Relugolix (ORGOVYX)
Criteria for Use
May 2025

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at the *PBM INTERnet* or *PBM INTRAnet* site for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive relugolix.

- ☐ Unmanageable drug interaction identified
- ☐ End stage renal disease (with or without hemodialysis)
- ☐ Child-Pugh class C
- ☐ QTc > 470 msec, Q-wave infarction or congenital long QT syndrome
- ☐ Uncontrolled or symptomatic ventricular arrhythmias in the prior 6 months
- ☐ Congestive heart failure (NYHA Class 3 or 4) in the prior 6 months
- ☐ A thromboembolic event in the prior 6 months
- ☐ Gastrointestinal condition that may interfere with relugolix absorption or inability to swallow tablets whole
- ☐ Known history of non-adherence with oral medication, follow-up appointments or laboratory visits

Inclusion Criteria

All of the following must be fulfilled to meet criteria:

- ☐ Care provided by a VA or VA Community Care provider of urology or hematology/oncology services
- ☐ Goals of care and role of Palliative Care consult have been discussed and documented.
- ☐ Hormone-sensitive, advanced adenocarcinoma of the prostate

Additional Inclusion Criteria

One of the following must be fulfilled to meet criteria^:

- ☐ Inability to maintain castrate levels of serum testosterone on LHRH agonist therapy (taking into consideration the initial time required to reach castrate level)
- ☐ Known hypersensitivity to LHRH agonist analogs or their components
- ☐ Rapid decrease in testosterone levels needed due to organ-threatening disease

^ There is a lack of conclusive prospective data to support use of relugolix for cardiovascular benefit alone (i.e. reduction in Major Cardiovascular Events), therefore is not an appropriate indication for use.

Additional Inclusion Criteria *if applicable*

- ☐ Advise male patients with female partners of childbearing potential to use effective contraception during and for 2 weeks following the last dose of relugolix