

## Local Enhanced Service Specification:

### Complex Injections

<b>Service Specification No.</b>	
<b>Service</b>	Complex injections management in Primary Care
<b>Commissioner Lead</b>	Lancashire and South Cumbria ICB
<b>Provider Lead</b>	GP Practices in Lancashire and South Cumbria
<b>Period</b>	1 <sup>st</sup> May 2025 – 31 <sup>st</sup> March 2026
<b>Date of Review</b>	To be reviewed annually

#### 1. Population Needs and Background

NHS Lancashire and South Cumbria ICB covers 196 GP Practices and has a total registered population of 1,853,016 (as of Jan 2024) patients.

The scope of this specification will cover all 196 practices and registered patients along with temporary residents (where appropriate) that live within the geographical area of Lancashire and South Cumbria.

This enhanced service is for the treatment of patients who require complex injections as part of their ongoing treatment plans.

This specification will cover patients:

- at risk of osteoporotic fracture who require 60mg Denosumab injections at 6 monthly intervals

#### **Denosumab**

The shared care management of patients on Denosumab is paid separately to this specification which is for the administration of the medication only.

Osteoporosis is a condition characterised by reduced bone mass density and deterioration of bone tissue which results in increased bone fragility and susceptibility to fracture in simple falls.

Denosumab is suitable for GP prescribing following recommendations/initiation by specialist and under ongoing shared care agreement.

Denosumab 60mg is recommended as a treatment option for the **primary prevention** of osteoporotic fragility fractures in postmenopausal women and men from the age of 50 years at increased risk of fracture, who are unable to comply with the special instructions for administering alendronate and risedronate, or have an intolerance of, or a contraindication to, those treatments and the patient has a combination of T-score, age and number of independent clinical risk factors for fracture as indicated in NICE TA204.

Table 1. T-scores (SD) at (or below) which denosumab is recommended when alendronate and either risedronate or etidronate are unsuitable

Age (years)	Number of independent clinical risk factors for fracture		
	0	1	2
65-69	Denosumab not recommended	4.5	4.0
70-74	-4.5	-4.0	-3.5
75 or older	-4.0	-4.0	-3.0

T-scores measure BMD using central (hip and/or spine) dual-energy X-ray scanning, and are expressed as the number of standard deviations (SD) below peak BMD. A Tscore of -1 or higher is considered normal, whereas a T-score  $\leq$  -2.5 is associated with osteoporosis.

Denosumab injection comes as a solution (liquid) to be injected subcutaneously (under the skin) in the upper arm, upper thigh, or stomach area. When denosumab injection is used to treat osteoporosis, it is usually given as a 60mg dose once every 6 months.

Denosumab as a treatment option for the **secondary prevention** of osteoporotic fragility fractures in postmenopausal women and men from the age of 50 years at increased risk of fracture, who are unable to comply with the special instructions for administering alendronate and risedronate, or have an intolerance of, or a contraindication to, those treatments.

Denosumab should only be prescribed in accordance with the following guidelines: [NICE Guidelines - Denosumab for postmenopausal women](#)

Further guidance from the Lancashire Medicines Management Group is available via [Denosumab-Position-Statement-Version-1.0.pdf](#)

## 2. Scope & Service Standards

### 2.1 Aims

The aim of the service is to ensure a consistent approach in the administration of complex injections to patients in Lancashire and South Cumbria, setting out the services that General Practice are expected to deliver to their registered and temporary registered patients.

This specification is not intended to create a Shared Care arrangement. It is not considered that a shared care protocol is necessary to allow the transfer of clinical responsibility for prescribing and administration of complex injections for this indication.

To deliver high quality and responsive services for local people that improve patient outcomes and the experience of service delivery for both patients and the General

Practice team.

Furthermore, the aim of the service is to ensure an equitable and consistent service to all patients across Lancashire and South Cumbria and this will include:

- Patients with an established diagnosis and agreed treatment plan from secondary care can undergo part of their treatment safely, effectively and conveniently close to their home.
- With greater integration of primary and secondary care services, this specification recognises the increasing contribution that primary care can make in medical management and treatment of the hitherto predominantly hospital-based approach.
- Improved call and recall processes in general practice – supported by DQ case finding searches to improve the safety of clinical recall for patients who have historically been discharged from follow up and for any new patients discharged from secondary care.
- Implementation of complex injection services will positively impact secondary care pathways and release capacity to support new referrals to secondary care.

### **2.1.1 Requirements**

Complex injections should be initiated by a specialist within secondary care and the first dose administered in secondary care and thereafter prescribing and administration responsibility is transferred to primary care.

The practice will be required to create a register of patients that require complex injections administration and monitoring (searches will be provided to help practices where patients have not previously been coded and recalled).

### **2.2 Service Description/Care Pathway**

The service will be provided to patients deemed suitable for transfer from hospital-based follow-up care.

#### **Referrals to Primary Care**

New referrals will be made to primary care by a secondary care specialist, who will have agreed a management plan that safely allows patients to be monitored and followed up in primary care.

The clinic discharge letter will include:

- Patient Details (incl. name, address, dob, NHS Number)
- Details of Diagnosis including the date that the therapy was initiated.
- Recommendation / Management Plan (incl. assessment interval and threshold for fast-track re-referral)
- A clear explanation when advice deviates from agreed local guidelines (incl. substantial management/active management received by the patient to date)
- Confirmation that appropriate information has been given to the patient (incl. explanation of condition and that their ongoing follow up care will be managed in primary care)

Patients moving into the area from outside the ICB area or patients transferring from private to NHS care may be suitable for primary care follow up. Where discharge information is not accessible, appropriate guidance should be sought via advice and guidance to the local specialist service.

### **Acceptance onto Practice Register**

Patients who have been monitored in primary care prior to the commencement of this contract will need to be identified and added to the register using DQ case finding searches, or the previous practice register if available and using the relevant SNOMED code to identify the patients.

New patients discharged from secondary care follow up should have the relevant SNOMED code added to their record and a diary entry invite where appropriate.

### **Referral back to Secondary Care**

The Practice will re-refer the patient to the secondary care provider if:

- The criteria for re-referral as specified in the discharge letter are reached
- There are other clinical concerns that require specialist intervention

Practices will be responsible for:

- Holding and maintaining a register of patients who are being treated as part of this enhanced service
- Maintains adequate records – the practice should keep 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.
- Injection initiation dates are recorded in the patient records and included in the repeat medication information
- Providing a robust recall system (6 monthly intervals) from the register to ensure patients receive monitoring in a timely manner and follow up those patients who fail to attend
- Agrees a joint clinical management programme – patients should be managed on the basis of individual treatment plans that will normally be drawn up by local consultants. The practices will be expected to follow these treatment plans unless there has been discussion and agreement with local consultants to modify them.
- Supports the education of both newly diagnosed patients and those with established disease
- Ensures primary care staff training – the practice should ensure that all staff involved in providing any aspect of care under this scheme have the necessary training and skills to do so. The practice should be able to demonstrate that they have in place a policy to cover staff training and maintenance of skills.
- Provides safe and suitable facilities for undertaking invasive procedures – the practice should be able to demonstrate that they not only have appropriate facilities but also the policies and procedures in place for their correct use.

- Reports untoward events – the practice must undertake to notify the Health Board clinical governance lead of untoward events within 72 hours of their occurrence. These are in addition to any statutory obligations and should include:
  - Significant adverse events;
  - Emergency admissions or deaths of any patient treated under this service.
- Provides an outline individual management plan – wherever possible the practice should ensure that the patient has an individual management plan which has been developed by secondary care and giving:
  - The reason for treatment;
  - The agreed treatment programme;
  - The planned duration.

### **2.3 Population covered**

NHS Lancashire and South Cumbria ICB covers 196 GP Practices and has a total registered population of 1,853,016 (as of Jan 2024) patients.

The scope of this specification will cover all 196 practices and registered patients along with temporary residents (where clinically appropriate) that live within the geographical area of Lancashire and South Cumbria.

### **2.4 Any acceptance and exclusion criteria and thresholds**

The service will not accept referrals for the following:

- Any patients felt inappropriate for this pathway by secondary care or the receiving GP practice.

### **2.5 Interdependence with other services/providers**

- Acute trust providers
- Independent sector secondary care services

### **2.6 Applicable national standards (e.g. NICE)**

- [Denosumab for the prevention of osteoporotic fractures in postmenopausal women](#)
- [Denosumab-Position-Statement-Version-1.0.pdf](#)

### **Applicable quality requirements and CQUIN goals**

Providers may be accepted for the provision of this enhanced service if it has a partner or partners, employee or sub-contractor, who has the necessary skills and experience to carry out the contracted procedures.

Clinicians will need to satisfy, at appraisal, that they have the necessary medical experience, training and competence to enable them to provide for a safe and effective complex injection enhanced service.

Clinicians taking part in this enhanced service should be competent in resuscitation and, as for other areas of clinical practice, have a responsibility for ensuring that their

skills are regularly updated. Clinicians carrying out complex injection administration should demonstrate a continuing sustained level of activity, conduct regular audits, be appraised on what they do and take part in necessary supportive educational activities.

### **3. Location of Provider Premises**

Service delivery must be from the premises identified within the providers NHS Contract or where the service has been sub-contracted, the premises must be in suitable premises for delivery of the services set out in the specification.

### **4. Finance**

Practices will be paid £20 per injection.

#### **Fraud Policy**

In the event of suspected fraud or other illegality being uncovered at any stage the ICB will implement the ICB Fraud Policy and will investigate.

Information supporting reported activity and monitoring information must be made available to the ICB or its representatives upon request. Failure to provide this information, or the provision of incomplete or inaccurate information, may result in suspension of payments or clawback, as well as further investigation by the ICB and its representatives.

### **5. Contract and Monitoring Arrangements**

The provider will need to ensure that they maintain accurate records, including:

1. A register of patients requiring complex injection administration and monitoring
2. A record of patients first dose administration in secondary care
3. A record of subsequent injection dates
4. A robust recall system for all patients (at 6 monthly intervals)
5. Provide patients with a copy of their individual management plan developed by secondary care

The provider will need to submit monthly claims stating the number of injections provided to patients under this specification.

These should be recorded using the appropriate READ/SNOMED codes and an appropriate Data Quality Template will be supplied by the commissioner to support automated extraction where possible.

All details regarding data quality and submission of data can be found in the supporting Technical Guidance Document.