BlueCross BlueShield of Arizona
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PHARMACY COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 11/17/16**
SECTION: DRUGS	**LAST REVIEW DATE: 11/15/18**
	LAST CRITERIA REVISION DATE: 11/15/18
	ARCHIVE DATE:

OSPHENA® (ospemifene) oral tablet

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

OSPHENA® (ospemifene) oral tablet (cont.)

Criteria:

- **Criteria for initial therapy:** Osphena (ospemifene) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Individual is 18 years of age or older

2. A confirmed diagnosis of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause

3. Individual has failure, contraindication or intolerance **THREE** preferred products (estrogen product with a progestin if have an intact uterus and progestin is not needed if the woman has had an hysterectomy) :
    - Preferred estrogen, oral tabs
        - Conjugated estrogen (such as Premarin)
        - Esterified estrogen (such as Menest)
        - Estradiol (such as Estrace)
        - Estropipate
    - Preferred estrogen, transdermal
        - Estradiol transdermal (such as Alora, Climara, Vivelle-Dot)
    - Preferred estrogen, vaginal
        - Conjugated estrogen Cream (such as Premarin)
        - Estradiol acetate cream (such as Estrace)
        - Estradiol ring (such as Femring)
        - Estradiol tablet (such as Vagifem)
    - Esterified Estrogen-Progestin, oral tabs (such as Prempro, Premphase, Mimvey)
    - Estrogen-Progestin, transdermal (such as CombiPatch)
    - Preferred progestins, if needed:
        - Medroxyprogesterone
        - Micronized progesterone

4. There are **NO** contraindications:
    - Contraindications include:
        - Undiagnosed abnormal genital bleeding
        - Known or suspected estrogen-dependent neoplasia
        - Active DVT, pulmonary embolism (PE), or a history of these conditions
        - Active arterial thromboembolic disease (for example, stroke and myocardial infarction [MI]), or a history of these conditions)
        - Hypersensitivity (for example, angioedema, urticaria, rash, pruritus) to Osphena or any ingredients
        - Known or suspected pregnancy

5. Will not be used simultaneously with other estrogens, or estrogen agonist/antagonists

6. Will not be used simultaneously with fluconazole

7. Will not be used simultaneously rifampin

OSPHENA® (ospemifene) oral tablet (cont.)

8. Will not be used in an individual with severe hepatic impairment (Child-Pugh Class C)

9. Will not be used in an individual with known or suspected breast cancer or a history of breast cancer

Initial approval duration: 12 months

- **Criteria for continuation of coverage (renewal request):** Osphena (ospemifene) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Individual's condition responded while on therapy
    - Response is defined as:
        - Achieved and maintains at least a 50% reduction in dyspareunia

2. The indication for use is one that requires a longer duration than the usual and the provider assesses need for continuation of therapy at least yearly
    - Moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause
        - Any previous attempts at discontinuation have failed as seen by recurrence of symptoms
        - Other alternatives as listed in the criteria for initial therapy section cannot be used

3. Individual has been adherent with the medication

4. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use
    - Contraindications as listed in the criteria for initial therapy

5. There are no significant interacting drugs

Renewal duration: 12 months

Description:

Osphena (ospemifene) is an estrogen agonist-antagonist with tissue selective effects is indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause. Osphena (ospemifene) has agonistic effects on the endometrium, when a product with estrogenic agonistic effects on the endometrium is used, a progestin should be considered to reduce the risk of endometrial cancer. A woman without a uterus does not need a progestin. The use of Osphena (ospemifene) with a progestin was not evaluated in clinical trials.

Menopausal symptoms include hot flushes and night sweats, but may also include other symptoms such as sleep disturbance, joint aches, irritability, mood changes, and genitourinary problems. Numerous studies have been conducted that show the efficacy of hormonal replacement therapy in controlling menopausal symptoms. Treatment options for dyspareunia include vaginal moisturizers and lubricants, vaginal estrogen replacement (e.g. ring, vaginal tablet, cream), and oral estrogen replacement.

OSPHENA® (ospemifene) oral tablet (cont.)

Estrogen-containing products are the most effective FDA-approved therapies for treatment of moderate to severe vasomotor symptoms (such as hot flashes and night sweats) associated with menopause and for treatment of moderate to severe symptoms of vulvar and vaginal atrophy (such as dryness, itching, and burning) associated with menopause. Estrogen alone may be prescribed for women who have undergone a hysterectomy. In women with an intact uterus, a progestational agent should be added to the estrogen to protect the endometrium from the risk of unopposed estrogen causing development of hyperplasia and endometrial cancer.

For women who cannot use estrogen for control of severe vasomotor symptoms, non-estrogen containing medications have been used. Other agents that have been shown to be effective in the management of menopausal symptoms include other selective serotonin receptor inhibitors such as citalopram, escitalopram, fluoxetine, and paroxetine and venlafaxine, a selective serotonin norepinephrine reuptake inhibitor.

Definitions:

Vaginal atrophy: also known as atrophic vaginitis, vulvovaginal atrophy, or urogenital atrophy:
Is characterized by dryness, inflammation, and thinning of the epithelial lining of the vagina and lower urinary tract due to loss of estrogen.

Dyspareunia:
Painful sexual intercourse which can be moderate to severe, is a symptom of vulvar & vaginal atrophy from menopause.

Resources:

Osphena. Package Insert. Revised by manufacturer 8/2015. Accessed 9/16/16.
Gass MLS, Bachmann GA, Goldstein SR, et al.: Management of symptomatic vuvovaginal atrophy: 2013 position statement of The North American Menopause Society. Menopause 2013, 20 (9):888-902

Goodman NF, Cobin RH, Ginzburg SB, et al.: American Association of Clinical Endocrinologists Medical Guidelines for Clinical Practice for the Diagnosis and Treatment of Menopause. Endocrine Pract 2011, 17 (Sup 6 Nov/Dec):1-25

UpToDate: Clinical manifestations and diagnosis of genitourinary syndrome of menopause (vulvovaginal atrophy). Current through Sep 2017. https://www-uptodate-com.mwu.idm.oclc.org/contents/clinical-manifestations-and-diagnosis-of-genitourinary-syndrome-of-menopause-vulvovaginal-atrophy?source=search_result&search=vulvar%20and%20vaginal%20atrophy&selectedTitle=5~150

UpToDate: Treatment of genitourinary syndrome of menopause (vulvovaginal atrophy). Current through Sep 2017. https://www-uptodate-com.mwu.idm.oclc.org/contents/treatment-of-genitourinary-syndrome-of-menopause-vulvovaginal-atrophy?source=search_result&search=vulvar%20and%20vaginal%20atrophy&selectedTitle=1~150

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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information

Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information

Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information

Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information

Medication Name:	Strength:	Dosage Form:
Directions for Use:	Quantity: / Refills:	Duration of Therapy/Use:

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

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6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

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