**Letter for transfer of care for denosumab from specialist to GP for:**

**post menopausal osteoporosis**

**osteoporosis in men**

(1 copy to be given to the patient and 2nd copy sent to the GP: letter to be emailed or posted to ensure that documentation arrives in good time for GP to arrange ongoing care.)

Dear Dr

Re your patient:

I am recommending the use of denosumab in line with the Hertfordshire and west Essex osteoporosis guidelines because of:

* inability to tolerate  alendronate and/or  risedronate and/or  zoledronic acid
* contraindication to  alendronate and/or  risedronate and/or  zoledronic acid
* reduced bone density despite the use of  alendronate and/or  risedronate and/or  zoledronic acid

The first injection of denosumab was given under my care on      . The next injection is due on      .

*(For patients with eGFR 15-30ml/min)* The patient’s calcium level was checked 2 weeks after the first injection and was found to be within range. The patient was followed up at 3 months and is tolerating the treatment. The patient is stable and it is therefore appropriate to transfer ongoing care to you.

*(For all other patients)* The patient was followed up at 3 months and is tolerating the treatment. The patient is stable and it is therefore appropriate to transfer ongoing care to you.

Denosumab as the Prolia® brand (60mg once every 6 months) is licensed and recommended by NICE (TA 204) for use in osteoporosis in post-menopausal women and is also licensed (although not considered by NICE) for osteoporosis in men. It is for one of these indications that I have commenced denosumab for your patient.

Unlike bisphosphonates the beneficial effects on bone density begin to decline as soon as a dose is missed. It is therefore important to deliver the injection on time and preferably no more than 2 weeks either side of the due date. I have discussed this with your patient, and the importance of arranging a prescription every 6 months so that timely injections continue twice yearly. I have provided the patient with information about how to access the patient support programme provided by the drug manufacturer. They are also aware that you will not be able to issue a prescription for denosumab if they have not had their calcium level checked, or if it is low. Please make arrangements to **check calcium and vitamin D levels 4 weeks prior to the date of any future injections**, and for an appointment with the practice nurse for the patient or his/her carer to be taught to self-administer the first injection prescribed by you.

Denosumab is placed after the oral bisphosphonates alendronate and risedronate, and IV zoledronic acid in the Hertfordshire and west Essex Guidelines on Management of Osteoporosis, because it is a relatively new drug (10+ years safety data available), and is more expensive than the other treatments and has to be given by injection. Following changes in the licensing of strontium in March 2014, it is now placed ahead of strontium.

There have been recent reports of severe low calcium levels with all doses of denosumab, although fatalities only occurred in the group of patient receiving the higher dose and frequency associated with the XGEVA® brand (for specialist prescribing only for the prevention of skeletal related events in adults with bone metastases from solid tumours).

I have discussed the symptoms associated with a low calcium level (muscle spasms, numbness and tingling) and your patient knows to seek advice if they develop these symptoms as they will need their calcium level checking. Calcium levels should be routinely checked no more than 4 weeks before every injection (2 weeks prior in patients with eGFR less than 30ml/min). DO NOT GIVE THE NEXT INJECTION/PROVIDE A PRESCRIPTION FOR SELF-ADMINISTRATION IF THE CALCIUM LEVEL IS BELOW THE NORMAL RANGE, BUT SEEK URGENT ADVICE FROM ME ABOUT ON-GOING TREATMENT.

Renal function should also be checked. If the eGFR has dropped below 15ml/min, DO NOT GIVE THE NEXT INJECTION/PROVIDE A PRESCRIPTION FOR SELF-ADMINISTRATION, BUT SEEK URGENT ADVICE FROM ME ABOUT ON-GOING TREATMENT.

If the eGFR is between 15 and 30 ml/min, recheck the calcium 2 weeks after the next injection (hypocalcaemia is more common in those with renal impairment).

I have discussed the need to take on-going calcium and vitamin D supplements, in order to make denosumab treatment effective, and to reduce the risk of developing low calcium levels. Supplements should usually provide a daily dose of 1-1.2 grams of calcium and 20 micrograms (800IU) of vitamin D. For your patient, I would recommend supplementing with       grams calcium and       units of vitamin D daily. Please ensure that a suitable product is added to the patient’s repeat prescription list to help them maintain a stable supply.

Given the risk of osteonecrosis of the jaw, I have discussed the precautions to take (maintaining good oral hygiene, need for routine dental check-ups, telling doctor and dentist if they need dental treatment/surgery, and telling doctor and dentist immediately if they have any problems with their mouth or teeth during treatment). I have also discussed the risk of osteonecrosis of the external auditory canal, and discussed the need to report any ear pain, discharge from the ear, or an ear infection during denosumab treatment. The patient has been advised to seek medical advice if there are new symptoms suggestive of atypical femoral fracture.

I attach a copy of the Hertfordshire and west Essex denosumab prescribing support document. The current version of the guideline can be found on the Hertfordshire and west Essex ICB Prescribing, Policies and Pathways website <https://www.hweclinicalguidance.nhs.uk/home>

According to the current guidelines, your patient will need a DXA scan after the 5th injection (i.e. after 2 years of treatment) to ensure they are responding to the treatment. After the 10th injection (i.e. after 5 years of treatment) the patient will need a further DXA scan arranged and should be referred back to secondary care in order to decide on continuing treatment.

Yours sincerely