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| **2V — Vertebral augmentation (vertebroplasty or kyphoplasty) for painful osteoporotic vertebral fractures** |
| **Summary of Intervention** |
| Osteoporotic bones are of reduced density and are more susceptible to fractures. Vertebral compression fractures are a break in a bone of the spinal column that results in a reduction in height of that bone. Osteoporotic vertebral fractures can cause pain and potentially an associated reduction in mobility. The pain can often improve as healing occurs. Deformity and respiratory or gastrointestinal disturbance as a result of fractures may be permanent.  Vertebral augmentation, including vertebroplasty (VP) and kyphoplasty (KP), refers to spinal procedures which involve the injection of bone cement (typically polymethylmethacrylate (PMMA)) into the fractured vertebral body via a needle inserted through the skin, using image guidance). These procedures aim to increase stability and strengthen the bone with the intention of reducing pain and further collapse. The procedure can be performed under local anaesthetic with sedation, or general anaesthesia interventional radiologist, spinal surgeon or pain specialist. Decisions regarding the need for vertebral augmentation are made by the operator, in conjunction with metabolic and pain specialists, geriatricians and the patient.  The alternative to vertebral augmentation is conservative management. This consists of pain relief, bracing, and manual therapy, although the evidence for bracing and manual therapy has shown to be of no benefit. Bone healing can take place over 2-12 weeks. Hospitalisation, immobility and opioid pain medication often have significant side effects, particularly in older patients. The majority of older hospitalised patients treated conservatively still have significant pain at three months and over one third at six months.  **This guidance applies to adults aged 19 years and over.** |
| **Number of interventions in 18/19** |
| **303** |
| **Proposal** |
| Vertebroplasty (VP) or kyphoplasty (KP) should be offered as a treatment for painful osteoporotic vertebral fractures on a case-by-case basis.  As per advice in the NICE Technology Appraisal Guidance 279 (TAG 279), VP or KP may be considered:  — In cases where patients have ‘severe (7/10 or greater on VAS scale) ongoing pain after a recent, unhealed vertebral fracture despite optimal pain management’ and in particular hospitalised older people  — Where the acute vertebral fracture has been proven on imaging and correlates with the site of maximal pain on clinical examination  — The decision to treat should be taken after multidisciplinary team discussion  — The procedure should take place at a facility with access to spinal surgery services  — Processes for audit and clinical governance should be in place  — VP/KP must be performed in conjunction with additional measures to improve bone health.  NICE TAG 279 (https://www.nice.org.uk/guidance/ta279) delegates the eligible timeframe for intervention to the clinician. However, evidence from a 2016 randomised controlled trial (RCT) offers evidence that older patients (>60  years old) with fractures at most 6 weeks old and severe pain despite optimal pain management that benefit most from the procedure. |
| **Rationale for Recommendation** |
| The evidence for VP in the management of vertebral compression is heterogeneous in population, comparators and outcomes. In 2013 and 2016 NICE TAG 279 reviewed the available evidence. NICE stated that the available open label randomised controlled trials comparing VP with conservative management better reflected the clinical reality. These studies demonstrated improvement in pain post VP. NICE acknowledged double blind RCTs which had demonstrated no significant improvement post VP but felt these to be less relevant.  Since 2016, two further double blind RCTs assessing VP compared to sham procedure have been completed. A 2016 RCT with more specific inclusion criteria (including patients over 60 years old, with fractures less than 6 weeks old and severe pain despite medication). compared VP with subcutaneous local anaesthetic. It demonstrated improved pain management in VP. A 2018 RCT, which included fractures up to 9 weeks old demonstrated no difference between VP and periosteal injection of local anaesthetic. A 2018 Cochrane systematic review stated that there was no evidence to support the use of VP in painful osteoporotic fractures. However, this review has been subject to criticism.  NICE TAG 279 and a number of publications since 2016 have shown a reduction in mortality in those treated with VA as opposed to conservative management.  Currently, there is no convincing body of evidence to alter the stance of the NICE TAG 279. There is general agreement that further adequately powered trials are needed for further assessments of subgroups, particularly hospitalised older people. VAPOUR (2016) showed a significant reduction in length of stay for their inpatient cohort. Risk of serious adverse event following VA is rare. VA has not shown to cause an increase in additional/adjacent vertebral fractures. It is clear that aggressive treatment of the underlying osteoporosis is paramount. |
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