Gonadorelin analogues (goserelin, leuprorelin* and triptorelin) for use in prostate and breast cancers.

*ESNEFT only

Specialist responsibilities

- Assess the patient and provide diagnosis; ensure that this diagnosis is within scope of this shared care protocol and communicated to primary care.
- Discuss the benefits and risks of the treatment with the patient and/or their carer and provide the appropriate counselling to enable the patient to reach an informed decision. Obtain and document patient consent. Provide an appropriate patient information leaflet.
- Assess for contraindications and cautions and interactions.
- Conduct required baseline investigations and initial monitoring.
- Initiate and optimise treatment as outlined below. Prescribe the maintenance treatment for at least 4 weeks and until optimised.
- Once treatment is optimised, complete the shared care documentation and send to patient's GP practice detailing the diagnosis, current and ongoing dose, any relevant test results and when the next monitoring is required. Include contact information.
- Prescribe sufficient medication to enable transfer to primary care, including where there are unforeseen delays to transfer of care.
- Conduct the scheduled reviews and monitoring in and communicate the results to primary care. After a review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined below remains appropriate.
- Reassume prescribing responsibilities if a woman becomes or wishes to become pregnant.
- Provide advice to primary care on the management of adverse effects if required.

Primary care responsibilities

- Respond to the request from the specialist for shared care in writing within 14 days.
- If accepted, prescribe ongoing treatment as detailed in the specialist's request , taking into any account potential drug interactions listed below.
- Adjust the dose prescribed as advised by the specialist.
- Conduct the required monitoring as outlined below. Communicate any abnormal results to the specialist.
- Manage adverse effects as detailed below and discuss with specialist team when required.
- Refer the management back to the specialist if the patient becomes or plans to become pregnant.
- Stop treatment as advised by the specialist.

Patient and/or carer responsibilities

- Take the medication as prescribed and avoid abrupt withdrawal unless advised by the primary care prescriber or specialist.
- Attend regularly for monitoring and review appointments with primary care and specialist, and keep contact details up to date with both prescribers. Be aware that medicines may be stopped if they do not attend.
- Report adverse effects to their primary care prescriber. Seek immediate medical attention if they develop any symptoms as detailed below.
- Report the use of any over the counter medications to their primary care prescriber and be aware they should discuss the use of the medication with their pharmacist before purchasing any OTC medicines.
- Patients of childbearing potential should take a pregnancy test if they think they could be pregnant, and inform the specialist or GP immediately if they become pregnant or wish to become pregnant.

1. Indications

Prostate cancer indications:

- Metastatic prostate cancer
- Locally advanced prostate cancer

Breast cancer indications:

- For advanced breast cancer in pre and perimenopausal women suitable for hormonal manipulation.
- As an alternative to chemotherapy in the standard of care for pre/perimenopausal women with oestrogen receptor (ER) positive early breast cancer (EBC).

2. Initiation and ongoing dose regime

- The duration of treatment & frequency of review will be determined by the specialist, based on clinical response and tolerability.
- Termination of treatment will be the responsibility of the specialist.

Initial stabilisation (provides 4 weeks of treatment):

The first dose may be prescribed and administered in primary care.

Prostate Cancer:

Decapeptyl SR (Triptorelin) 3mg IM injection

OR

Zoladex (Goserelin) 3.6mg S/C injection

OR

Prostap SR DCS (Leuprorelin*) 3.75mg S/C or IM injection

During the initial stage of GnRHa treatment for prostate cancer, increased production of testosterone may be associated with progression of prostate cancer. In susceptible patients this tumour 'flare' may cause spinal cord compression, ureteric obstruction or increased pain. It should be closely supervised in the first month of treatment.

Concomitant use of bicalutamide 50 mg PO once daily may be recommended by the specialist for some patients. Bicalutamide is started 7 to 10 days prior to initiating the GnRHa and is continued for 28 days. The bicalutamide treatment duration will be specified by the specialist at the time of recommending initiation of the GnRHa. If the GnRHa needs to be started urgently, the specialist may prescribe it and then inform the GP of the date when the first GnRHa dose needs to be administered

Breast Cancer:

Zoladex (Goserelin) 3.6mg S/C injection

OR

Prostap SR DCS (Leuprorelin*) 3.75mg S/C injection

Maintenance dose (following initial stabilisation):

For prostate cancer: Decapeptyl SR (Triptorelin) 22.5mg IM every 6 months is recommended first line for maintenance treatment. This is to minimise administration burden on patients and because it is the least best value option considering drug and administration needs. Exceptions include patients receiving short term treatment with a GnRH e.g. for neo-adjuvant treatment.

Drug	Indication	Dose
Decapeptyl SR (Triptorelin) powder to reconstitute	Prostate Cancer **(First line maintenance option within SNEE)**	22.5mg IM **every 6 months**
Decapeptyl SR (Triptorelin) powder to reconstitute	Prostate Cancer	3.6mg S/C **every 4 weeks**
Decapeptyl SR (Triptorelin) powder to reconstitute	Prostate Cancer	11.25mg IM **every 12 weeks**
Zoladex (Goserelin) Implant in Prefilled syringe	Prostate Cancer/Breast Cancer	3.6mg S/C into the anterior abdominal wall **every 4 weeks**
Zoladex LA (Goserelin) Implant in Prefilled syringe	Prostate Cancer/Breast Cancer	10.8mg S/C into the anterior abdominal wall **every 12 weeks**
Prostap SR DCS (Leuprorelin*) powder to reconstitute	Prostate Cancer/Breast Cancer	3.75mg S/C or IM **every 4 weeks** (S/C for Breast Cancer)
Prostap SR DCS (Leuprorelin*) powder to reconstitute	Prostate Cancer/Breast Cancer	11.25mg S/C **every 12 weeks**

***ESNEFT only**

Conditions requiring dose adjustment: Goserelin - No dose reduction in renal/liver impairment or the elderly. Triptorelin – No dose reduction in the elderly. Leuprorelin – Hepatic dysfunction and jaundice with elevated liver enzyme reported. Close observation recommended and appropriate measures taken if necessary

Duration of Treatment

Prostate Cancer

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. Can be used intermittently if treatment supervised by Urologist/Oncologist.

Breast Cancer

Advanced breast cancer: dependant on disease response

As alternative to chemotherapy in low-risk estrogen receptor positive breast cancer: up to 2 years

In addition to tamoxifen/exemestane in high-risk estrogen receptor positive breast cancer: up to 5 years

Fertility preservation in breast cancer: first dose to be given up to 1 week prior to commencement of chemotherapy and throughout duration of chemotherapy.

4. Baseline investigations, initial monitoring and ongoing monitoring to be undertaken by specialist

Specialist to undertake:

- FBC

- U&Es (including serum calcium for breast cancer patients)
- LFTs
- PSA (prostate cancer)
- Regular review of disease status and radiology as appropriate

Routine monitoring will be completed by specialist as appropriate. No routine monitoring within primary care is required unless specifically requested by specialist.

5. Adverse effects and other management

Result	Action for primary care
As well as responding to absolute values in laboratory tests, a rapid change or a consistent trend in any value should prompt caution and extra vigilance	
Symptoms suggestive of local, regional or metastatic progression.	Refer to specialist

6. Significant medicine interactions

The following list is not exhaustive. Please see BNF & SPC for comprehensive information and recommended management.

- Drugs which raise prolactin levels can reduce the level of GnRH receptors in the pituitary gland (e.g. antipsychotics). Discuss usage with the specialist
- Drugs which prolong the QT interval can interact additively with gonadorelin analogues, consider ECG monitoring or discuss with specialist if interaction is suspected.

7. Specialist contact information

West Suffolk Hospital Contact Details		
Oncology	Dr Alex Martin Dr Cathryn Woodward Dr Kent Yip Clare Cross – Clinical Nurse Specialist Helen Small – Clinical Nurse Specialist	Email: OncologySecretaries@wsh.nhs.uk
Urology	Consultant Urologists Mr John McLoughlin: 01284 712549 Miss Georgina Wilson: 01284 713520 Mr Anup Sengupta: 01284 713520 Ms Emma Gordon: 01284 713457 Mr Adham Ahmed: 01284 713160 Urology Nurse Specialists Jane Thacker – 01284 712735 Melanie Pearce - 01284 712735 Kimberly Armstrong - 01284 712735 Lisa Millar - 01284 712735 Sarah Last - 01284 712735	Email: urologysec@wsh.nhs.uk
Ipswich Hospital Contact Details		

Oncology	Dr. R. Venkitaraman - 01473 704915 Dr S Nawaz – 01473 704908 Alex Knights (Macmillan Radiotherapy Specialist) - 01473 704361	
Urology	Mr. Gautam Banerjee - 01473 703689 Mr George Yardy - 01473 703799 Mr Azad Hawizy - 01473 703521 Miss Sona Kapoor - 01473 702647 Mr Mohamed Tourky – 01473 703689 Charlotte Etheridge (Macmillan Urology CNS) - 01473 702773	

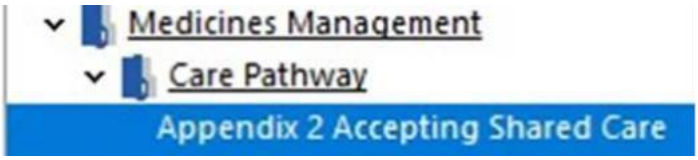
Templates for response to shared care guidelines are available in SNEE on DXS and Ardens. The listings are:

For Suffolk practices (DXS)

Form Name - Appendix 2 Accepting Shared Care

Form Reference - SUF2133

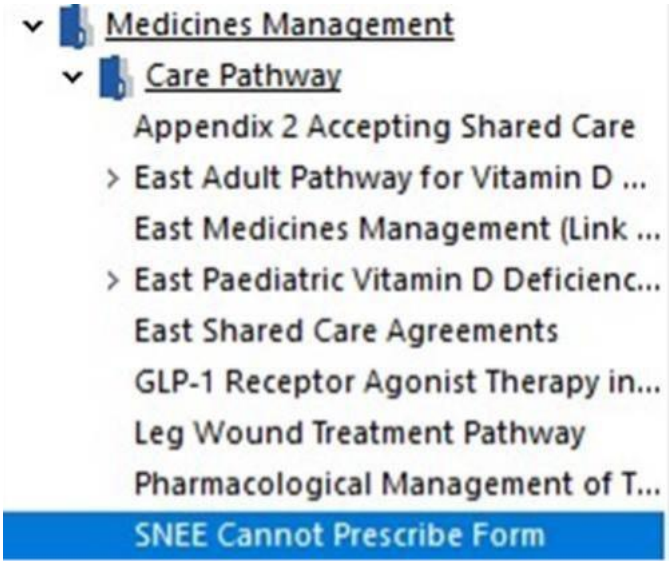
Folder Location - Medicines Management – Care Pathway



Form Name – SNEE Cannot Prescribe Form

Form Reference - SUF2132

Folder Location - Medicines Management – Care Pathway



For North East Essex practices (Ardens)

SystmOne

Form Name - Accepting Shared Care Appendix 2 (Primary Care Prescriber to Specialist)

Form Reference - SUF2133

Folder Location - Secondary Care Referrals P – Prescribing

Form Name –Unable to Prescribe Form – North East Essex

Form Reference – NEE2129

Folder Location – Secondary Care Referrals P – Prescribing



EMIS

Form Name - Accepting Shared Care Appendix 2 (Primary Care Prescriber to Specialist)

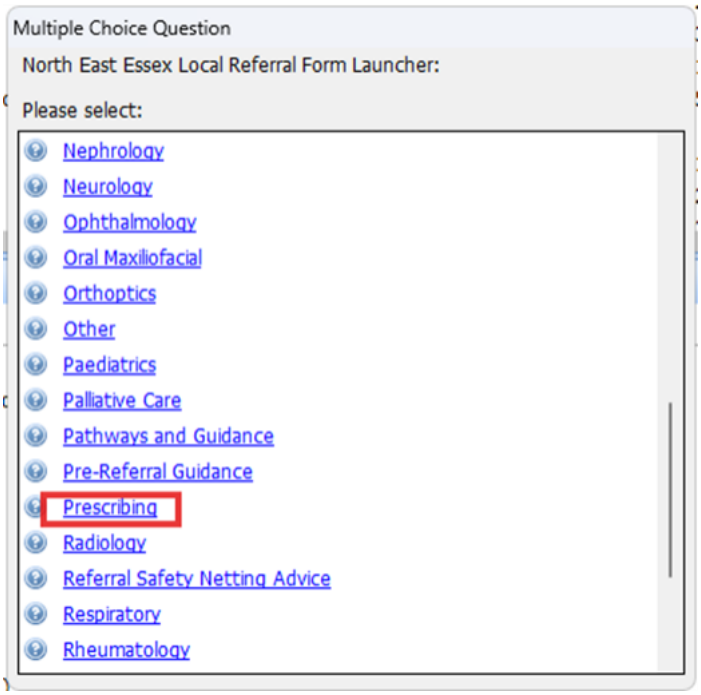
Form Reference - NEE2133

Folder Location - Prescribing

Form Name – Unable to Prescribe Form – North East Essex

Form Reference – NEE2129

Folder Location – Prescribing



The documents are also copied below for reference

Appendix 2: Shared Care Agreement Letter (Primary Care Prescriber to Specialist)

Primary Care Prescriber Response

Dear *[insert Doctor's name]*

Patient *[insert Patient's name]*

NHS Number *[insert NHS Number]*

Identifier *[insert patient's date of birth and/oraddress]*

Thank you for your request for me to accept prescribing responsibility for this patient under a shared care agreement and to provide the following treatment

Medicine	Route	Dose & frequency

I can confirm that I am willing to take on this responsibility from *[insert date]* and will complete the monitoring as set out in the shared care protocol for this medicine/condition.

Primary Care Prescriber signature: Date:

Primary Care Prescriber address/practice stamp

Appendix 3: Shared Care Refusal Letter (Primary Care Prescriber to Specialist)

Re:

Patient *[insert Patient's name]*

NHS Number *[insert NHS Number]*

Identifier *[insert patient's date of birth and/oraddress]*

Thank you for your request for me to accept prescribing responsibility for this patient.

In the interest of patient safety NHS *[insert CCG name]***,** in conjunction with local acute trusts have classified *[insert medicine name]*as a Shared Care drug, and requires a number of conditions to be met before transfer can be made to primary care.

I regret to inform you that in this instance I am unable to take on responsibility due to the following:

		Tick which apply
1.	**The prescriber does not feel clinically confident in managing this individual patient's condition, and there is a sound clinical basis for refusing to accept shared care** As the patients primary care prescriber I do not feel clinically confident to manage this patient's condition because *[insert reason]*. I have consulted with other primary care prescribers in my practice who support my decision. This is not an issue which would be resolved through adequate and appropriate training of prescribers within my practice. **I have discussed my decision with the patient and request that prescribing for this individual remain with you as the specialist, due to the sound clinical basis given above.**	
2.	**The medicine or condition does not fall within the criteria defining suitability for inclusion in a shared care arrangement** As the medicine requested to be prescribed is not included on the national list of shared care drugs as identified by RMOC or is not a locally agreed shared care medicine I am unable to accept clinical responsibility for prescribing this medication	

	at this time. **Until this medicine is identified either nationally or locally as requiring shared care the responsibility for providing this patient with their medication remains with you**	
3.	**A minimum duration of supply by the initiating clinician** As the patient has not had the minimum supply of medication to be provided by the initiating specialist I am unable to take clinical responsibility for prescribing this medication at this time. Therefore can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. ***Until the patient has had the appropriate length of supply the responsibility for providing the patient with their medication remains with you.***	
4.	**Initiation and optimisation by the initiating specialist** As the patient has not been optimised on this medication I am unable to take clinical responsibility for prescribing this medication at this time. Therefore can you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. ***Until the patient is optimised on this medication the responsibility for providing the patient with their medication remains with you.***	
5.	**Shared Care Protocol not received** As legal responsibility for clinical care lies with the clinician who signs the prescription, I need to ensure that I am in possession of sufficient clinical information for me to be confident to prescribe this treatment for my patient and it is clear where each of our responsibilities lie to ensure the patient is safely managed**.** For this reason I am unable to take clinical responsibility for prescribing this medication at this time, therefore would you please contact the patient as soon as possible in order to provide them with the medication that you have recommended. ***Until I receive the appropriate SCP, responsibility for providing the patient with their medication remains with you.***	
6.	**Other (Primary Care Prescriber to complete if there are other reasons why shared care cannot be accepted)**	

I would be willing to consider prescribing for this patient once the above criteria have been met for this treatment.

NHS England 'Responsibility for prescribing between Primary & Secondary/Tertiary care' guidance (2018) states that "when decisions are made to transfer clinical and prescribing responsibility for a patient between care settings, it is of the utmost importance that the GP feels clinically competent to prescribe the necessary medicines. It is therefore essential that a transfer involving medicines with which GPs would not normally be familiar should not take place without full local agreement, and the dissemination of sufficient, up-to-date information to individual GPs." In this case we would also see the term GP being interchangeable with the term Primary Care Prescriber.

Please do not hesitate to contact me if you wish to discuss any aspect of my letter in more detail and I hope to receive more information regarding this shared care agreement as soon as possible

Yours sincerely

Primary Care Prescriber signature: **Date:**

Primary Care Prescriber address/practice stamp