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NHS
Cambridgeshire and Peterborough
Clinical Commissioning Group

Administration of Denosumab (PROLIA®▼) for the treatment of osteoporosis in postmenopausal women and in men at increased risk of fractures 2019-20

(1st October 2019 – 31st March 2020)

1. Purpose of Agreement

This agreement outlines the expectations and obligations of clinical practice, on practices that choose to undertake the administration of denosumab (Prolia®) for treatment of osteoporosis in postmenopausal women and in men at increased risk of fractures.

2. Duration of Agreement

This agreement is for a period of six months, commencing **1st October 2019** and ending on **31st March 2020.**

3. Background

The administration of denosumab within primary care is designed to be an enhanced service which allows patients who require treatment to have it prescribed and administered safely, effectively and conveniently close to their home following initial assessment and recommendation by a hospital specialist.

Primary care teams are ideally placed to play a role in the management of patients with osteoporosis[1] and pharmacological intervention forms part of this. Most treatments can be administered in the primary care setting and NICE guidance is available to support appropriate use of available therapies:

- Primary prevention of osteoporosis: www.nice.org.uk/TA160
- Secondary prevention of osteoporosis: http://guidance.nice.org.uk/TA161

Denosumab (Prolia®) became available in the UK in May 2010. Denosumab for the treatment of osteoporosis in postmenopausal women has been assessed by NICE under a Single Technology Appraisal (STA) 204 issued (October 2010 (http://guidance.nice.org.uk/TA204)

Denosumab is administered as a single subcutaneous injection once every six months into the thigh, abdomen or back of arm. It can be administered by an individual who is adequately trained in injection techniques so is appropriate for administration in primary care.

4. Scope of service to be provided

This locally commissioned service will fund:

[1] Dr Pam Brown; Osteoporosis: Fracture Prevention in Primary Care; MIMS Women's Health. Available at: http://www.healthcarerepublic.com/search/mims_specialist/news/631249/Osteoporosis-fracture-prevention-primary-care/www.nice.org.uk/page.aspx?o=TA087

- The administration and monitoring of denosumab injections for the treatment of osteoporosis in postmenopausal women and men at increased risk of fractures.

5. Requirements under the Service

The roles and responsibilities of primary and secondary care and the patient are outlined below:

Specialist responsibilities

1 Confirm diagnosis and suitability for treatment (For post menopausal women as per NICE TA204).
2 Screen patients for any contraindications, such as hypocalcaemia, reduced renal function (<30 ml/minute/1.73m^2), and suitability for treatment including eGFR and calcium levels.
3 Discuss with the patient the benefits and potential side effects of treatment.
4 Baseline monitoring of the patient (see page 3).
5 To contact the GP practice to see if they will prescribe / administer as not all practices sign up to provide the service
6 Undertake a DEXA scan and review patient at the request of the GP six months after the patient's last injection.
7 Report any significant or unexpected adverse events to the MHRA via the Yellow Card Reporting Scheme.
8 Ensure clear arrangements for back-up, advice, and support to patient and GP.

Under this service level agreement the GP responsibilities are:

General Practitioner responsibilities

1 Prescription and administration of denosumab injection from the first dose every 6 months by a trained professional competent in administering injections
2 Ensure adequate supplementation with vitamin D and calcium
3 Reporting to and seeking advice from the specialist on any aspect of patient care which is of concern to the GP and may affect treatment
4 Screen patients for any contraindications, such as hypocalcaemia, reduced renal function (<30 ml/minute/1.73m^2) , or infection before each injection (except the first dose)
5 Report any significant or unexpected adverse events to specialist and MHRA via the Yellow Card Reporting Scheme
6 Maintain an up to date register of patients being treated under this service
7 Maintain a call and recall system to identify and follow up patients on a 6 monthly basis.
8 Refer patient to hospital specialist for DEXA scan and review six months after the patient's last injection.
9 Ensure adequate staff training and facilities for assessing patients and administering the injection.

Patient's role

1 Report any adverse effects to the specialist or GP whilst taking denosumab
2 Share any concerns in relation to treatment with denosumab
3 Report to the specialist or GP if they do not have a clear understanding of their treatment.
4 Arrange pre treatment dental inspection and treatment

6. Drug Treatment Monitoring & Evaluation

Indications: Treatment of osteoporosis in postmenopausal women (NICE TA 204) and in men at increased risk of fractures.

Denosumab may be used in men who have had a fragility fracture and a diagnosis of osteoporosis **ONLY** when alendronate and risedronate have not been tolerated or are contra-indicated.

Dose: 60 mg once every 6 months, Patient must be adequately supplemented with calcium and Vitamin D

Route of administration: Subcutaneous injection into thigh, abdomen or back of the arm

Course length: up to 3 years, in line with the patient's individual treatment plan. Followed by a clinical review and DEXA scan 6 months after last injection.

Side effects: common side effects include urinary tract infection, upper respiratory tract infection, sciatica, cataracts, constipation, skin rash, pain in the extremity.

Atypical femoral fractures (AFF) have been reported rarely (≥ 1/10,000 to < 1/1,000) in patients receiving denosumab. AFF may occur with little or no trauma in the subtrochanteric and diaphyseal regions of the femur. Specific radiographic findings characterize these events. Atypical femoral fractures have also been reported in patients with certain comorbid conditions (e.g. vitamin D deficiency, rheumatoid arthritis, hypophosphatasia) and with use of certain pharmaceutical agents (e.g. bisphosphonates, glucocorticoids, proton pump inhibitors). These events have also occurred without antiresorptive therapy. Similar fractures reported in association with bisphosphonates are often bilateral; therefore the contralateral femur should be examined in denosumab-treated patients who have sustained a femoral shaft fracture.

Discontinuation of denosumab therapy in patients suspected to have an AFF should be considered pending evaluation of the patient based on an individual benefit risk assessment. If AFF is detected, stop denosumab, minimise the patient's mobility and contact the Metabolic Bone Team. The Osteoporosis Helpline at Addenbrooke's Hospital is 01223 254933 (Advice Line: dial options 2, then 2).

Caution: Renal impairment – increased risk of hypocalcaemia if e-GFR is less than 30 ml/minute/1.73m^2 – monitor calcium levels

Contraindications:
(1) Hypocalcaemia
(2) Hypersensitivity to the active substance or to any of the excipients. Patients with known rare hereditary problems of fructose intolerance should not use denosumab
Notable drug interactions (refer to BNF and SPC)
(1) No interaction studies have been performed

Fertility, Pregnancy and breast feeding (Note indication is post menopausal women only):
(1) Not recommended for use in pregnant women
(2) No data are available on effect of Denosumab on human fertility
(3) Avoid in breast feeding women

Monitoring schedule:
(a) **Pre-treatment assessment**: Check for risk factors for osteonecrosis of the jaw. A dental examination and appropriate preventative dentistry is recommended for patients with risk factors.
(b) **Monitoring:** Monitor calcium levels and eGFR before each treatment. Patients with risk factors for hypocalcaemia, e.g. severe renal impairment, creatinine clearance < 30 ml/min, should have calcium levels checked within two weeks after the initial dose.

Patients should be advised to report any signs or symptoms of cellulitis. Patients should be advised to report new or unusual thigh, hip, or groin pain whilst on denosumab. Patients presenting with such symptoms should be evaluated for an incomplete femoral fracture.

Patients should also be advised to report any symptoms of hypocalcaemia, e.g. muscle spasms, twitches, or cramps; numbness or tingling in the fingers, toes, or around the mouth.

Advise patients to maintain good oral hygiene, receive routine dental check-ups, and immediately report any oral symptoms such as dental mobility, pain, or swelling to a doctor or dentist.

Prescribing Information: Summary of Product Characteristics (https://www.medicines.org.uk/emc/)

7. Pricing & Payment Arrangements

- **Pricing**

Practices will receive **£50.50 per injection** for administering denosumab injections and for providing the monitoring from the 1st injection as outlined in this specification, in line with the patient's individual treatment plan.

We do not expect this to be any more than 2 injections per patient per year administered in Primary care

- **Payment Arrangements**

Practices will be commissioned in the first instance against their commissioned levels of activity and the indicative budget for the provision of each service for the forthcoming year. Practices will receive monthly payments based on the total indicative budget for the year with any adjustments to be made at year end if necessary.

If a practice performs within their indicative budget for that service they will be paid at the full rate. However, payment for over performance will only be paid the full rate for activity above their budget if there is sufficient funding in the enhanced services cash pool.

Practices may be paid a marginal rate for activity above their budget if there is insufficient funding in the Enhanced Services cash pool to pay the full rate. The marginal rate for excess activity may be between 0-99% of the full rate depending on level of over performance across all practices.

8. Activity Reporting

Practices must provide the numbers of denosumab injections administered by the Practice in each quarter on via the Practice Commissioning Statement to capccg.enhancedservices@nhs.net by the 15th day of the following month, following Quarter end.

Practices are also required to record the following information to be retained at the practice but made available to the Commissioner on request.

- Number of patients currently on the register
- Number of injections performed
- Number of pre injection assessments have been carried out prior to injection
- Name of trained person administering the injection

If Practices require help or advice on clinical recording, coding and reporting, please contact The Primary Care Information team via the following email address: capccg.primarycareinformation@nhs.net

9. Payment Verification

Practices entering into this contract agree to participate fully in the post payment verification/validation process determined by the Commissioner and LMC. Practices should ensure that they keep accurate records to ensure a full and proper audit trail is available and Practices are encouraged to utilise Practice computer systems to enable this condition to be met.

10. Performance

The CCG reserves the right to suspend the commissioning of this service where there are concerns around compliance and patient safety.

11. Safeguarding Adults

It is important that practices protect adults from avoidable harm (as defined in Safeguarding Adults guidelines) including safeguarding training, training on the Mental Capacity Act and Deprivation of Liberty. A Safeguarding lead should be identified in each practice.

12. Care Quality Commission (CQC)

The provider must meet CQC standards and where appropriate be registered with the Care Quality Commission (CQC). The standards and the relevant services are contained in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 and the Care Quality Commission (Registration) Regulations 2014.

13. Termination

Should either party wish to terminate this agreement, a minimum period of 3 months notice must be provided in writing.

14. Signatories to the Agreement

Practices will be commissioned to provide the service as outlined in this agreement, based on the original sign up for 19/20. Practices are advised to inform the CCG if there are any changes to these current arrangements.