Clinical Policy Title:	triptorelin pamoate
Policy Number:	RxA.522
Drug(s) Applied:	Trelstar®, Triptodur®
Original Policy Date:	03/06/2020
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Prostate Cancer (must meet all)**:**

1. Diagnosis of prostate cancer;
2. Request is for Trelstar®;
3. Prescribed by or in consultation with an oncologist or a urologist;
4. Age ≥ 18 years;
5. Request meets one of the following (a or b):*
   a. Dose does not exceed 3.75 mg per 4 weeks, 11.25 mg per 12 weeks, or 22.5 mg per 24 weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).
   *Prescribed regimen must be FDA-approved or recommended by NCCN

Approval duration
Commercial: 12 months
Medicaid: 12 months

B. Central Precocious Puberty (must meet all)**:**

1. Diagnosis of CPP confirmed by all of the following (a, b, and c):
   a. Elevated basal luteinizing hormone (LH) level > 0.2 - 0.3 mIU/L (dependent on type of assay used) and/or elevated leuprolide-stimulated LH level > 3.3 - 5 IU/L (dependent on type of assay used);
   b. Difference between bone age and chronological age was > 1 year (bone age- chronological age);
   c. Age at onset of secondary sex characteristics is < 8 years if female, or < 9 years if male;
2. Request is for Triptodur®;
3. Prescribed by or in consultation with a pediatric endocrinologist;
4. Member meets one of the following age requirements (a or b):
   a. Female: 2 - 11 years;
   b. Male: 2 - 12 years;
5. Dose does not exceed 22.5 mg per 24 weeks.

Approval duration
Commercial: 12 months
Medicaid: 12 months

C. Gender Dysphoria, Gender Transition (off-label) (must meet all):

1. Diagnosis of gender dysphoria or request is for gender transition;
2. Prescribed by or in consultation with an endocrinologist and an expert in gender dysphoria and transgender medicine (e.g., mental health professional such as psychologist, psychiatrist);
3. Age and pubertal development - meets (a or b):
   a. Member has reached or passed through Tanner Stage 2* and is < 18 years of age;
      *Age ranges approximating Tanner Stage 2 pubertal development extend from 8 to 13 years of age in girls and 9 to 14 years of age in boys.
   b. Member is ≥ 18 years of age and has failed to achieve physiologic hormone levels with gender-affirming hormonal therapy (e.g., estrogen, testosterone) unless contraindicated or clinically significant adverse effects are experienced;
4. Member demonstrates understanding of expected GnRH analogue treatment outcomes and has given consent for such treatment;
5. If member has a psychiatric comorbidity, member is followed by mental health provider;
6. Psychosocial support will be provided during treatment;
7. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

Approval duration
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

A. Prostate Cancer (must meet all)**:**

1. Member is currently receiving medication that has been authorized by RxAdvance or member has met initial approval criteria for the covered indications and has received this medication for at least 30 days;
2. Request is for Trelstar®;
3. Member is responding positively to therapy;
4. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed 3.75 mg per 4 weeks, 11.25 mg per 12 weeks, or 22.5 mg per 24 weeks;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

   *Prescribed regimen must be FDA-approved or recommended by NCCN

Approval duration
Commercial: 12 months
Medicaid: 12 months

B. Central Precocious Puberty (must meet all)**:**

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Request is for Triptodur®;
3. Member is responding positively to therapy as evidenced by, including but not limited to, improvement in any of the following parameters: decreased growth velocity, cessation of menses, softening of breast tissue or testes, arrested pubertal progression;
4. Member meets one of the following age requirements (a or b):
   a. Female: ≤ 11 years;
   b. Male: ≤ 12 years.
5. If request is for a dose increase, new dose does not exceed: 22.5 mg per 24 weeks.

Approval duration

Commercial: 12 months
Medicaid: 12 months

C. Gender Dysphoria, Gender Transition (off-label) (must meet all)**:**

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

Approval duration
Commercial: 12 months
Medicaid: 12 months

References

1. National Comprehensive Cancer Network. Prostate cancer Version 1.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate_detection.pdf. Accessed September 8, 2022.
2. Emmanual M, Bokor BR. Tanner Stages. Treasure Island, FL: StatPearls Publishing; 2019 Jan. Available at https://www.ncbi.nlm.nih.gov/books/NBK470280/. Last update: May 13, 2019. Accessed September 9, 2022.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Clinical Policy title was updated. 2. Line of business policy applies to was updated to All lines of business 3. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 4. Reference was reviewed and updated.	09/21/2020	12/07/2020
Policy was reviewed: 1. Continued Therapy Criteria II.A.1, II.B.1 and II.C.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 2. References were reviewed and updated.	10/01/2021	12/07/2021

Policy was reviewed: 1. Initial Approval Criteria I.C, I.C.1 and Continued Therapy Criteria II.C: Updated to add term gender dysphoria. 2. References were reviewed and updated.	09/09/2022	10/19/2022
Policy was reviewed.	10/19/2023	10/19/2023