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## Relugolix for Prostate Cancer

The details of side-effects, cautions, contraindications and interactions are not a complete list and the current BNF (<https://bnf.nice.org.uk/>) and the SPC (<https://www.medicines.org.uk/emc/>) remain authoritative.

The SY ICB Medicines Optimisation Team will alert primary care prescribers if any significant changes in review or monitoring arrangements of Specialist Initiation medicines they prescribe are recommended.

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| <b>Background Information</b>    | <ul style="list-style-type: none"> <li>Androgen deprivation therapy (ADT) is an effective treatment for prostate cancer.</li> <li>It can be used in the: <ul style="list-style-type: none"> <li>non-metastatic setting- on its own as palliative treatment, or alongside radiotherapy to improve efficacy of curative intent treatment</li> <li>metastatic setting- on its own, or alongside hormonal treatment or chemotherapy to optimise palliative treatment</li> </ul> </li> <li>A multi-disciplinary approach is adopted to select the most appropriate treatment plan for a patient diagnosed with prostate cancer, with involvement of (but not limited to) urologists, oncologists and clinical nurse specialists.</li> <li>If ADT is indicated, this will be initiated in the secondary care setting. At least 4 weeks of medication will be supplied at initiation.</li> <li>ADT may need to continue indefinitely (lifelong), or for a limited duration (6 months to 3 years) depending on treatment intent. This information will be communicated to the primary care team.</li> </ul> |
| <b>Therapeutic class</b>         | <p>Androgen Deprivation Therapy (ADT) reduces circulating testosterone levels and is an effective treatment option for advanced hormone-sensitive prostate cancer. Other ADT drug treatments are given as injections, and are associated with cardiovascular events, initial testosterone surge and prolonged time to testosterone recovery after stopping treatment.</p> <p>Injectable ADT is also associated with site reactions, infections and swollen and sore injection sites. Relugolix is an oral treatment, so may be more convenient for some people than injectable ADT drug treatments.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Indication</b>                | <p>Relugolix is an androgen deprivation therapy (ADT). It is indicated as an option for treating prostate cancer in adults:</p> <ul style="list-style-type: none"> <li>With advanced hormone-sensitive prostate cancer</li> <li>Alongside radiotherapy for high-risk localised or locally advanced hormone-sensitive prostate cancer</li> <li>As neoadjuvant treatment before radiotherapy for high-risk localised or locally advanced hormone-sensitive prostate cancer.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Dosage and administration</b> | <p><b>Starting dose on day 1</b> (to be prescribed by secondary care):360mg<br/> <b>Maintenance dose on days 2 onwards:</b> 120mg daily</p> <p>If a dose is missed, relugolix must be taken as soon as the patient remembers. If the dose was missed by more than 12 hours, the missed dose must not be taken and regular dosing schedule should be resumed the following day.</p> <p>If treatment with relugolix is interrupted for greater than 7 days, it must be restarted with a loading dose of 360 mg on the first day, followed with a dose of 120 mg once daily.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |

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| <b>Cautions and Contraindications</b> | <p>Hypersensitivity to the active substance or to any of the excipients listed in section 6.1 of the SmPC. Caution advised in history or risk of QT-interval prolongation; risk factors for cardiovascular disease; risk factors for osteoporosis. Monitor liver function in patients with known or suspected hepatic disorder. The kinetics of relugolix in patients with severe hepatic impairment has not been evaluated. Severe renal impairment: exposure to relugolix in patients with severe renal impairment may be increased by up to two-fold and thus caution in patients with severe renal impairment is warranted. The amount of relugolix removed by haemodialysis is unknown. Cardiovascular disease such as myocardial infarction and stroke has been reported in the medical literature in patients with androgen deprivation therapy. Therefore, all cardiovascular risk factors should be considered.</p> <p><b>Please see SmPC for comprehensive information.</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                  |
| <b>Contraception and fertility</b>    | <p><u>Contraception</u><br/>It is not known whether relugolix or its metabolites are present in semen. Based on findings in animals and mechanism of action, if a patient engages in sexual intercourse with a woman of childbearing potential, effective contraception during treatment and for 2 weeks after the last dose of relugolix must be used.</p> <p><u>Fertility</u><br/>Based on findings in animals and mechanism of action, relugolix may impair fertility in males of reproductive potential</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                  |
| <b>Adverse Drug Reactions</b>         | <p><b>Very common (≥1/10):</b> Hot flush*, diarrhoea, constipation, musculoskeletal pain, fatigue</p> <p><b>Common (≥1/100 to &lt;1/10):</b> anaemia*, weight increase*, insomnia, dizziness, headache, nausea, hyperhidrosis (inc. night sweats) *, rash, gynaecomastia*, libido decrease*, depression, hypertension, glucose increased, triglyceride increased, blood cholesterol increased</p> <p>*known physiological consequence of testosterone suppression</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                                                  |
| <b>Monitoring</b>                     | <p><b>Specialist- Baseline</b></p> <ul style="list-style-type: none"> <li>• Serum PSA</li> <li>• U+Es, bone profile, liver function test</li> <li>• Blood glucose levels</li> <li>• Full blood count</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <p><b>GP- Every 6 months*</b></p> <ul style="list-style-type: none"> <li>• PSA</li> </ul> <p>*In certain instances, specialists will monitor a patient's PSA</p> |
| <b>Interactions</b>                   | <ul style="list-style-type: none"> <li>• Co-administration of relugolix and oral P-glycoprotein (P-gp) inhibitors should be avoided. Co-administration of relugolix with other oral P-gp inhibitors also may increase the AUC and Cmax of relugolix, therefore may increase the risk of adverse reactions. If co-administration with once or twice daily oral P-gp inhibitors cannot be avoided, relugolix should be taken first, with the oral P-gp inhibitors taken 6 hours after. Patients should be monitored more frequently for adverse reactions. Alternatively, treatment with relugolix may be interrupted for up to 2 weeks for a short course of treatment with a P-gp inhibitor. For further advice please see <a href="#">Relugolix   Interactions   BNF   NICE</a>.</li> <li>• Since androgen deprivation treatment may prolong the QTc interval, the concomitant use of relugolix with medicinal products known to prolong the QTc interval or medicinal products able to induce torsades de pointes such as class IA (e.g. quinidine, disopyramide) or class III (e.g. amiodarone, sotalol, dofetilide, ibutilide) antiarrhythmic medicinal products, methadone, moxifloxacin, antipsychotics, etc. should be carefully evaluated. A thorough QT/QTc study showed that there was no intrinsic effect of relugolix on prolongation of the QTc interval.</li> <li>• Co-administration of relugolix with combined P-gp and strong CYP3A inducers may decreased the AUC and Cmax of relugolix and may therefore reduce the therapeutic effects of relugolix. Therefore, it should be avoided where possible. If co-administration cannot be avoided, the relugolix dose should be increased to 240mg once daily. After discontinuation of the combined P-gp and strong CYP3A inducer, the recommended dose of relugolix should be resumed.</li> </ul> |                                                                                                                                                                  |

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|                               |                                                                                                                                                                        |                                                           |                                                |                                                               |
|                               | <b>Medicine</b>                                                                                                                                                        | <b>Therapeutic dose of relugolix</b>                      | <b>Therapeutic dose of associated medicine</b> | <b>Comments</b>                                               |
|                               | Abiraterone                                                                                                                                                            | No dose adjustment required                               | No dose adjustment required                    | Abiraterone is not an inhibitor/inducer of CYP3A4 and/or P-gp |
|                               | Apalutamide                                                                                                                                                            | An increased dose of relugolix is recommended (240mg/day) | No dose adjustment required                    | Apalutamide is a strong inducer of P-gp and CYP3A4            |
|                               | Darolutamide                                                                                                                                                           | No dose adjustment required                               | No dose adjustment required                    | Darolutamide is a weak inducer of CYP3A4                      |
|                               | Docetaxel                                                                                                                                                              | No dose adjustment required                               | No dose adjustment required                    | Docetaxel is not an inhibitor/inducer of CYP3A4 and/or P-gp   |
|                               | Enzalutamide                                                                                                                                                           | No dose adjustment required                               | No dose adjustment required                    | Enzalutamide is a strong CYP3A4 inducer and P-gp inhibitor    |
| <b>Additional information</b> | <b>Specialist support/resources available to GP including patient information:</b><br>Summary of Product Characteristics (SPC) <a href="#">Orgovyx, INN: relugolix</a> |                                                           |                                                |                                                               |
| <b>Patient information</b>    | Patient information leaflet (PIL) <a href="#">orgovyx-patient-information.pdf</a>                                                                                      |                                                           |                                                |                                                               |

## **Contact names and details**

| <b>Hospital</b>                         | <b>Contact Details</b>                                                                                                     | <b>Telephone number</b>     | <b>Email</b>                                                                             |
|-----------------------------------------|----------------------------------------------------------------------------------------------------------------------------|-----------------------------|------------------------------------------------------------------------------------------|
| <b>Royal Hallamshire Hospital (RHH)</b> | Main Switchboard                                                                                                           | 01142711900                 |                                                                                          |
|                                         | Crucible pharmacy at the Royal Hallamshire Hospital, C Floor, Royal Hallamshire Hospital, Glossop Road, Sheffield, S10 2SB | 0114 2712658 / 0114 2712552 | <a href="mailto:sth.pharmacydispensaryrhh@nhs.net">sth.pharmacydispensaryrhh@nhs.net</a> |
|                                         | RHH Urology Outpatient Department                                                                                          | 0114 27 12255               |                                                                                          |
|                                         | Main Switchboard                                                                                                           | 0114 226 5000               |                                                                                          |

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|-------------------------------------------------------------|---------------------------|------------------------------------|----------------------------------------------------------------------------------------------|
| <b>Weston Park Cancer Centre (WPCC)</b>                     | Pharmacy                  | 0114 226 5102                      | <a href="mailto:sth.pharmacydispensarywph@nhs.net">sth.pharmacydispensarywph@nhs.net</a>     |
| <b>Barnsley Hospital NHS Foundation Trust (BHFT)</b>        | Main switchboard          | 01226 730000                       |                                                                                              |
|                                                             | BHFT Pharmacy direct line | 01226 432857                       | <a href="mailto:barnsley.pharmacy@nhs.net">barnsley.pharmacy@nhs.net</a>                     |
|                                                             | BHFT Urology              |                                    | <a href="mailto:bdg-tr.urology@nhs.net">bdg-tr.urology@nhs.net</a>                           |
| <b>Doncaster and Bassetlaw Teaching Hospitals NHS Trust</b> | Main switchboard          | 01302 366666                       |                                                                                              |
|                                                             | Pharmacy                  | 01302 644763<br>Or<br>01302 644325 | <a href="mailto:dbth.medicines.information@nhs.net">dbth.medicines.information@nhs.net</a>   |
|                                                             | DBTH Urology              |                                    | <a href="mailto:dbth.urologyreferrals@nhs.net">dbth.urologyreferrals@nhs.net</a>             |
| <b>The Rotherham NHS Foundation Trust</b>                   | Main Switchboard          | 01709 820000                       |                                                                                              |
|                                                             | Main Pharmacy Dept        | 01709 424472                       | <a href="mailto:rgh-tr.pharmacyclinicalteam@nhs.net">rgh-tr.pharmacyclinicalteam@nhs.net</a> |
|                                                             | TRFT Urology              | 01709 425964                       | <a href="mailto:rgh-tr.urologycns@nhs.net">rgh-tr.urologycns@nhs.net</a>                     |

## **References**

1. National Institute for Health and Care Excellence. Technology Appraisal 995; Relugolix for treating hormone-sensitive prostate cancer 14th August 2024. Available at: [Overview | Relugolix for treating hormone-sensitive prostate cancer | Guidance | NICE](#)
2. Accord Healthcare S.L.U.. Summary of Product Characteristics; Orgovyx 120mg film-coated tablets ▼ updated 3rd October 2024.
3. Derbyshire Joint Area Prescribing Committee Shared Care Agreement - RELUGOLIX in the treatment of adult patients with advanced hormone-dependant Prostate Cancer

## **Development Process**

*This guidance has been produced by Dr Jessica Tay Sheffield Consultant Clinical Oncologist & Orla Reddington Urology Pathway Lead AHP Lead South Yorkshire and Bassetlaw Cancer Alliance following a Specialist Initiation classification status of previously known as Amber G by South Yorkshire Integrated Medicines Optimisation Committee (IMOC) in July 2026. This guideline has been subject to consultation and endorsement by Dr Jessica Tay & Orla Reddington and was ratified by IMOC chair in October 2026.*

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