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| <p><b>NICE Health Technology Appraisal</b><br/> <b>On</b><br/> <b>PERCUTANEOUS VERTEBROPLASTY AND PERCUTANEOUS</b><br/> <b>BALLOON KYPHOPLASTY FOR OSTEOPOROTIC VERTEBRAL</b><br/> <b>FRACTURES - ACD</b></p> |  |
| <p><b>TO: NICE</b></p>  | <p><b>FROM: Healthcare Improvement<br/>Scotland</b></p> <p><b>23 November 2012</b></p> |

1. Do you consider that all the relevant evidence has been taken into account? *If not, what evidence do you consider has been omitted, and what are the implications of this omission on the results?*

This comprehensive review appears to have taken account of all available evidence together with a sober assessment of its likely significance.

2. Do you consider that the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence? *If not, in which areas do you consider that the summaries are not reasonable interpretations?*

The summaries of clinical effectiveness are reasonable and rightly refer to the deficiencies in the evidence currently available.

The summaries of cost effectiveness detail several models and the assumptions on which the analyses are based. These also appear reasonable

3. Are the provisional recommendations of the Appraisal Committee sound and do they constitute a suitable basis for the preparation of guidance to the NHS? *If not, why do you consider that the recommendations are not sound?*

The provisional recommendations are sound and provide a good basis for guidance.

4. Are the patient pathways and treatment options described in the assessment applicable to NHSScotland? *If not, how do they differ in Scotland?*

These are equally applicable to NHSScotland.

5. Would the provisional recommendations change the patient pathways and/or patient numbers in NHSScotland? *If so, please describe what these changes would be.*

Currently the few patients referred for vertebroplasty or kyphoplasty in Scotland have frequently been suffering pain for more than 6 months. Implementation of this guidance would mandate a patient pathway which would allow patients to be identified, assessed by suitable clinicians, imaged and treated within 6 weeks. This would require an education campaign aimed at GPs and hospital doctors, and the setting up of multidisciplinary teams involving some or all of bone metabolism physicians, pain anaesthetists, orthopaedic surgeons and interventional radiologists. Funding for imaging and for the procedures, and access to hospital beds will also be needed.

6. Do you think there is any reason why this provisional guidance would not be as valid in Scotland as it is in England and Wales? *If yes, please explain why this is the case.*

No.

7. Please add any other information which you think would be useful to NICE or helpful in guiding the Scottish response to this assessment

Clinicians with experience of these techniques know that they can be very effective in reducing pain and improving quality of life. However NICE is correct in identifying that achieving good results is dependent on identifying and treating patients within a tight timescale, and their suggestion of 6 weeks is reasonable. There is a large number of these patients spread around all areas of the country. The minimum requirements for providing access to a satisfactory service are summarised at 5.above. This will need significant commitment and investment to realise.

***The above comment is provided to Healthcare Improvement Scotland by; Dr Grant Urquhart, Consultant Interventional Radiologist, Greater Glasgow Health Board.***

1. Do you consider that all the relevant evidence has been taken into account? *If not, what evidence do you consider has been omitted, and what are the implications of this omission on the results?*

YES

2. Do you consider that the summaries of clinical and cost effectiveness are reasonable interpretations of the evidence? *If not, in which areas do you consider that the summaries are not reasonable interpretations?*

No. I do not think the summary of cost effectiveness is accurate since the blinded (sham procedure controlled) evaluations of vertebroplasty showed no benefit of the intervention and by the same token (through network meta-analysis) kyphoplasty can also not be considered to be superior to a sham procedure. To advise use of a procedure in the NHS where there is a clear risk of adverse effects with no evidence of benefit over a sham procedure cannot be supported in my view. If this was a drug treatment it would not and could not be approved.

3. Are the provisional recommendations of the Appraisal Committee sound and do they constitute a suitable basis for the preparation of guidance to the NHS? *If not, why do you consider that the recommendations are not sound?*

No. The recommendations are not evidence based for the reasons outlined above. Further research need to be done to clarify the role of these procedures.

4. Are the patient pathways and treatment options described in the assessment applicable to NHSScotland? *If not, how do they differ in Scotland?*

Yes

5. Would the provisional recommendations change the patient pathways and/or patient numbers in NHSScotland? *If so, please describe what these changes would be.*

Possibly – they might lead to an increase in demand for VP or KP which would have cost implications

6. Do you think there is any reason why this provisional guidance would not be as valid in Scotland as it is in England and Wales? *If yes, please explain why this is the case.*

No

**The above comment was provided to Healthcare Improvement Scotland by:**

**Western General Hospital, Edinburgh**