Pharmacy Policy

GnRH Agents

Policy Number: 9.136
Version Number: 16.0
Version Effective Date: 05/11/2020

Product Applicability	☐ **All Plan+ Products**
Well Sense Health Plan	**Boston Medical Center HealthNet Plan**
☒ New Hampshire Medicaid	☒ MassHealth - MCO
☒ NH Health Protection Program	☒ 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

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:

Covered Use	All FDA approved indications not otherwise excluded
Exclusion Criteria	Orilissa: contraindicated in pregnancy, known osteoporosis and severe hepatic impairment
Required	

+ *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

Medical Information	**Leuprolide, Lupron (leuprolide)** Documentation of one of the following diagnosis: 1. Advanced Prostate Carcinoma; 2. Endometriosis; AND a. An inadequate response, intolerance or contraindication to non-steroidal anti-inflammatory drugs (NSAIDs); AND b. An inadequate response, intolerance, contraindication to hormonal therapy with one of the following: oral contraceptives, progestins or androgens; 3. Uterine leiomyomas (uterine fibroids); AND a. Anticipated surgery date (date of surgery required) or clinical rationale why surgical intervention is not appropriate; OR 4. Central Precocious Puberty and member is between the age of 2 and 12 years; 5. Breast, Ovarian, and Endometrial Cancer **Lupaneta (leuprolide/norethindrone), Orilissa (elagolix)** Documentation of all the following: 1. A diagnosis of endometriosis; AND 2. An inadequate response, intolerance or contraindication to non-steroidal anti-inflammatory drugs (NSAIDs); AND 3. An inadequate response, intolerance, contraindication to hormonal therapy with one of the following: oral contraceptives, progestins or androgens **Eligard (leuprolide), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)** Documentation of the following diagnosis: 1. Advanced Prostate Carcinoma **Supprelin LA (histrelin), Triptodur (triptorelin)** Documentation of all the following: 1. A diagnosis of central precocious puberty; AND 2. Intolerance to a trial of leuprolide injection **Zoladex® (goserelin)** Documentation of one of the following diagnosis: 1. Advanced Breast Cancer 2. Advanced Prostate Carcinoma 3. Endometrial thinning 4. Endometriosis; AND a. An inadequate response, intolerance or contraindication to non-steroidal anti-inflammatory drugs (NSAIDs); AND b. An inadequate response, intolerance, contraindication to hormonal therapy with one of the following: oral contraceptives, progestins or androgens

	<u>Gender dysphoria/gender incongruence treatment</u> **Preferred Agents:** **Leuprolide, Lupron (leuprolide), Trelstar (triptorelin), Zoladex (goserelin)** Documentation of the one of following: 1. Member is less than 18 years of age; AND a. A diagnosis of gender dysphoria/gender incongruent; AND b. Have experienced puberty to at least Tanner stage 2; AND c. Absence of psychiatric comorbidity that interferes with the diagnostic work-up or treatment; AND d. Have adequate psychological and social support during treatment; AND e. Demonstrate knowledge and understanding of the expected outcomes of GnRH analog treatment; **OR** 2. Member age is 18 years or older; AND a. A diagnosis of gender dysphoria/gender incongruent; AND b. Capacity to make a well-informed decision and consent to treatment; AND c. Medical or mental issues if present are well-controlled; AND d. The regimen is a trans-feminine regimen (male to female); AND e. Failure to achieve physiologic hormone levels or an intolerance with use of oral estrogens and spironolactone **Non Preferred Agents:** Vantas (histrelin), Supprelin LA (histrelin) Documentation of the following: 1. An inadequate response to trial of at least two preferred agents
Age Restriction	Central Precocious Puberty: age of 2 to 12 years Orilissa: 18 years or older
Prescriber Restriction	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
Coverage Duration	General: 12 months Endometriosis: 6 months Uterine fibroids: 3 months
Quantity Limit	Orilissa 150mg: 30 per 30 days Orilissa 200mg: 60 per 30 days Supprelin LA for central precocious puberty: one implant per year
Other criteria	Reauthorization: 1. Initial criteria are met; AND 2. Continuation of therapy is clinically appropriate; AND

	3. The treatment has been effective and well tolerated; AND 4. Additionally, for Gender Dysphoria, a clinical rationale for not transitioning member to oral estrogens for maintenance after surgery.

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, I mg
J3315	Injection, triptorelin acetate 3.75 mg

Clinical Background Information and References

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2. Dawson N. Overview of treatment for advance prostate cancer. Up to Date®, accessed December 2012; available from: http://www.uptodate.com
3. Loenen A.C., Huirne J., Schats R., et.al. GnRH Agonists, Antagonists, and Assisted Conception. Semin Reprod Med. 2002;20(4)
4. Histrelin Acetate. *Drug Facts and Comparisons*. Facts and Comparisons 4.0 [online]. 2007. Available from Wolters Kluwer Health, Inc.
5. Trelstar Depot [package insert]. Corona, CA: Watson Pharma; November 2004
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Metabolism, Volume 102, Issue 11, 1 November 2017, Pages 3869–3903. Available at: https://doi.org/10.1210/jc.2017-01658
15. Guss C, Shumer D, Katz-Wise SL. Transgender and Gender Nonconforming Adolescent Care: Psychosocial and Medical Considerations. Curr Opin Pediatr. 2015 Aug; 26(4): 421–426. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4522917/
16. Rosenthal SM. Transgender youth: current concepts. Ann Pediatr Endocrinol Metab. 2016 Dec; 21(4): 185–192. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5290172/pdf/apem-21-185.pdf

Original Approval Date	Original Effective Date	Policy Owner	Approved by
01/11/2007	01/11/2007	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History

Review Date	Summary of Revisions	Revision Effective Date	Approved by
1/10/2008	P&T Annual Review, no changes required	05/01/2008	P&T Committee
3/12/2009	P&T Annual Review, Viadur® removed	08/01/2009	P&T Committee
1/14/2010	P&T Annual Review, title changed from Leuprolide to GnRH Agents, prior authorization criteria added for Trelstar, Supprelin LA, Vantas, Zoladex and Firmagon.	05/01/2010	P&T Committee
01/13/2011	P&T Annual Review, continuation of therapy criteria added.	05/01/2011	P&T Committee
07/14/2011	Policy applied to Commercial	11/01/2011	P&T Committee
01/12/2012	P&T Annual Review, no changes required	05/01/2012	P&T Committee
01/10/2013	P&T Annual Review, no changes required	05/01/2013	P&T Committee
12/13/2013	Policy applied to ConnectorCare/Qualified Health Plan (QHP)	04/01/2014	P&T Committee
01/09/2014	P&T Annual Review, rephrased continuation criteria	05/01/2015	P&T Committee NH DHHS
01/08/2015	P&T Annual Review, no criteria changes	05/01/2015	P&T Committee NH DHHS
01/01/2016	P&T Annual Review, no criteria changes	05/01/2016	P&T Committee NH DHHS
05/01/2016	Policy revision, added coverage criteria for gender dysphoria	09/15/2016	P&T Committee NH DHHS
01/12/2017	P&T Annual Review, no criteria changes	05/01/2017	P&T Committee NH DHHS
5/31/2017	Policy Revision; Lupaneta Pack added to	5/31/2017	P&T Committee

Policy Revisions History			
	policy with criteria of other leuprolide agents		NH DHHS
01/11/2018	P&T Annual Review, separated Lupenata criteria with diagnosis of endometriosis per FDA approval; added Triptodur; gender dysphoria/gender incongruence criteria changes- moved Eligard and Lupron to preferred agents, diagnosis no longer needs to be defined by DSM V, removed increase gender dysphoria due to pubertal changes for less than 18 year of age, prescriber criteria expanded to include medical providers with expertise in transgender care	05/08/2018	P&T Committee NH DHHS
01/17/2019	P&T Annual Review, updated endometriosis criteria for leuprolide, Lupron, Eligard, Lupeneta and Zoladex to require trial of NSAID and hormone therapy; removed anemia from uterine fibroids diagnosis and added surgery date requirement; added criteria and QL for Orilissa	05/01/2019	P&T Committee NH DHHS
2/13/2020	P&T Annual Review, separated criteria for Eligard as it has indication for prostate cancer only; removed benign prostatic hypertrophy as one of the approvable indications for Lupron; added coverage duration of 3 months for the diagnosis of uterine fibroids	5/11/2020	P&T Committee NH DHHS

Next Review Date

2/11/2021

Other Applicable Policies

9.080 Non Preferred Policy
9.015 Quantity Limitation Policy

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.

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.