapy.
- The member has been informed of fertility preservation options.

Authorization of 12 months may be granted for gender transition when all of the following criteria are met:

- The member has a diagnosis of gender dysphoria.
- The member is able to make an informed decision to engage in treatment.
- The member will receive the requested medication concomitantly with gender-affirming hormones.
- The member's comorbid conditions are reasonably controlled.
- The member has been educated on any contraindications and side effects to therapy.
- The member has been informed of fertility preservation options.

Preservation of Ovarian Function

Authorization of 3 months may be granted for preservation of ovarian function when the member is premenopausal and undergoing chemotherapy.

Prevention of Recurrent Menstrual-Related Attacks in Acute Porphyria

Authorization of 12 months may be granted for prevention of recurrent menstrual related attacks in members with acute porphyria.

CONTINUATION OF THERAPY

Central Precocious Puberty (CPP)

Authorization of up to 12 months may be granted for continued treatment ~~for~~ of CPP when the member meets ~~all~~ both of the following criteria:

- ~~The member is currently receiving the requested medication through a paid pharmacy or medical benefit.~~
- The member is either a female less than 12 years of age or a male less than 13 years of age.
- The member is not experiencing treatment failure (e.g., clinical pubertal progression, lack of growth deceleration, continued excessive bone age advancement).

Gender Dysphoria

*Individual is age 18 or older or the individual is less than age 18 as permissive under applicable law
Authorization of 12 months may be granted for continued treatment for pubertal hormonal suppression in adolescent members requesting reauthorization when all of the following criteria are met:

- The member has a diagnosis of gender dysphoria.
- The member is able to make an informed decision to engage in treatment.
- The member has previously reached Tanner stage 2 of puberty or greater.
- The member's comorbid conditions are reasonably controlled.
- The member has been educated on any contraindications and side effects to therapy.
- Before the start of therapy, the member has been informed of fertility preservation options.

Authorization of 12 months may be granted for continued treatment for gender transition in members requesting reauthorization when all of the following criteria are met:

- The member has a diagnosis of gender dysphoria.
- The member is able to make an informed decision to engage in treatment.
- The member will receive the requested medication concomitantly with gender-affirming hormones.
- The member's comorbid conditions are reasonably controlled.
- The member has been educated on any contraindications and side effects to therapy.
- Before the start of therapy, the member has been informed of fertility preservation options.

All Other Indications

All members (including new members) requesting authorization for continuation of therapy must meet all requirements in the coverage criteria section.

OTHER

Per state regulatory guidelines around gender dysphoria, age restrictions may apply.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

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Policy

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EFFECTIVE DATE

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