

## Pharmacy Policy

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# GnRH Agents

**Policy Number:** 9.703

**Revision Number:** R1

**Version Effective Date:** 1/1/2021

### Product Applicability All Plan<sup>+</sup> Products

#### Well Sense Health Plan

New Hampshire Medicaid

#### Boston Medical Center HealthNet Plan

MassHealth - MCO

MassHealth – ACO

Qualified Health Plans/ConnectorCare/Employer Choice Direct

Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

## Prior Authorization Policy

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### Products Affected:

- Eligard (leuprolide)
- Firmagon (degarelix)
- leuprolide
- Lupaneta Pack (leuprolide/norethindrone)
- Lupron (leuprolide)
- Orilissa (elagolix)
- Supprelin LA (histrelin)
- Trelstar (triptorelin)
- Triptodur (triptorelin)
- Vantas (histrelin)
- Zoladex (goserelin)

The Plan may authorize coverage of the above products for members meeting the following criteria:

<b>Covered Use</b>	All FDA approved indications not otherwise excluded
<b>Exclusion Criteria</b>	Orilissa: contraindicated in pregnancy, known osteoporosis and severe hepatic impairment
<b>Required Medical</b>	<b>Leuprolide, Lupron (leuprolide)</b>

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<b>Information</b>	<p>Documentation of one of the following diagnosis:</p> <ol style="list-style-type: none"> <li>1. Advanced Prostate Carcinoma;</li> <li>2. Endometriosis; AND <ol style="list-style-type: none"> <li>a. An inadequate response, intolerance or contraindication to non-steroidal anti-inflammatory drugs (NSAIDs); AND</li> <li>b. An inadequate response, intolerance, contraindication to hormonal therapy with one of the following: oral contraceptives, progestins or androgens;</li> </ol> </li> <li>3. Uterine leiomyomas (uterine fibroids); AND <ol style="list-style-type: none"> <li>a. Anticipated surgery date (date of surgery required) or clinical rationale why surgical intervention is not appropriate; OR</li> </ol> </li> <li>4. Central Precocious Puberty and member is between the age of 2 and 12 years;</li> <li>5. Breast, Ovarian, and Endometrial Cancer</li> </ol> <p><b>Lupaneta (leuprolide/norethindrone), Orilissa (elagolix)</b>  Documentation of all the following:</p> <ol style="list-style-type: none"> <li>1. A diagnosis of endometriosis; AND</li> <li>2. An inadequate response, intolerance or contraindication to non-steroidal anti-inflammatory drugs (NSAIDs); AND</li> <li>3. An inadequate response, intolerance, contraindication to hormonal therapy with one of the following: oral contraceptives, progestins or androgens</li> </ol> <p><b>Eligard (leuprolide), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)</b>  Documentation of the following diagnosis:</p> <ol style="list-style-type: none"> <li>1. Advanced Prostate Carcinoma</li> </ol> <p><b>Supprelin LA (histrelin), Triptodur (triptorelin)</b>  Documentation of all the following:</p> <ol style="list-style-type: none"> <li>1. A diagnosis of central precocious puberty; AND</li> <li>2. Intolerance to a trial of leuprolide injection</li> </ol> <p><b>Zoladex® (goserelin)</b>  Documentation of one of the following diagnosis:</p> <ol style="list-style-type: none"> <li>1. Advanced Breast Cancer</li> <li>2. Advanced Prostate Carcinoma</li> <li>3. Endometrial thinning</li> <li>4. Endometriosis; AND <ol style="list-style-type: none"> <li>a. An inadequate response, intolerance or contraindication to non-steroidal anti-inflammatory drugs (NSAIDs); AND</li> <li>b. An inadequate response, intolerance, contraindication to hormonal therapy with one of the following: oral contraceptives, progestins or androgens</li> </ol> </li> </ol>
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	<p><b><u>Gender dysphoria/gender incongruence treatment</u></b></p> <p><b>Preferred Agents:</b>  <b>Eligard (leuprolide), leuprolide, Lupron (leuprolide), Trelstar (triptorelin), Zoladex (goserelin)</b>  Documentation of the one of following:</p> <ol style="list-style-type: none"> <li>1. Member is less than 18 years of age; AND <ol style="list-style-type: none"> <li>a. A diagnosis of gender dysphoria/gender incongruent; AND</li> <li>b. Have experienced puberty to at least Tanner stage 2; AND</li> <li>c. Absence of psychiatric comorbidity that interferes with the diagnostic work-up or treatment; AND</li> <li>d. Have adequate psychological and social support during treatment; AND</li> <li>e. Demonstrate knowledge and understanding of the expected outcomes of GnRH analog treatment;</li> </ol> </li> </ol> <p style="text-align: center;"><b>OR</b></p> <ol style="list-style-type: none"> <li>2. Member age is 18 years or older; AND <ol style="list-style-type: none"> <li>a. A diagnosis of gender dysphoria/gender incongruent; AND</li> <li>b. Capacity to make a well-informed decision and consent to treatment; AND</li> <li>c. Medical or mental issues if present are well-controlled; AND</li> <li>d. The regimen is a trans-feminine regimen (male to female); AND</li> <li>e. Failure to achieve physiologic hormone levels or an intolerance with use of oral estrogens and spironolactone</li> </ol> </li> </ol> <p><b>Non Preferred Agents:</b>  Vantas (histrelin), Supprelin LA (histrelin)  Documentation of the following:</p> <ol style="list-style-type: none"> <li>1. An inadequate response to trial of at least two preferred agents</li> </ol>
<b>Age Restriction</b>	Central Precocious Puberty: age of 2 to 12 years Orilissa: 18 years or older
<b>Prescriber Restriction</b>	Gender dysphoria/gender incongruence: Medication is being prescribed by or in collaboration with an endocrinologist or medical provider with expertise in transgender medical care or pubertal assessment
<b>Coverage Duration</b>	General: 12 months Endometriosis: 6 months Uterine fibroids: 3 months
<b>Other criteria</b>	Reauthorization: <ol style="list-style-type: none"> <li>1. Initial criteria are met; AND</li> <li>2. Continuation of therapy is clinically appropriate; AND</li> <li>3. The treatment has been effective and well tolerated; AND</li> <li>4. Additionally, for Gender Dysphoria, a clinical rationale for not transitioning member to oral estrogens for maintenance after surgery.</li> </ol>

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## Applicable Coding:

Code	Medication
J9217	Leuprolide acetate (depot suspension) 7.5 mg
J9218	Leuprolide acetate, per 1 mg
J9219	Leuprolide acetate implant, 65 mg
J1950	Injection, leuprolide acetate (depot suspension), per 3.25 mg
J9225	Histrelin implant (Vantas), 50 mg
J9226	Histrelin implant (Supprelin LA), 50 mg
J1675	Histrelin acetate, 10 micrograms
J9202	Goserelin acetate implant, per 3.6 mg
J9155	Injection, degarelix, 1 mg
J3315	Injection, triptorelin acetate 3.75 mg

## Clinical Background Information and References

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5. Trelstar Depot [package insert]. Corona, CA: Watson Pharma; November 2004
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Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee, NH DHHS

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date	Approved by
12/10/2020	9.136 GnRH Agents Policy retired, new policy created. Removed Orilissa due to NH PDL limitations.	1/1/2021	Pharmacy & Therapeutics (P&T) Committee, NH DHHS

### Next Review Date

2021

### Other Applicable Policies

### Reference to Applicable Laws and Regulations, If Any

#### Disclaimer Information

Medical Policies are the Plan’s guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member’s benefit document, and when appropriate, coordinates with the Member’s health care Providers to consider the individual Member’s health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan’s service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member’s benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

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The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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