BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 5/20/2021
LAST REVIEW DATE:
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

ORGOVYX™ (relugolix)

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.

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.**

ORGOVYX™ (relugolix)

Criteria:

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

  1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with an Oncologist or Urologist

  2. Individual is 18 years of age or older

  3. A confirmed diagnosis of **ONE** of the following:
     a. Advanced prostate cancer

     b. Other request for a specific oncologic direct treatment use that is found and listed in the National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A

  4. Individual is a candidate for at least 1 year of continuous androgen deprivation therapy for the management of androgen-sensitive advanced prostate cancer with **ONE** of the following:
     a. Evidence of biochemical (PSA) or clinical relapse following local primary intervention with curative intent, such as surgery, radiation therapy, cryotherapy, or high-frequency ultrasound and not a candidate for salvage treatment by surgery

     b. Newly diagnosed androgen-sensitive metastatic disease

     c. Advanced localized disease unlikely to be cured by local primary intervention with either surgery or radiation with curative intent

  5. Individual has failure, contraindication or intolerance to Leuprolide acetate depot

  6. **ALL** of the following **baseline tests** have been completed before initiation of treatment with continued monitoring as clinically appropriate:
     a. Baseline serum testosterone of ≥ 150 ng/dL

     b. Baseline serum PSA concentration of > 2.0 ng/mL (2.0 microgram [µg]/L), or, when applicable, post radical prostatectomy of > 0.2 ng/mL (0.2 µg/L) or post radiotherapy, cryotherapy, or high frequency ultrasound > 2.0 ng/mL (2.0 µg/L) above the post interventional nadir

     c. Eastern Cooperative Oncology Group performance status of 0 or 1

  Initial approval duration: 6 months

ORGOVYX™ (relugolix)

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

  1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an Oncologist or Urologist

  2. Individual's condition has reponded while on therapy.
     a. Response is defined as:
        i. Achieved and is maintaining serum testosterone suppression to medical castration levels (< 50 ng/dL)
        ii. No disease progression

  3. Individual has been adherent with the medication

  4. Individual has not developed any significant level 4 adverse drug effects that may exclude continued use
     a. Significant adverse effect such as:
        i. QT/QTc interval prolongation

  5. There are no significant interacting drugs

  Renewal duration: 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

  1. **Off-Label Use of a Non-Cancer Medications**

  2. **Off-Label Use of a Cancer Medication for the Treatment of Cancer without a Specific Coverage Guideline**

Description:

Orgovyx (relugolix) is a gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the treatment of adult patients with advanced prostate cancer. GnRH receptor antagonists competitively bind to pituitary GnRH receptors, in so doing, reduce the release of luteinizing hormone (LH) and follicle-stimulating hormone (FSH), and consequently testosterone.

Resources:

Orgovyx (relugolix) product information, revised by Myovant 12-2020. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed March 01, 2021.

ORGOVYX™ (relugolix)

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Prostate Cancer Version 2.2021 – Updated February 17, 2021 ; https://www.nccn.org. Accessed March 01, 2021.

Shore ND, Saad F, Cookson MS, et al: Oral Relugolix for Androgen-Depravation Therapy in Advanced Prostate Cancer. NEJM 2020; 382 Jun 4:2187-2196.

Lee RJ, Smith MR. Initial systemic therapy for castration-sensitive prostate cancer. In: UpToDate, Volgelzan N, Lee WR, Ricjie JP, Savarese DMF (Eds), UpToDate, Waltham MA.: UpToDate Inc. http://uptodate.com. Accessed on March 03, 2021.

Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.

Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.