Oscar Clinical Guideline: Orgovyx (relugolix) (PG089-REG, Ver. 6)

Orgovyx (relugolix)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Orgovyx (relugolix) is FDA-approved for the treatment of adult patients with advanced prostate cancer. Treatment options for prostate cancer include observation (watching without treatment), surgery radiation (using strong beams of energy), and medicines (chemotherapy that stops cancer cells from increasing, targeted therapy that kills cancer cells only, or hormone treatment that stops the body from making hormones that may help cancer cells grow). Orgovyx (relugolix) is an oral gonadotropin-releasing hormone (GnRH) receptor antagonist that works by competitively binding to pituitary GnRH receptors, thereby, reducing the release of luteinizing hormone (LH) and follicle-stimulating hormone (FSH), and consequently testosterone. Testosterone helps prostate cancer to grow until or unless cellular adaptation results in hormonal resistance.

NOTE: The Plan requires that members be unable to use, or have tried and failed preferred product(s) first. Requests for non-formulary medications are also subject to Medical Necessity Criteria for Non-Formulary Drugs (PG069).

Definitions

"**Castration sensitive**"refers to a type of prostate cancer that is highly responsive to medical treatment.

"**Gonadotropin releasing hormone (GnRH)**" refers to a neurohormone that is responsible for the production of sex hormones.

"**Improvement in disease-related symptoms**" refers to a positive change in symptoms associated with prostate cancer. These symptoms could include pain reduction, improvement in urinary symptoms, or overall improvement in the quality of life.

"**Metastatic disease**" is the spread of disease from the initial site to another part or parts of the body.

"**PSA (prostate- specific antigen)**" refers to a protein produced by prostate cells that is often found at higher levels in most cancerous prostate cells. An elevated PSA can be indicative of a fast-growing tumor or a cancer that is more likely to spread to other parts of the body.

"**Stable disease by imaging**" refers to the absence of disease progression as observed through imaging tests such as CT scans, MRI scans, or bone scans. This indicates that the cancer has not worsened since starting Orgovyx treatment.

"**Testosterone**" is the primary sex hormone in males that is associated with the development of reproductive tissues such as the prostate.

Medical Necessity Criteria for Initial Authorization

The Plan considers **Orgovyx (relugolix)** medically necessary when **ONE** of the following criteria are met:

1. Orgovyx (relugolix) is being used to treat stage IV advanced, metastatic cancer [based upon applicable state regulations]***; OR***
2. The following criteria are met:
    a. The member is 18 years of age or older***; AND***
    b. The member has a diagnosis of androgen-sensitive advanced prostate cancer with **ONE** of the following:
        i. Evidence of biochemical (PSA) or clinical relapse following local primary intervention with curative intent (such as surgery, radiation therapy, cryotherapy, or high-frequency ultrasound)***; or***
        ii. Newly diagnosed androgen-sensitive metastatic disease***; or***

iii. Advanced localized disease not suitable for local primary surgical intervention with curative intent***; AND***

c. The member meets **ONE** (1) of the following:
   i. is unable to use, or has tried and failed leuprolide injection***; or***
   ii. has established cardiovascular disease (e.g., history of myocardial ischemia, coronary artery disease, myocardial infarction, cerebrovascular accident, angina pectoris, or coronary artery bypass) **OR** multiple cardiovascular risk factors (2 or more)***; AND***
d. Chart documentation and supporting laboratory test results are provided for review to substantiate the above listed requirements.

If the above prior authorization criteria are met, Orgovyx (relugolix) will be approved for 6 months.

Medical Necessity Criteria for Reauthorization

Reauthorization for 12 months will be granted if recent chart documentation (within the last 6 months) shows **ONE** of the following since starting Orgovyx (relugolix):

1. The member has achieved and maintained serum testosterone suppression to castrate levels, defined as serum total testosterone concentration <50 ng/dL***; OR***
2. The member has demonstrated a clinically significant response to Orgovyx therapy as evidenced by **ANY ONE** of the following:
   a. ≥50% PSA decline from baseline***; or***
   b. Improvement in disease-related symptoms (e.g., documented reduction in pain, improved urinary function, or enhanced quality of life scores)***; or***
   c. Stable disease by imaging (no new lesions or progression of existing lesions on bone scan, CT, or MRI)***; or***
   d. Reduction in size of measurable tumor lesions***; or***
   e. No initiation of new anti-cancer therapy***; or***
   f. Physician documentation of clinical benefit.

Experimental or Investigational / Not Medically Necessary

Orgovyx (relugolix) for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

References

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Clinical Guideline Revision / History Information

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