

Pharmacy Policy

Osphena

Policy Number: 9.300

Version Number: 2.0

Version Effective Date: 3/1/2022

Product Applicability <input type="checkbox"/> All Plan+ Products	
<p>Well Sense Health Plan</p> <input type="checkbox"/> New Hampshire Medicaid	<p>Boston Medical Center HealthNet Plan</p> <input checked="" type="checkbox"/> MassHealth - MCO <input checked="" type="checkbox"/> MassHealth - ACO <input type="checkbox"/> Qualified Health Plans/ConnectorCare/Employer Choice Direct <input type="checkbox"/> Senior Care Options

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:

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

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Age Restriction	None
Prescriber Restriction	None
Coverage Duration	Initial: 6 months Reauthorization: 12 months
Other criteria	Reauthorization: <ol style="list-style-type: none"> 1. Condition has improved with use of Osphe^a; AND 2. Prescriber attests that clinical benefit outweighs risk of chronic Osphe^a use

Clinical Background Information and References

1. Osphe^a (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

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date	Approved by
12/1/2020	9.045 Osphe ^a Policy retired, new policy created	1/1/2021	P&T Committee
11/11/2021	P&T Annual review: no changes	3/1/2022	P&T Committee

Next Review Date

11/2022

Other Applicable Policies

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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.

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