

Multiple Technology Appraisal (MTA) Percutaneous vertebroplasty and percutaneous balloon kyphoplasty for the treatment of osteoporotic vertebral fractures Appraisal Consultation Document

A response from the National Osteoporosis Society

Thank you for the opportunity to comment on the above appraisal consultation document (ACD). The National Osteoporosis Society welcome NICE's appraisal of percutaneous vertebroplasty and percutaneous balloon kyphoplasty. We were pleased to see the significant consideration by the committee of the debilitating impact that osteoporotic vertebral compression fractures have on patients' physical and emotional wellbeing.

In response to the specific questions posed, we make the following points.

Has all of the relevant evidence been taken into account?

We are not aware of any relevant evidence that has not been taken into account.

Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?

We feel that the interpretation of clinical and cost effectiveness are reasonable.

Are the provisional recommendations sound and a suitable basis for guidance to the NHS?

The National Osteoporosis Society supports the recommendations on the use of percutaneous vertebroplasty and percutaneous balloon kyphoplasty in patients with osteoporosis.

However the proposed time frame gives us cause for concern.

○ Given inherent delays in referral we feel it is unlikely that patients will make it from presentation in primary care, through a trial of optimum analgesia, subsequent referral to secondary care for assessment, imaging and re-referral for intervention within 6 weeks.

○ Throughout this 6 week window patients must be given time to consider the options available to them and make a considered decision about treatment.

○ Of additional concern is that patients may be fast-tracked, because of the time pressures, without proper trial of optimal analgesia.

○ In practice the proposed guidance means percutaneous vertebroplasty and percutaneous balloon kyphoplasty will be a realistic option only for those minority of patients admitted to hospital with acute vertebral fracture.

We would like further consideration to be given to a 12 week window, based on

○ The practical considerations outlined above.

- The evidence from the open label trials where many of these studies had inclusion criteria greater than 6 weeks.
- Current practice which considers the procedures as treatment options in patients with fractures at least up to 12 weeks (also see comment p515 "...given by the AG's clinical advisor that vertebral augmentation is typically performed around 3 months after the VCF...").
 - There is a lack of clarity within the document on what constitutes optimal pain management and how it should be achieved. From p6 of the ACD 'The Assessment Group adopted the term 'optimal pain management' to encompass comparator treatments in the trials that consisted of optimising pain medication, treating conservatively, or management without surgery.'
- It is important for patients to have a clear understanding of what they can expect to receive as part of optimal pain management.
- There are implications for services as achieving optimal pain management will result in greater referral rates into pain management services.
- Potentially relevant guidance on management of back pain (CG88 Low back pain: Early management of persistent non-specific low back pain) specifically excludes back pain from fractures.

Are there any aspects of the recommendations that need particular consideration to ensure that we avoid unlawful discrimination against any group of people on the grounds of gender, race, disability, age, sexual orientation, religion or belief?

We are not aware of any such issues.

We would like to see the following NICE guidance included in the section on related NICE guidance.

- Osteoporosis: assessing the risk of fragility fracture CG146
- Alendronate, etidronate, risedronate, raloxifene and strontium ranelate for the primary prevention of osteoporotic fragility fractures in postmenopausal women TA160
- Alendronate, etidronate, risedronate, raloxifene, strontium ranelate and teriparatide for the secondary prevention of osteoporotic fragility fractures in postmenopausal women TA161
- Denosumab for the prevention of osteoporotic fractures in postmenopausal women TA204

About us

The National Osteoporosis Society is the only charity dedicated to improving the diagnosis, prevention and treatment of osteoporosis across the UK. The organisation was established in 1986 and is a well-respected charity with approximately 25,000 members.

More information

For more information on this submission or our work, please contact [REDACTED]