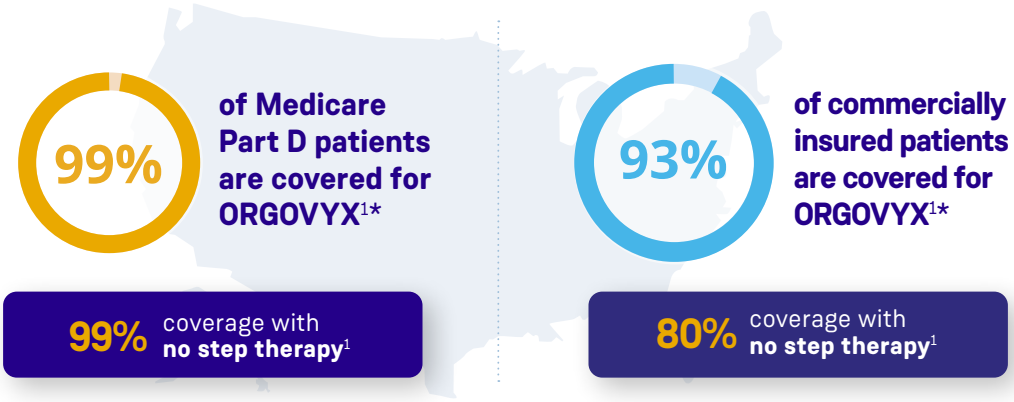
PRIOR AUTHORIZATION (PA) CONSIDERATIONS.

Some health plans may require a PA evaluation and approval before providing coverage.

This resource is provided to support patient access to ORGOVYX® as prescribed. It is for informational purposes only and is not intended to provide recommendations. This is not a comprehensive description of potential payer access and coding requirements for ORGOVYX. The prescriber is solely responsible for coding, determining coverage/reimbursement requirements, and submitting the necessary information to payers. Sumitomo Pharma America and Pfizer do not make any representation or guarantee concerning reimbursement, coverage, or coding for any item or service. Nothing within this resource is intended to be a substitute for, or influence on, prescribers' independent medical judgment.



Scan to see your local coverage

*This coverage information is provided for informational purposes only; individual plans vary, and this may not include all plans. Sumitomo Pharma America and Pfizer make no representation or guarantee concerning coverage or reimbursement; please check with individual payers for plan-specific coverage and reimbursement information and requirements. Nothing herein may be construed as an endorsement, approval, recommendation, representation, or warranty of any kind by any plan or insurer referenced. This information is subject to change without notice.

Understanding PA requirements after you prescribe ORGOVYX

When you prescribe ORGOVYX for the treatment of advanced prostate cancer, fill the prescription the way you normally do. Your patient's health plan may require a PA before coverage is approved for ORGOVYX. In such cases, the patient's health plan has certain requirements that must be met to determine whether the medication is covered for the particular patient. Inside this resource, healthcare providers can find information regarding:

- **Considerations for submitting a PA**
- **ICD-10-CM code information**
- **Examples of PA criteria for ORGOVYX**

ICD-10-CM=*International Classification of Diseases, Tenth Revision, Clinical Modification*.

INDICATION

ORGOVYX® (relugolix) is a gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the treatment of adult patients with advanced prostate cancer.

IMPORTANT SAFETY INFORMATION

Contraindication

ORGOVYX is contraindicated in patients with severe hypersensitivity to relugolix or to any of the product components.

Please see Important Safety Information throughout and full Prescribing Information for ORGOVYX.

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Prescriber considerations for submitting a PA.

Reminders and tips when completing a PA for your patients

Each health plan may have their own unique PA form with varying requirements. It is important to gather necessary information during the patient's first appointment to ensure successful navigation of the process with minimal delays.

This necessary information may include, but is not limited to:

- ☐ Patient demographics (date of birth, gender, phone, email, and address)
- ☐ Patient insurance information (copy front and back of patient's prescription [drug] and health [medical] card)
- ☐ Patient health charts and past medical history
  - Including comorbidities and treatment history (PSA, lab results, imaging, treatment plan)

Remember: Submit a PA through a patient's pharmacy benefits

Drug information

Prescribed by:

- ☐ Oncologist and/or urologist

Prescription information:

- ☐ Quantity
- ☐ Days supplied

Diagnosis coding.*

Remember, most payers require inclusion of an ICD-10-CM diagnosis code in order to evaluate PA submissions and determine coverage

Scan or click the QR code to search for ICD-10-CM codes

icd10cmtool.cdc.gov/?fy=FY2024

FDA=US Food and Drug Administration; ICD-10-CM=*International Classification of Diseases, Tenth Revision, Clinical Modification*; PA=prior authorization; PSA=prostate-specific antigen.

***The ICD-10-CM information provided above is intended for informational purposes only and is not a comprehensive list of potential coding requirements for ORGOVYX. Coding and coverage policies change periodically and often without warning. The healthcare provider is solely responsible for determining coverage and reimbursement parameters and accurate and appropriate coding for treatment of his/her patients. The information provided in this section should not be considered a guarantee of coverage or reimbursement for ORGOVYX. The code shown above is only a general suggestion and is not intended to encourage or suggest a use of any drug that is inconsistent with FDA-approved use.**

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions

QT/QTc Interval Prolongation: Androgen deprivation therapy, such as ORGOVYX may prolong the QT/QTc interval. Providers should consider whether the benefits of androgen deprivation therapy outweigh the potential risks in patients with congenital long QT syndrome, congestive heart failure, or frequent electrolyte abnormalities and in patients taking drugs known to prolong the QT interval. Electrolyte abnormalities should be corrected. Consider periodic monitoring of electrocardiograms and electrolytes.

Hypersensitivity: Angioedema was reported in 0.2% of patients treated with ORGOVYX in HERO. Hypersensitivity reactions, including pharyngeal edema and other serious cases of angioedema, have been reported in post-marketing with ORGOVYX. Advise patients who experience any symptoms of hypersensitivity to temporarily discontinue ORGOVYX and promptly seek medical care. Discontinue ORGOVYX for severe hypersensitivity reactions and manage as clinically indicated.

Please see Important Safety Information throughout and full Prescribing Information for ORGOVYX.

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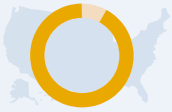
Examples of PA criteria questions.



For most insurance plans nationally (ie, commercial and Medicare Part D), ORGOVYX is covered with no step therapy[1]

These examples are provided for informational purposes only and are not a complete list of criteria that a health plan may consider when making coverage decisions. It is the prescriber's responsibility to verify payer-specific PA criteria to ensure accuracy/completeness, as requirements may change over time.

Common Patient History Questions

- Is the patient 18 years or older?
- Is the patient diagnosed with advanced prostate cancer?

Less Common Patient History Questions

- Is the patient at risk for cardiovascular disease?
- Is the patient not a candidate for another ADT?
- Is the patient currently receiving therapy with ORGOVYX?
- Is the patient using intermittent ADT?

Reauthorization Questions for Continuation

Some health plans may require periodic reauthorization of a patient's therapy as part of the plans' assessment to continue treatment coverage.

- Has the patient experienced a clinical benefit from ORGOVYX therapy?
- Does the patient show evidence of progressive disease while on ORGOVYX therapy?
- Has the patient experienced an unacceptable level of toxicity to ORGOVYX therapy?

ADT=androgen deprivation therapy.

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and Precautions (cont'd)

Embryo-Fetal Toxicity: The safety and efficacy of ORGOVYX have not been established in females. Based on findings in animals and mechanism of action, ORGOVYX can cause fetal harm and loss of pregnancy when administered to a pregnant female. Advise males with female partners of reproductive potential to use effective contraception during treatment and for 2 weeks after the last dose of ORGOVYX.

Laboratory Testing: Therapy with ORGOVYX results in suppression of the pituitary gonadal system. Results of diagnostic tests of the pituitary gonadotropic and gonadal functions conducted during and after ORGOVYX may be affected. The therapeutic effect of ORGOVYX should be monitored by measuring serum concentrations of prostate-specific antigen (PSA) periodically. If PSA increases, serum concentrations of testosterone should be measured.

Please see Important Safety Information throughout and full Prescribing Information for ORGOVYX.

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The ORGOVYX Support Program is dedicated to providing ongoing support to help patients prescribed ORGOVYX start and stay on track.

ORGOVYX® SUPPORT PROGRAM

Reimbursement Managers (RMs) are available to help educate providers about ORGOVYX Support Program services and payer coverage criteria

Once written patient consent is on file:

- RMs can discuss patient-specific information
- RMs can receive copies of approved/denied PA documents from HCP offices to assist with resolving coverage issues

Learn more by calling 1-833-ORGOVYX (1-833-674-6899), Monday–Friday, 8 AM-8 PM ET.

IMPORTANT SAFETY INFORMATION (cont'd)

Adverse Reactions

Serious adverse reactions occurred in 12% of patients receiving ORGOVYX. Serious adverse reactions in ≥0.5% of patients included myocardial infarction (0.8%), acute kidney injury (0.6%), arrhythmia (0.6%), hemorrhage (0.6%), and urinary tract infection (0.5%). Fatal adverse reactions occurred in 0.8% of patients receiving ORGOVYX including metastatic lung cancer (0.3%), myocardial infarction (0.3%), and acute kidney injury (0.2%). Fatal and non-fatal myocardial infarction and stroke were reported in 2.7% of patients receiving ORGOVYX.

Most common adverse reactions (≥10%) and laboratory abnormalities (≥15%) in patients receiving ORGOVYX were hot flush (54%), glucose increased (44%), triglycerides increased (35%), musculoskeletal pain (30%), hemoglobin decreased (28%), alanine aminotransferase increased (27%), fatigue (26%), aspartate aminotransferase increased (18%), constipation (12%), and diarrhea (12%).

Drug Interactions

Co-administration of ORGOVYX with a P-gp inhibitor increases the area under the curve (AUC) and maximum concentration (C_{max}) of ORGOVYX, which may increase the risk of adverse reactions associated with ORGOVYX. Avoid co-administration of ORGOVYX with oral P-gp inhibitors. If co-administration is unavoidable, take ORGOVYX first, separate dosing by at least 6 hours, and monitor patients more frequently for adverse reactions. Treatment with ORGOVYX may be interrupted for up to 2 weeks for a short course of treatment with certain P-gp inhibitors. If treatment with ORGOVYX is interrupted for more than 7 days, resume administration of ORGOVYX with a 360 mg loading dose on the first day, followed by 120 mg once daily.

Co-administration of ORGOVYX with a combined P-gp and strong CYP3A inducer decreases the AUC and C_{max} of ORGOVYX, which may reduce the effects of ORGOVYX. Avoid co-administration of ORGOVYX with combined P-gp and strong CYP3A inducers. If co-administration is unavoidable, increase the ORGOVYX dose to 240 mg once daily. After discontinuation of the combined P-gp and strong CYP3A inducer, resume the recommended ORGOVYX dose of 120 mg once daily.

Please see Important Safety Information throughout and full Prescribing Information for ORGOVYX.

Reference: 1. Data on file. Formulary data provided by MMIT, LLC, as of April 2024. Sumitomo Pharma America, Inc.

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