wellsense.org | 877-957-1300

## Pharmacy Policy

# Osphena

**Policy Number:** 9.300
**Revision Number:** R0
**Version Effective Date:** 1/1/2021

| Product Applicability | ☐ **All Plan[+] Products** |
|---|---|
| **Well Sense Health Plan**<br>☒ New Hampshire Medicaid<br><br>☐ _____ | **Boston Medical Center HealthNet Plan**<br>☐ MassHealth - MCO<br>☐ MassHealth - ACO<br>☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct<br>☐ Senior Care Options<br>☐ _____ |

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

## Prior Authorization Policy

**Products Affected:**

- Osphena (ospemifene)

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

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|---|---|
| **Covered Use** | All FDA approved indications not otherwise excluded |
| **Exclusion Criteria** | None |
| **Required Medical Information** | 1. A diagnosis of moderate to severe dyspareunia, or vaginal dryness with symptoms of vulvar and vaginal atrophy due to menopause; ***AND***<br>2. An inadequate response, intolerance or contraindication to one non-hormonal vaginal product such as vaginal moisturizers and vaginal lubricants; ***AND***<br>3. An inadequate response, intolerance, or contraindication to at least two vaginal estrogen products |

[+] *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.

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|---|---|
| **Age Restriction** | None |
| **Prescriber Restriction** | None |
| **Coverage Duration** | Initial: 6 months<br>Reauthorization: 12 months |
| **Other criteria** | Reauthorization:<br>1. Condition has improved with use of Osphena; ***AND***<br>2. Prescriber attests that clinical benefit outweighs risk of chronic Osphena use |

## Clinical Background Information and References


1. Osphena (ospemifene) [prescribing information]. Florham Park, NJ: Shionogi Inc; September 2014
2. The North American Menopause Society. Management of Symptomatic Vulvovaginal Atrophy: 2013 Position Statement of The North American Menopause Society. Menopause: The Journal of The North American Menopause Society. 2013;20( 9):888-902
3. Lewis R. ACOG Revises Guidelines on Treating Menopause Symptoms. Medscape. Accessed April 17, 2014. Available: http://www.medscape.com/viewarticle/818280.
4. Bachmann G, Santen R. Treatment of Vaginal Atrophy. UpToDate. Last updated April 4, 2014. Accessed: April, 2014. Available: www.uptodate.com


| 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** |
| 12/1/2020 | 9.045 Osphena Policy retired, new policy created | 1/1/2021 | 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.

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.