



STANDARD COMMERCIAL DRUG FORMULARY  
PRIOR AUTHORIZATION GUIDELINES

LEUPROLIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LEUPROLIDE ACETATE	LEUPROLIDE ACETATE		84597	GPI-14 (21405010106407)	

**GUIDELINES FOR USE**

**INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)**

1. Is the requested medication being used for gender dysphoria?

If yes, **approve for 12 months by HICL or GPI-10 and override quantity limits.**  
If no, continue to #2.

2. Does the patient have a diagnosis of advanced prostate cancer?

If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of #2 kits per 28 days.**  
If no, continue to #3.

3. Is the request for a female patient who has a diagnosis of central precocious puberty (CPP) and meets **ALL** of the following criteria?

- The patient is 2 years of age or older
- Therapy is prescribed by or in consultation with a pediatric endocrinologist
- The patient has elevated levels of follicle-stimulating hormone (FSH) (level >4.0 mIU/mL) and luteinizing hormone (LH) (level > 0.2 to 0.3 mIU/mL) at diagnosis
- The patient is younger than 8 years of age at the onset of CPP
- There is documentation of pubertal staging using the Tanner scale for breast development (stage 2 or above) AND pubic hair growth (stage 2 or above)

If yes, **approve for 12 months by GPID or GPI-14.**  
If no, continue to #4.

**CONTINUED ON NEXT PAGE**



STANDARD COMMERCIAL DRUG FORMULARY  
PRIOR AUTHORIZATION GUIDELINES

LEUPROLIDE

INITIAL CRITERIA (CONTINUED)

4. Is the request for a male patient who has a diagnosis of central precocious puberty (CPP) and meets **ALL** of the following criteria?
- The patient is 2 years of age or older
  - Therapy is prescribed by or in consultation with a pediatric endocrinologist
  - The patient has elevated levels of follicle-stimulating hormone (FSH) (level >5.0 mIU/mL) and luteinizing hormone (LH) (level > 0.2 to 0.3 mIU/mL) at diagnosis
  - The patient is younger than 9 years of age at the onset of CPP
  - There is documentation of pubertal staging using the Tanner scale for genital development (stage 2 or above) AND pubic hair growth (stage 2 or above)

If yes, **approve for 12 months by GPID or GPI-14.**

If no, do not approve.

**INITIAL DENIAL TEXT: \*Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **LEUPROLIDE** requires the following rule(s) be met for approval:

- A. You have ONE of the following diagnoses:
1. Gender dysphoria (your gender identity conflicts with your sex assigned at birth)
  2. Advanced prostate cancer (prostate cancer that has spread to nearby tissue or organs)
  3. Central precocious puberty (CPP: early sexual development in girls and boys)
- B. **If you are female and have central precocious puberty, approval also requires:**
1. You are 2 years of age or older
  2. Therapy is prescribed by or in consultation with a pediatric endocrinologist (hormone doctor)
  3. You have high levels of follicle-stimulating hormone (FSH) (level greater than 4.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
  4. You are/were younger than 8 years of age when your condition started
  5. There is documentation of pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for breast development (stage 2 or above) AND pubic hair growth (stage 2 or above)
- C. **If you are male and have central precocious puberty, approval also requires:**
1. You are 2 years of age or older
  2. Therapy is prescribed by or in consultation with a pediatric endocrinologist (hormone doctor)
  3. You have high levels of follicle-stimulating hormone (FSH) (level greater than 5.0 mIU/mL) and luteinizing hormone (LH) (level greater than 0.2 to 0.3 mIU/mL) at diagnosis
  4. You are/were younger than 9 years of age when your condition started  
**(Initial denial text continued on next page)**

**CONTINUED ON NEXT PAGE**



STANDARD COMMERCIAL DRUG FORMULARY  
PRIOR AUTHORIZATION GUIDELINES

LEUPROLIDE

INITIAL CRITERIA (CONTINUED)

5. There is documentation of pubertal staging using the Tanner scale (scale of physical measurements of development based on external sex characteristics) for genital development (stage 2 or above) AND pubic hair growth (stage 2 or above)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

**NOTE:** For the diagnoses of gender dysphoria or advanced prostate cancer, please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of central precocious puberty (CPP) and meet **ALL** of the following criteria?
  - The Tanner scale staging at initial diagnosis of CPP has stabilized or regressed during three separate medical visits in the previous year
  - The patient has not reached the actual age which corresponds to their current pubertal age

If yes, **approve for 12 months by GPID or GPI-14.**

If no, do not approve.

**RENEWAL DENIAL TEXT: \*Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **LEUPROLIDE** requires the following rule(s) be met for renewal:

- A. You have central precocious puberty (CPP: early sexual development in girls and boys)
- B. Your Tanner scale staging (scale of physical measurements of development based on external sex characteristics) at initial diagnosis of CPP has stabilized or regressed (lowered) during three separate medical visits in the previous year
- C. You have not reached the actual age which corresponds to your current pubertal age

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

**CONTINUED ON NEXT PAGE**



**STANDARD COMMERCIAL DRUG FORMULARY  
PRIOR AUTHORIZATION GUIDELINES**

**LEUPROLIDE**

---

**RATIONALE**

For further information, please refer to the Prescribing Information and/or Drug Monograph for Leuprolide.

**REFERENCES**

- Leuprolide acetate [Prescribing Information]. Princeton, NJ: Sandoz Inc.; Aug 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/23/23

Created: 09/18

Client Approval: 01/23

P&T Approval: 04/22