North Central London
Joint Formulary Committee

Interface Prescribing Document

TRIPTORELIN (Decapeptyl® SR) 3mg 11.25mg 22.5mg
LEUPRORELIN (Prostap®) 3.75mg 11.25mg
RELUGOLIX ▼(Orgovyx®) 120mg Tablets
Treatment of Prostate Cancer

Document Control		
Date	**Version**	**Action**
November 2021	V1.0	Factsheet produced by Simon Jenkinson, Dr Mark Prentice and Enfield Borough team Approved by NCL Shared Care Group (Chairs action): 01/11/2021
October 2025	V2.0	Document reviewed and updated by Simon Jenkinson, Anne O'Connor, Dr Sonia Mansukhani Dr Georgios Imseeh and Dr Matthew Fittall

Background Information

Interface prescribing documents support primary care prescribers in NCL to take on prescribing of medicines initiated in secondary care. This document has undergone extensive consultation across the region from specialists, primary care prescribers and ICB teams, specifically acknowledging that primary care providers outside of NCL will need to utilise it.

This document is for guidance only; its interpretation and application remain the responsibility of the individual clinician. If in doubt, contact a senior colleague or expert. Clinicians are advised to refer to the manufacturer's current prescribing information before treating individual patients.

Indication information

As per local formulary agreement, **triptorelin** (Decapeptyl® SR) and **leuprorelin** (Prostap®) are recommended for the treatment of prostate cancer. The licenced uses of triptorelin and leuprorelin are:

- Treatment of patients with locally advanced, non-metastatic prostate cancer, as an alternative to surgical castration.
- Treatment of metastatic prostate cancer.
- As adjuvant treatment to radiotherapy in patients with high-risk localised or locally advanced prostate cancer.
- As neoadjuvant treatment prior to radiotherapy in patients with high-risk localised or locally advanced prostate cancer.
- As adjuvant treatment to radical prostatectomy in patients with locally advanced prostate cancer at high risk of disease progression.

Relugolix (Orgovyx®) is recommended as per NICE TA995 for the treatment of prostate cancer in adults with advanced hormone-sensitive prostate cancer, alongside radiotherapy for high-risk localised or locally advanced hormone-sensitive prostate cancer and as neoadjuvant treatment before radiotherapy for high-risk localised or locally advanced hormone-sensitive prostate cancer.

Treatment should be initiated by a clinician with expertise in the treatment of prostate cancer who will consider contraindications and cautions for use (triptorelin (BNF and SPC), leuprorelin (BNF and SPC), relugolix (BNF and SPC).

Prior to transfer of care, the hospital team will:

1. **Ask the GP if they are willing to shared care and only transfer prescribing if this is agreed in writing. Refer to appendix 1 and 2 for a transfer of care template letter.**
2. Provide the patient with initial information regarding the treatment and possible adverse effects. This includes the incidence of depression, osteoporosis and diabetes. Diabetic patients will be counselled to increase the frequency of glucose monitoring as appropriate. Advice on diet and exercise will be given. A calcium and vitamin D supplement will be prescribed unless contraindicated.
3. Perform baseline monitoring as outlined below.
4. Initiate and optimise (stabilise) treatment and inform GP when patient is stable on the product so that the GP can continue prescribing. This will usually be *3 months* after initiation of a gonadotropin releasing hormone (GnRH) agonist or usually *2 months* after initiation of relugolix.
5. Change preparation if necessary and inform patient and GP of the changes.
6. Clinically supervise patient by routine clinic follow-ups as clinically indicated up to a minimum frequency of every 12 months, to include the relevant tests (such as prostate specific antigen) and assessments to monitor clinical response and toxicity. Inform GP of review and blood results after each monitoring appointment.
7. Provide emergency support for administering GnRH analogues where a practice is unexpectedly unable to provide this within a week of the date the injection is due (e.g. due to unexpected staff absence).

Dose

Preparation	Drug	Strength	Dosage
Orgovyx® film coated tablets	Relugolix*	120mg	360mg (3 tablets) loading dose orally followed the next day by 120mg (one tablet) orally once daily
Decapeptyl® SR 3mg powder for suspension with diluent	Triptorelin**	3mg	3mg by IM injection 4 weekly
Decapeptyl® SR 11.25mg powder for suspension with diluent	Triptorelin**	11.25mg	11.25mg by IM injection 3 monthly
Decapeptyl® SR 22.5mg powder for suspension with diluent	Triptorelin**	22.5mg	22.5mg by IM injection 6 monthly
Prostap® SR DCS powder plus solvent in prefilled syringe	Leuprorelin	3.75mg	3.75mg by SC injection monthly
Prostap® 3 DCS powder plus solvent in prefilled syringe	Leuprorelin	11.25mg	11.25mg by SC injection 3 monthly

* Relugolix may be preferable for patients who have cardiac disease (e.g. myocardial infarction within 12 months, stroke or uncontrolled angina or coronary artery disease) or favour an oral agent. As it is a GnRH antagonist, it does not induce a "tumour flare" and therefore no bicalutamide cover is required on initiation.

** **Triptorelin is the preferred GnRH agonist in NCL.**

It is recommended that suitable patients be initiated on a 6 monthly preparation of triptorelin OR a 3-monthly preparation of leuprorelin if not suitable for triptorelin. e.g. if on warfarin.

Triptorelin can **only** be administered by intramuscular injection. It is NOT contraindicated to use intramuscular triptorelin in patients who are on anti-coagulation but there is a higher risk of haematoma. Triptorelin has been safely administered to patients intramuscularly who are stabilised on a direct oral anti-coagulant.

Warfarin patients should have subcutaneous leuprorelin prescribed as an alternative.

Maintenance dose:

The relugolix maintenance dose is 120mg daily (1 tablet) following a loading dose of 360mg dose (3 tablets).

Conditions requiring dose adjustment

Triptorelin and Leuprorelin

- **Triptorelin** - No dose reduction required in elderly or in liver or renal impairment.
- **Leuprorelin** - Liver dysfunction and jaundice with elevated liver enzyme have been reported. Liver dysfunction on leuprorelin is uncommon and often transient. Therefore, close observation will be made by secondary care with a blood test prior to each injection (which may be given in primary care) and appropriate measures will be taken if necessary. If liver function test (LFT) dysfunction is seen on pre-treatment bloods, then LFTs should be repeated 1-2 weekly until improvement seen. The GP will be contacted to hold off leuprorelin until LFTs have normalised. If LFT derangement is persistent, secondary care will initiate further management.

Relugolix

- Dose adjustment is not required for mild or moderate renal impairment.
- Dose reduction is not required for mild or moderate liver dysfunction.
- Clinical interaction studies with P-gp inhibitors (erythromycin and azithromycin) and combined P-gp and strong CYP3A4 inducers (rifampicin) have shown to affect the exposure of relugolix to a clinically relevant extent.
- Dose modification for use with P-gp inhibitors:
    - Co-administration of relugolix with oral P-glycoprotein (P-gp) inhibitors is not recommended. If co-administration is required, relugolix should be taken first and dosing should be separated by at least 6 hours. Treatment with relugolix may be interrupted for up to 2 weeks if a short course of treatment with a P-gp inhibitor is required.
- Dose modification for use with combined P-gp and strong CYP3A inducers:
    - Co-administration of relugolix with combined P-gp and strong cytochrome P450 (CYP) 3A inducers is **not recommended.**
    - If co-administration is required, the dose of relugolix must be increased to **240 mg once daily**.
    - After discontinuation of the combined P-gp and strong CYP3A inducer, the recommended 120 mg dose of relugolix once daily must be resumed.
    - See relugolix BNF and SPC for the most up-to-date information.

Medicine	Therapeutic dose of relugolix	Therapeutic dose of associated medicine	Comments
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

Common P-glycoprotein (P-gp) inhibitors	Strong CYP3A4 inducers
Amiodarone	Carbamazepine
Azithromycin	Phenytoin
Carvedilol	Rifampicin
Clarithromycin	
Erythromycin	
Ketoconazole (oral)	
Itraconazole	
Quinine	
Ranolazine	
Verapamil	

This list is not exhaustive – please check the latest BNF and SPC for the most up-to-date information.

If no alternatives to the above drugs can be used, please refer patient back to parent urology team.

Missed doses

For Relugolix (see SPC)

- If a dose is missed, it 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.
- 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.

<table>
<tr><td>Duration of treatment</td><td>

Neo-adjuvant patients suitable for radical radiotherapy: 3 to 6 months treatment to reduce tumour burden and prostate size prior to radiotherapy.
Adjuvant treatment after radiotherapy (in selected higher risk patients with adverse histological features): up to 3 year's treatment; lifelong if particularly high risk.
Metastatic prostate cancer: treatment may continue lifelong. Triptorelin or leuprorelin can be used intermittently, which will be directed by the Oncologist.

</td></tr>
<tr><td>Stopping criteria and treatment discontinuation</td><td>See above for duration of treatment. Oncologist is to advise on cessation of therapy.</td></tr>
<tr><td>Baseline monitoring (by specialist)</td><td>
<u>Baseline monitoring:</u>

Prostate specific antigen (PSA), liver function and urea & electrolytes
Total cholesterol and lipids and HbA1c - Results do not have to return prior to the first dose. Any irregular metabolic parameters will be referred to the GP for management or onward referral e.g. cholesterol or HbA1c
Patients who have diabetes may need to increase monitoring
Testosterone
Blood pressure
Ensure concomitant medicines are optimised before initiation (if applicable)

</td></tr>
<tr><td>Ongoing monitoring (by primary care clinician)</td><td>
<table>
<tr><th>Test</th><th>Frequency of test</th><th>Action if out of range</th></tr>
</table>

No tests are to be undertaken in primary care.
In the event of a practice being unable to give a patient their GnRH agonist injection, due to unforeseen circumstances, the specialist nurse in secondary care should be contacted for advice and, if required, will provide the injection.
The table below provides information on when a query should be raised with secondary care regarding a delayed injection if the patient does not attend for their injection on time.

<table>
<tr><th>GnRH Agonist</th><th>Frequency of administration</th><th>Information regarding delayed injections</th></tr>
<tr><td>Decapeptyl SR (triptorelin) 3mg</td><td>3mg by IM injection 4-weekly</td><td>Query with secondary if >7 days late</td></tr>
<tr><td>Decapeptyl® SR (triptorelin) 11.25mg</td><td>11.25mg by IM injection 3 monthly</td><td>Query with secondary if >7 days late</td></tr>
<tr><td>Decapeptyl® SR (triptorelin) 22.5mg</td><td>22.5mg by IM injection 6 monthly</td><td>Query with secondary if >7 days late</td></tr>
<tr><td>Prostap® SR DCS (leuprorelin)</td><td>3.75mg by SC injection monthly</td><td>Query with secondary care if >7 days late</td></tr>
<tr><td>Prostap® 3 DCS (leuprorelin)</td><td>11.25mg by SC injection 3 monthly</td><td>Query with secondary care if >7 days late</td></tr>
</table>
</td></tr>
<tr><td>Adverse effects and management</td><td>For a full list of adverse effects, please refer to the triptorelin BNF and SPC, leuprorelin BNF and SPC and relugolix BNF and SPC.

Healthcare professionals are asked to report any suspected adverse reactions to the MHRA via the Yellow Card Scheme.</td></tr>
</table>

	Adverse effect	Frequency of ADR (as per SPC)	Action for GP
	Decreased libido	Very common	If an intolerable adverse effect, refer back to specialist to discuss alternative treatment options
	Hot flushes	Very common	Consider treatment as per NICE CKS; If severe/intractable, refer back to initiating specialist
	Erectile dysfunction	Very common	Consider treatment as per NICE CKS and local pathway. If severe/refractory/intolerable, refer back to initiating specialist
	Hyperhidrosis	Very common	Offer advice/treatment as per NICE CKS; if resistant consider referral to dermatologist
	Weight fluctuation	Very common	Consider referral to dietitian, if severe/intolerable refer back to initiating specialist
	Fatigue	Very common	Consider therapy as per NICE CKS; If severe/intractable, refer back to initiating specialist
	Impaired glucose tolerance	Common	Management of diabetes will remain the responsibility of the patient's routine supervising specialist (e.g., GP, diabetes specialist nurse etc)
	Mood changes leading to depression	Common	Refer back to initiating specialist if depression develops
	Paraesthesia	Common	Refer back to initiating specialist if paraesthesia develops
	Bone pain	Common	Refer back to initiating specialist if bony pain develops
	Hypertension	Common	Consider treatment as per local/NICE guidance; refer back to initiating specialist if persistent
	Rash	Common	Treat as appropriate; If thought to be an allergy, stop immediately and refer back to the specialist for advice
	Gynaecomastia	Common	Refer back to initiating specialist if gynaecomastia develops
	Reduction in bone mass	Common	Consider guidance in NICE CKS; if resistant consider referral to rheumatologist
	Injection site reactions if GnRH agonist	Common	Treat as appropriate; If thought to be an allergy, stop immediately and refer back to the specialist for advice

	Nausea	Common	Treat as appropriate; If severe, stop immediately and refer back to the specialist for advice
	QT prolongation is caused by androgen deprivation therapy	Unknown	The risk/benefit ratio in patients with risk factors will be assessed prior to initiation of therapy. If suspected, refer for immediate assessment.
	Pulmonary embolism	Unknown	If suspected, refer to A&E for immediate assessment
	Thrombocytopenia and leucopenia	Unknown /Uncommon	Should be identified by secondary care blood tests; incidental findings should be referred back to specialist.
	GnRH agonists may reveal the presence of a previously unknown gonadotroph cell pituitary adenoma.	Rare	If suspected, refer back to specialist.
	Jaundice and hepatic enzyme elevation	Unknown	Should be identified by secondary care blood tests; incidental findings should be referred back to specialist.
Advice to patients and carers	Patients should be encouraged to report any side effects to their GP or hospital specialist.		
Resources and key references	• Triptorelin SPC (accessed on 19/01/2025) • Leuprorelin SPC (accessed on 22/04/2025) • Relugolix SPC (accessed on 19/01/2025)		

Contact Details

Royal Free London NHS Foundation Trust
(including Royal Free London NHS Foundation Trust (RFL), Barnet Hospital (BH), Chase Farm Hospital (CFH) and North Middlesex University Hospital (NMUH))
Please see individual consultant secretaries below

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*Whittington Health NHS Trust currently do not have an oncology consultant in post and therefore their patients are being seen at UCLH.

Appendix 1: Template transfer letter - GnRH Agonist: from Secondary care Trust to Primary care organisation

PRIVATE AND CONFIDENTIAL

Date: [Insert Date]

To: [GP Practice Name]

Re: [Patient Name]	[ADDRESS]
Hospital Number: [Insert]	[ADDRESS]
Date of Birth: [Insert]	[ADDRESS]
NHS Number: [Insert]	[ADDRESS]

Diagnosis: [Insert Diagnosis]

Management Plan:

[Insert Management Plan]

Dear GP Practice,

This document is to request the shared care pathway of your patient and comprises an agreement between the primary or secondary care clinician and named consultant. The patient will continue to be seen by the named consultant's team as regular follow up.

[Patient Name] was reviewed in our Oncology Clinic on [insert date], where they commenced on [insert GnRH agonist, e.g. Decapeptyl 22.5mg] injection. The first dose was administered on [insert date].

In view of their ongoing treatment, we would like to request that your practice continue to administer the succeeding injections in the community.

- **Medication:** [Insert GnRH agonist name and dose e.g. triptorelin 22.5mg or leuprorelin 11.25mg]
- **Route:** [e.g. Intramuscular if triptorelin or subcutaneous if leuprorelin]
- **Frequency:** [e.g. every 6 months if Triptorelin or every 3 months if Leuprorelin]
- **Next dose due:** [insert date]
- **Duration:** Until further notice from the Oncology Team

[Patient Name] has tolerated treatment to date without significant side effects.

Known drug allergies: [insert details / NKDA].

Please note: PSA monitoring and further blood tests and oncology follow-up will continue to be managed by the hospital team.

The patient has been counselled on possible side effects of hormone therapy (e.g. hot flushes, fatigue, muscle weakness, erectile dysfunction, metabolic changes) and advised on lifestyle

measures such as regular exercise and pelvic floor exercises. Referral pathways for management of side effects (e.g. erectile dysfunction clinic, exercise support) have been discussed.

We have also advised the patient to maintain a record of injections and attend all hospital follow-up appointments. Our CNS team will provide ongoing safety-netting and support between oncology appointments.

Thank you for your support in continuing [Patient Name]'s care. Please do not hesitate to contact us if you have any queries.

Kind regards,
CNS Team / Uro-Oncology Team
[Hospital/Trust Name]
[Contact Details]

Appendix 2: Template transfer letter - Relugolix: from Secondary care Trust to Primary care organisation

PRIVATE AND CONFIDENTIAL

Date: [Insert Date]

To: [GP Practice Name]

Re: [Patient Name]	[ADDRESS]
Hospital Number: [Insert]	[ADDRESS]
Date of Birth: [Insert]	[ADDRESS]
NHS Number: [Insert]	[ADDRESS]

Diagnosis: [Insert Diagnosis]

Management Plan:

[Insert Management Plan]

Dear GP Practice,

This document is to request the shared care pathway of your patient and comprises an agreement between the primary or secondary care clinician and named consultant. The patient will continue to be seen by the named consultant's team as regular follow up.

[Patient Name] was reviewed in our Oncology Clinic on [insert date], where they commenced on oral relugolix.

In view of their ongoing treatment, we would like to request that your practice continue to prescribe this medicine on an ongoing basis in the community.

- **Medication:** Relugolix (Orgovyx) Tablets
- **Route:** Oral
- **Dose and directions**: 120mg (one tablet) daily (patients are loaded on day 1 of therapy only)
- **Next prescription due:** [insert date]- patient has been prescribed an initial two-month supply from secondary care to enable safe transfer of care.
- **Duration:** Until further notice from the Oncology Team

[Patient Name] has tolerated treatment to date without significant side effects.

Known drug allergies: [insert details / NKDA].

Please note: PSA monitoring and further blood tests and oncology follow-up will continue to be managed by the hospital team.

The patient has been counselled on possible side effects of hormone therapy (e.g. hot flushes, fatigue, muscle weakness, erectile dysfunction, metabolic changes) and advised on lifestyle measures such as regular exercise and pelvic floor exercises. Referral pathways for management of

side effects (e.g. erectile dysfunction clinic, exercise support) have been discussed.

We have also advised the patient to attend all hospital follow-up appointments. Our CNS team will provide ongoing safety-netting and support between oncology appointments.

Thank you for your support in continuing [Patient Name]'s care. Please do not hesitate to contact us if you have any queries.

Kind regards,
CNS Team / Uro-Oncology Team
[Hospital/Trust Name]
[Contact Details]

Section B: [Accept Shared Care] to be completed by practice *Send back **FAO referring consultant** above*

The above patient has been accepted into our practice for either (delete as appropriate):

- ongoing prescriptions alone in the case of relugolix
- ongoing prescriptions and administration of a GnRH agonist

Practice date for next Prescription or prescription and administration		Practice stamp
Signed / Designation		
Date		

Section B: [Reject Shared Care] to be completed by practice *Send back **FAO referring consultant** above*

The above patient has not been accepted for shared care.

Reason		Practice stamp
Signed / Designation		
Date		