Reference number(s)
2504-A, 6055-A

Specialty Guideline Management Triptodur

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Triptodur	triptorelin

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[1]

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)[9,10,15]
- Preservation of ovarian function[11,12]
- Prevention of recurrent menstrual related attacks in acute porphyria[13,14]

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

Documentation

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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 LH assay.

Prescriber Specialties[13,14,17]

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)[1-8]

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 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 variants]).

Gender Dysphoria[9,10,15]

Authorization of 12 months may be granted for pubertal hormonal suppression in an adolescent member who is seeking gender-affirming care when all of the following criteria are met:

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- 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 in a member who is seeking gender-affirming care 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[11,12]

Authorization of 6 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[13,14]

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)[2,4,7]

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

- 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[16]

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Authorization of 12 months may be granted for continued treatment for pubertal hormonal suppression in an adolescent member who is seeking gender-affirming care and 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 a member who is seeking gender-affirming care and 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.

Other

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

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