

**Service Specification Template Department of Health,
updated November 2016**

Service Specification No. :	9
Service:	Administration of Gonadorelin Analogues (Goserelin -Zoladex®) for patients with Carcinoma (Ca) of the Breast.
Commissioner Lead:	Lucy Morris, Primary Care Project Officer
Provider Lead:	
Period:	1 st April 2017 – 30 th June 2020 (3 months' notice will be required to terminate this contract by either party)
Date of Review:	1 st April 2019

1. Population Needs

1.1 National/local context and evidence base

Gonadorelin analogues are options in the treatment of carcinoma of the breast.

Prescriptions issued for injectable Gonadorelin analogues are written by GPs for continuing treatment and most of these are also administered by GPs. In some practices an appropriately trained practice nurse will site the depot implants or injection.

2. Outcomes

NHS Outcomes Framework domains & Indicators

<https://www.wp.dh.gov.uk/publications/files/2012/11/121109-NHS-Outcomes-Framework-2013-14.pdf>

Domain 1	Preventing People from dying prematurely	✓
Domain 2	Enhancing quality of life for people with long term conditions	✓
Domain 3	Helping people to recover from episodes of ill health or following injury	✓
Domain 4	Ensuring people have a positive experience of care	✓
Domain 5	Treating and caring for people in a safe environment and protecting them from avoidable harm	✓

3. Scope

3.1 Aims and objectives of service

Patients with an established diagnosis and agreed treatment plan for the conditions specified above can undergo part of their treatment safely, effectively and conveniently close to their home in accordance with the locally agreed prescribing guidelines.

3.2 Service description/care pathway

This service is delivered under an agreed prescribing guideline approved by the South Devon Formulary and in accordance with the British National Formulary (BNF). The Provider is required to:

1. **Provide a register** – The provider will need to produce and maintain a valid up-to-date register of patients being treated as part of this CCG Commissioned Service.
2. **Demonstrate a call and recall system** - The provider will need to ensure a systematic call and recall of patients on this register is taking place, and have in place the means to identify and follow up patients in default.
3. **Agree a joint clinical management programme** - Patients should be managed on the basis of individual treatment plans which will normally be drawn up by local consultants. The provider will be expected to follow these treatment plans unless there has been discussion and agreement with local consultants to modify them. The plan should give the reason for treatment, the agreed treatment programme and the planned duration. This plan should be consistent with any agreed prescribing guidelines.
4. **Support the education of both newly diagnosed patients and those with established disease.** The secondary care oncology teams will provide the main source of advice for both newly diagnosed patients and those with established disease. The provider will reinforce and supplement that advice where appropriate to do so.
5. **Record keeping** - To maintain adequate records of the service provided, incorporating all known information relating to any significant events e.g. adverse reactions, hospital admissions, and relevant deaths of which the practice has been notified.
6. **Ensure primary care staff training** – The provider must ensure that all staff involved in providing any aspect of care under this scheme has the necessary training and skills to do so. Practices should be able to demonstrate that they have in place a policy to cover staff training and maintenance of skills.
7. **Provide safe and suitable facilities for undertaking invasive procedures** – The CCG should be satisfied that the provider undertaking the “Administration of Gonadorelin Analogues” for this service have adequate and appropriate facilities and equipment comparable to those required for the safe provision of any invasive procedure.

Providers will be required to record activity for this service with the following READ Code: Insertion of Gonadorelin analogue Implant 7G2AC.

3.3 Population covered

The registered practice population

3.5 Interdependencies with other services

Responsibility of Secondary Care:

- Diagnosis of condition and ensuring other treatment options have been fully explored
- Initiation of treatment. The first dose of Gonadorelin is prescribed and given in secondary care
- Monitoring for response and adverse drug reactions (ADRs) during initiation period
- Liaisons with the provider to share the patient’s care after the first dose has been given. The default duration of gonadorelin treatment is life-long unless specified otherwise for Ca of the breast. Goserelin 3.6mg 4 weekly is the only preparation licensed for Ca of the breast. If a three monthly preparation becomes licenced then this contract will be renegotiated in line with the policy for three monthly administration for males.
- Arrange follow up schedule and monitoring of patient’s response and inform GP of results and any change in condition or treatment
- Responding to issues raised by GP after care of patient has been shared
- Advising the provider on related issues such as drug interactions etc.

Responsibility of The Provider:

- Confirm or decline request to share patient’s care as soon as possible. Monitoring the patient’s overall

health and well-being and observing patient for evidence of ADRs/abnormalities and raising with secondary care clinician if necessary

- Prescription of drug
- Arranging for regular administration
- Ensuring advice is sought from the secondary care clinician if there is any significant change in the patient's physical health status
- Will advise women of childbearing age that the use of non-hormonal barrier methods of contraception be used during the whole treatment period
- Stopping treatment in line with secondary care clinician's request.
- Formal incidents should continue to be reported to NHS England using the [SEA form](#).

<https://www.england.nhs.uk/south/wp-content/uploads/sites/6/2015/08/sea-incident-report-form.doc>

For any other issues of poor quality or service, parts of the system not working well or negative patient experience. Please continue to complete a Yellow Card form which can be found on the CCG's website:

http://www.southdevonandtorbayccg.nhs.uk/contact-us/yellow_card/Pages/default.aspx

The prescriber of the medication legally assumes clinical responsibility for the drug and the consequences of its use. The prescriber should:

- keep informed about the medicines that are prescribed for the patient
- be able to recognise serious and frequently occurring adverse side effects
- make sure appropriate clinical monitoring arrangements are in place and that the patient and healthcare professionals involved understand them
- keep up to date with relevant guidance on the use of the medicines and on the management of the patient's condition

4. Applicable Service Standards

Please use the online version of the South Devon formulary and BNF for guidance on the appropriate administration of Gonadorelin Analogues (Goserelin - Zoladex®) for patients with Carcinoma of the Breast

<https://southwest.devonformularyguidance.nhs.uk/formulary/chapters/8.-malignant-disease/8-3-sex-hormones-and-hormone-antagonists/8-3-4-hormone-antagonists>

	Triptorelin SR 3mg (every 4 wks)	Goserelin 3.6mg (every 4 wks)	Triptorelin SR 11.25mg (every 3 months)	Goserelin 10.8mg (every 3 months)	Triptorelin SR 22.5mg (every 6 months)
Ca breast		✓			

https://www.medicinescomplete.com/mc/bnf/current/PHP92492-breast-cancer.htm?q=Goserelin&t=search&ss=text&tot=5&p=4#_hit

5. Key Service Outcomes

Patients will receive care in a primary care setting, reducing the number of patient contacts with secondary care and the number of journeys to hospital.

6. Applicable Quality Requirements

Further guidance on the diagnosis and treatment of Breast Cancer can be found at

<https://www.nice.org.uk/guidance/conditions-and-diseases/cancer/breast-cancer>

7. Financial Requirements

All patients within the scheme will attract an annual fee of **£155.82**

8. Information Requirements

The provider shall submit every six months the number of patients to whom the service is provided.

9. Location of Provider Premises

The provider premises.