



Briefing on Denosumab:

Change to AMBER Shared Care – ACTION needed by all practices

Denosumab prescribing guidance has recently led to the reclassification of this medication to AMBER Shared Care, which means that a formal shared care agreement with rheumatology is required. The new Shared Care Protocol was published by the ICB on 7th May.

It has historically been prescribed as GREEN +, with GPs taking full prescribing responsibility on the advice of an appropriate specialist, and patients not necessarily continuing under specialist review.

This creates a particular issue regarding patients who are established on denosumab and are not currently under active rheumatology review.

What's the concern?

There is increasing awareness of safety issues regarding the need for vitamin D monitoring and management in patients on denosumab, and the risks of delay or discontinuation.

What needs to happen?

Every patient who is being prescribed and administered denosumab in general practice will need a review by their local rheumatology team. If it is appropriate for the patient to continue this medication, a formal shared care agreement will be offered to you. As a reminder, it is always reasonable to decline to accept a shared care agreement at the discretion of the practice, in which case prescribing transfers to secondary care.

Secondary care teams are aware of this change in status of denosumab and we understand that you will also be receiving some advice from the ICB about this.

Any patients prescribed denosumab who are **not currently under rheumatology follow-up will need a new referral**. There is no clinical urgency to this referral unless there are current concerns regarding monitoring or use.

What's in the Shared Care agreement?

The full Shared Care Protocol can be found here - <https://ntag.nhs.uk/shared-care-guidelines/> Please be assured that CLMC have been actively involved in the process of agreeing this new guideline.

The workload for general practice reflects the current monitoring guidance and includes blood tests 4 weeks prior to each 6 monthly injection.

It is considered that this is covered by the LES contract.

GPs should not be expected to request any repeat DEXA scans.

What's the size of the problem?

In the Tees Valley, there are around 550 patients currently being prescribed denosumab. This is likely to represent around 10 patients per practice, depending on list size.

How should this be managed?

As a reminder, the individual who signs a prescription is medicolegally responsible for this prescription. **To continue to prescribe denosumab without a shared care agreement poses a clinical risk that would be difficult to defend should a patient come to harm.**

We recommend a simple search of your practice list to identify patients who are being prescribed denosumab, and a manual review of their records to determine whether they are under active rheumatology follow-up.

All patients will need a formal rheumatology review, which will require a new referral for patients who are no longer under hospital care. If a patient is already under the care of rheumatology, there is no need to generate a new referral; a short letter requesting a shared care agreement should be sufficient to provide medicolegal assurance until the next outpatient appointment. *We include sample letters to rheumatology at Appendix 1.*

It is essential that patients are advised of the reason for referral to ensure that they attend their hospital appointments. *We include some sample patient communications at Appendix 2.*

You will want to consider how you manage the work needed here e.g. waiting for the next injection attendance, waiting for the next medication review, or immediately referring / writing to rheumatology regarding all patients found via your search.

However, it is worth noting that patients with CKD 4 or 5 should be fully managed in secondary care, and are not suitable for Shared Care, according to the new guidance. You should consider prioritising for referral any patients found to be prescribed denosumab by you and who *also* have CKD 4 or 5.

CLMC recommends searches of your patient list at regular intervals to ensure that all patients for whom you are prescribing denosumab have attended their rheumatology review and have been provided with a shared care agreement. The results of these searches can also be used to provide evidence to CQC or at individual GP appraisals.

Please do feedback any questions about this briefing and any issues you may have with enacting this guidance to us on nencicb-tv.adminclmc@nhs.net



Cleveland Local Medical Committee

Appendix 1 – Communications with secondary care

For patients who are already being seen by rheumatology:

Re: Denosumab Shared Care

Many thanks for your ongoing care of our mutual patient who is receiving denosumab. We note the change in status of this drug to AMBER Shared Care. We will be happy to continue to prescribe until your next clinic review, after which we look forward to you sending us a shared care protocol for consideration.

For patients who are no longer under rheumatology follow-up:

Re: Denosumab Shared Care

Many thanks for your review of this patient who is being prescribed denosumab and is not currently under rheumatology follow-up. We note the change in status of this drug to AMBER Shared Care and request your review of this medication to ensure that ongoing prescribing remains appropriate.

Denosumab has been prescribed since XX/XX/XXXX. The last injection was given in practice on XX/XX/XXXX.

Last DEXA scan was on XX/XX/XXXX.

We are not aware of any current significant issues with the monitoring and administration of this drug and will be happy to continue to prescribe until your clinic review, after which we look forward to you sending us a shared care protocol for consideration, or your advice about discontinuation.

For patients who are no longer under rheumatology follow-up AND have CKD 4/5:

Re: Denosumab – currently prescribed in primary care but patient has CKD [4/5]

Many thanks for your review of this patient who is being prescribed denosumab and has CKD [4/5] and who is not currently under rheumatology follow-up. We note the change in status of this drug to AMBER Shared Care, but that in the shared care guidance, patients with this renal function are advised to be managed in secondary care. We therefore request your review of this medication, and if ongoing prescribing remains appropriate, we expect that you will arrange this in your service. If discontinuation is suggested, we are sure you will advise regarding this.

Denosumab has been prescribed since XX/XX/XXXX. The last injection was given in practice on XX/XX/XXXX.

Last DEXA scan was on XX/XX/XXXX.

We will be happy to continue to prescribe and administer until your clinic review, after which we look forward to your correspondence confirming future management.

Appendix 2 – Communications with patients

Communications should be sent either by AccuRx or by formal letter to ensure that there is a written record of the information that has been shared. This will provide robust medicolegal evidence if needed.

For patients already under the care of rheumatology:

There is new safety guidance about denosumab injections, which you receive to help your bones and prevent fractures, including a need for this to be reviewed regularly by rheumatology (bone) specialist doctors. Experts advise extra awareness about vitamin D levels and the importance of not delaying injections. Please continue to attend for your monitoring blood tests and injections at the practice, and for your hospital appointments – we just wanted to emphasise how important all these appointments are, considering the new guidance. If you have any concerns, please contact the practice or your hospital consultant.

[Include option to reply by AccuRx.]

For patients who need a new referral:

There is new safety guidance about denosumab injections, which you receive to help your bones and prevent fractures, including a need for this to be reviewed regularly by rheumatology (bone) specialist doctors. Experts advise extra awareness about vitamin D levels and the importance of not delaying injections. We have arranged a routine referral for you to see the specialist, which may take a few months. In the meantime, please continue to attend the practice for your monitoring blood tests and injections. If you have any concerns, please contact the practice.

[Include option to reply by AccuRx.]

For patients who need a new referral AND have CKD 4/5:

There is new safety guidance about denosumab injections, which you receive to help your bones and prevent fractures, including a need for this to be reviewed regularly by rheumatology (bone) specialist doctors. Experts advise extra awareness about vitamin D levels and the importance of not delaying injections. There is advice that those with kidney problems, like you, have closer specialist input, with checks and injections usually done at the hospital. We have arranged a routine referral for you to see the specialist, which may take a few months. In the meantime, please continue to attend the practice for your monitoring blood tests and injections. If you have any concerns, please contact the practice.

[Include option to reply by AccuRx.]