Pharmacy Medical Necessity Guidelines:
Osphena™ (ospemifene)

Effective: May 12, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FDA-APPROVED INDICATIONS

Osphena (ospemifene) is indicated for:

- The treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause, and
- The treatment of moderate to severe vaginal dryness, a symptom of vulvar and vaginal atrophy, due to menopause

COVERAGE GUIDELINES

The plan may authorize coverage of **Osphena™ (ospemifene)** for Members when the following criterion is met:

1. The Member has had an inadequate response or adverse reaction to, or the provider indicates clinical inappropriateness of treatment with, at least two alternative products, such as oral estrogen therapy and topical estrogen therapy

LIMITATIONS

None

CODES

None

REFERENCES

1. North American Menopause Society. The 2022 hormone therapy position statement of The North American Menopause Society. *Menopause*. 2022;29(7):767-794.
2. Osphena (ospemifene) [prescribing information]. Princeton, NJ: Duchesnay USA, Inc.; February 2024.
3. Premarin (conjugated estrogens) vaginal cream [prescribing information]. Philadelphia, PA: Pfizer Inc.; November 2017.

APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. August 8, 2023: No changes.
2. May 14, 2024: Effective August 1, 2024, updated RxUM fax number and previous trial language.
3. May 13, 2025: No changes
4. May 12, 2026: No changes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services