

# NYRx Drug Class Coverage Overview: Pubertal Suppressants and Hormone Replacement Therapy for Treatment of Gender Dysphoria

## NYRx Drug Utilization Review Requirements

Pubertal Suppressants and Hormone Replacement Therapy for Treatment of Gender Dysphoria drug classes are subject to prior authorization (PA) requirements of the <u>NYRx Drug Utilization Review (DUR)</u> <u>Program</u>:

Drug / Class Name	Step Therapy (ST) Parameters	Frequency / Quantity / Duration (F/Q/D) Parameters	Additional / Alternate Parameter(s)
Hormone Replacement Therapy for Treatment of Gender Dysphoria • conjugated estrogens • estradiol • testosterone cypionate • testosterone enanthate (Xyosted™) • testosterone gel 1.62% (AndroGel®)* • testosterone patch (Androderm)*			<ul> <li>Confirm diagnosis of FDA- approved or compendia- supported indication</li> <li>For diagnosis of gender dysphoria please refer to October 2023 edition of the Medicaid Update:</li> <li><u>https://www.health.ny.gov/health_ care/medicaid/program/update/2</u> 023/no15_2023-10.htm#hormones</li> </ul>
			*Subject to Anabolic Steroids – Topical PDL class criteria
<ul> <li>Pubertal Suppressants</li> <li>leuprolide acetate (Lupron Depot- PED<sup>®</sup>, Fensolvi<sup>®</sup>)</li> <li>nafarelin acetate (Synarel<sup>®</sup>)</li> <li>triptorelin (Triptodur<sup>®</sup>)</li> </ul>			<ul> <li>Confirm diagnosis of FDA- approved or compendia- supported indication</li> <li>Refer to <u>https://www.health.ny.gov/health</u> <u>care/medicaid/program/update/</u> <u>2017/2017-01.htm#transgender</u> for Transgender Related Care and Services Update</li> </ul>

NYRx, the Medicaid Pharmacy Program, covers medically necessary pubertal suppressants and hormone replacement therapies that are FDA-approved or compendia-supported for the treatment of gender dysphoria consistent with the guidance provided in the <u>January 2017</u> and <u>July 2020</u> Medicaid Updates. The official compendia sources include <u>American Hospital Formulary Service</u> and <u>Micromedex DrugDex</u>.



#### **Pubertal Suppressant Coverage Criteria**

Drugs listed within the Pubertal Suppressants drug class are subject to the following clinical criteria:

• Confirmed diagnosis of FDA-approved or compendia-supported indication.

Pubertal suppressant therapy for the treatment of gender dysphoria is based upon a determination by a qualified medical professional that an individual is eligible and ready for such treatment and meets the following criteria:

- Diagnosis of gender dysphoria.
- Has experienced puberty to at least Tanner stage 2, and pubertal changes have resulted in an increase in gender dysphoria.
- Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment.
- Has adequate psychological and social support during treatment.
- Demonstrates knowledge and understanding of the expected outcomes of treatment with pubertal suppressants as well as the medical and social risks and benefits of sex reassignment.

## Hormone Replacement Therapy Coverage Criteria

Drugs listed in the Hormone Replacement Therapy for Treatment of Gender Dysphoria drug class are subject to the following clinical criteria:

Individuals 18 years of age and older:

• Confirmed diagnosis of FDA-approved or compendia-supported indication.

Individuals under 18 years of age PA required to confirm the following criteria:

- Diagnosis of gender dysphoria.
- Has experienced puberty to at least Tanner stage 2, and pubertal changes have resulted in an increase in gender dysphoria.
- Does not suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment.
- Has adequate psychological and social support during treatment.
- Demonstrates knowledge and understanding of the expected outcomes of treatment with crosssex hormones, as well as the medical and social risks and benefits of sex reassignment.

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Individuals under 15 years of age:

• Letter of medical necessity, signed by the prescribing provider, and chart notes to confirm and document the criteria listed above.

**Note:** Topical testosterone agents are listed in the *Anabolic Steroids – Topical* drug class on the <u>NYRx</u> <u>Preferred Drug List (PDL)</u> and are subject to class criteria.

#### What Pharmacy Providers Need to Do

Pharmacy providers should become familiar with the Pubertal Suppressants and Hormone Replacement Therapy for Treatment of Gender Dysphoria coverage criteria in the <u>DUR Program</u> section of the PDL and incorporate this information when discussing the need for PA with prescribers.

#### What Prescribers Need to Do

Prescribers should become familiar with the Pubertal Suppressants and Hormone Replacement Therapy for Treatment of Gender Dysphoria coverage criteria in the <u>DUR Program</u> section of the <u>PDL</u>.

Review the <u>NYRx Prior Authorization Submission Guide</u> and utilize <u>Pubertal Suppressants (GnRH</u> <u>Agonists) / Hormone Replacement Therapy for Treatment of Gender Dysphoria Prior Authorization</u> <u>Worksheet</u>. Prescribers should consider the age of the individual, and ensure information is complete and in accordance with NYRx documentation requirements. Refer to the chart below for age considerations:

Age of Individual	NYRx Documentation Requirements for Obtaining a Prior Authorization	
15 to less than 18 years of	Do one of the following:	
age	<ul> <li>Fax completed <u>Pubertal Suppressants (GnRH Agonists) / Hormone</u> <u>Replacement Therapy for Treatment of Gender Dysphoria Prior</u> <u>Authorization Worksheet</u> to 1-800-268-2990.</li> <li>Call the NYRx Education &amp; Outreach Call Center at 1-877-309-9493 and answer the following questions:</li> </ul>	
	<ol> <li>Does the individual meet the criteria for a diagnosis of gender dysphoria?</li> </ol>	
	2. Has the individual experienced puberty to at least Tanner stage 2, and pubertal changes have resulted in an increase in gender dysphoria?	



Age of Individual	NYRx Documentation Requirements for Obtaining a Prior Authorization	
	3. Does the individual suffer from psychiatric comorbidity that interferes with the diagnostic work-up or treatment?	
	4. Does the individual have adequate psychological and social support during treatment?	
	5. Does the individual demonstrate knowledge and understanding of the expected outcomes of treatment with pubertal suppressants and hormone replacement therapy for treatment of gender dysphoria, as well as the medical and social risks and benefits of sex reassignment?	
Less than 15 years of age	Fax or call for a PA as indicated above. If calling NYRx to obtain a PA, the following additional required information must be faxed to NYRx at 1-800-268-2990:	
	• Letter of Medical Necessity: A brief written explanation from the treating provider describing the medical need for the requested treatment. The Letter of Medical Necessity <b>must be signed by the treating provider</b> .	
	Note: Electronic and Stamped Signatures are acceptable.	
	<ul> <li>Individual's medical chart, which includes documentation supporting the answers to the questions listed above.</li> </ul>	

#### Resources

- New York State Medicaid Update January 2017 Volume 33 Number 1
- New York State Medicaid Update October 2023 Volume 39 Number 15
- <u>NYRx Education & Outreach Website</u>
- <u>NYRx Preferred Drug List</u>
- <u>NYRx Prior Authorization Submission Guide</u>
- <u>NYRx the Medicaid Pharmacy Program Pubertal Suppressants (GnRH Agonists) / Hormone</u> <u>Replacement Therapy for Treatment of Gender Dysphoria Prior Authorization Worksheet</u>



## **Contact Information**

The NYRx Education & Outreach Call Center is available by phone at 1-833-967-7310 or by email at <u>NYRxEO@primetherapeutics.com</u> from 8:00 AM to 5:00 PM ET, Monday through Friday, excluding holidays.

The NYRx Education & Outreach team hosts virtual office hours every week for stakeholders to ask questions related to NYRx and care coordination. Visit the <u>NYRx Education & Outreach website</u> for more information.