NHS
North East London

Primary Care Prescribing Support Factsheet

Prescribing and Supply of Relugolix (Orgovyx®)

Document control	
Version	1.0
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1. What is Relugolix (Orgovyx®)?

Relugolix (Orgovyx®) is a non-peptide GnRH receptor antagonist that competitively binds to GnRH receptors in the anterior pituitary gland preventing the secretion of luteinising hormone (LH) and follicle-stimulating hormone (FSH). Consequently, the production of testosterone from the testes is reduced.

Clinical trial evidence suggest that relugolix is superior to other androgen deprivation therapy (e.g. leuprolide) at reducing testosterone to levels that stop cancer growth in the long term, and reduces the risk of serious cardiovascular events. An indirect treatment comparison suggests that relugolix works as well as other ADTs, but this is uncertain.

2. Indication: for treating hormone-sensitive prostate cancer in adults

3. Formulary and Pathway Group (FPG) approval

NEL Formulary status	Amber, specialist initiated
Date approved	Oct 2024

4. National approval e.g. NICE

NICE TA995 has approved its use for treating hormone-sensitive prostate cancer in adults:

- with advanced hormone-sensitive prostate cancer
- alongside radiotherapy for high-risk localised or locally advanced hormone sensitive prostate cancer
- as neoadjuvant treatment before radiotherapy for high-risk localised or locally advanced hormone-sensitive prostate cancer.

For full information refer to Summary of Product Characteristics for relugolix (Orgovyx).

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5. Prescribing and Supply Information

<table>
<tr><td>Dose</td><td>120mg once daily</td></tr>
<tr><td>Duration</td><td>Lifelong – unless switched by oncologist due to disease progression.</td></tr>
<tr><td>Supply</td><td>Following specialist initiation, 1 month supply issued from hospital.
Then, ongoing supply to be issued from GP on repeat prescription.</td></tr>
<tr><td>Renal impairment</td><td>No dose adjustment in patients with mild or moderate renal impairment is required.</td></tr>
<tr><td>Hepatic impairment</td><td>No dose adjustment in patients with mild or moderate hepatic impairment is required.</td></tr>
<tr><td>Monitoring</td><td>All monitoring will be done by urology team via automated remote monitoring system (RMS). Patients will be reviewed in clinic every 4 months to check PSA, re-imaging (frequency will depend on patient and disease-specific state).

No active monitoring required from GP.</td></tr>
<tr><td>Criteria for referral back to Parent Team</td><td>• Progression to CKD stage 5
• Incidental finding of QTc prolongation
• Initiation of antipsychotics or methadone due to risk of QTC prolongation.</td></tr>
<tr><td>Interactions</td><td>Subject to interactions with P-glycoprotein (P-gp) inhibitors and strong CYP3A4 inducers

<table>
<tr><th>Common P-glycoprotein (P-gp) inhibitors</th><th>Strong CYP3A4 inducers</th></tr>
<tr><td>Amiodarone</td><td>Carbamazepine</td></tr>
<tr><td>Azithromycin</td><td>Phenytoin</td></tr>
<tr><td>Carvedilol</td><td>Rifampicin</td></tr>
<tr><td>Clarithromycin</td><td></td></tr>
<tr><td>Erythromycin</td><td></td></tr>
<tr><td>Ketoconazole (oral)</td><td></td></tr>
<tr><td>Itraconazole</td><td></td></tr>
<tr><td>Quinine</td><td></td></tr>
<tr><td>Ranolazine</td><td></td></tr>
<tr><td>Verapamil</td><td></td></tr>
</table>
This list is not exhaustive – please check the latest BNF and SPC for the</td></tr>
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	most up-to-date information. **If no alternatives to the above drugs can be used please refer patient back to parent urology team.**

6. Prescribing Support

Referrals and enquiries sent via email are to be answered within **5 working days** of receipt.

Team	Email Address
Barts Health	
Whipps Cross/Royal London Prostate Team	urology.prostate@nhs.net
St Bartholemew's Oncology Team	bartshealth.guonccns@nhs.net
Homerton	
CNS Team	huh-tr.urologyspecialistnurses.nhs.uk
Secretaries	huh-tr.urologymedsec@nhs.net
Barking, Havering and Redbridge University Hospitals	
Helen Killen, Urology Consultant	helen.killen@nhs.net
Maria Martinou, Urology Consultant	maria.martinou@nhs.net
Andrew Bartlett, Urology Consultant	andrew.bartlett2@nhs.net
Urology CNS	bhrut.urologycns@nhs.net