

Subject:	<b>Vertebroplasty and balloon kyphoplasty</b>
Summary	<p>CVZ has assessed whether vertebroplasty (VP) and balloon kyphoplasty (BK) for the treatment of vertebral compression fractures can be regarded as insured provisions under the <i>Zorgverzekeringswet</i> (Zvw, Health Insurance Act).</p> <p>About 30% of the patients with radiological detectable fractures experience symptoms of vertebral compression fractures due to osteoporosis. If symptoms are presents, they often involve pain and reduce mobility and functioning as a result of the pain. Over the course of time, most patients find that these symptoms disappear spontaneously (on the whole). An uncontrolled study of a disorder such as this, which often clears up on its own and which is assessed on the basis of subjective outcome measures, involves the risk of overestimating the efficacy of the intervention. If the intervention also involves operative procedures there is the possibility of an extra placebo effect due to the operative procedures themselves. Clearly, double-blind, randomised research reduces the risk of bias considerably; particularly when sham-procedures are also involved. Two independent, double-blind, placebo-controlled studies into the efficacy of VP for the treatment of osteoporotic vertebral compression fractural concluded that the VP and the sham-operation had a non-significant positive effect on pain reduction and increased mobility. Instead of confirming the findings of previous research of a lower level of evidence, in which VP seemed to be effective, these results shed serious doubts on their validity. Detailed responses to these two studies can be found in scientific journals and in the responses of 2 of the 5 scientific associations that CVZ contacted. Doubts exist about the methodological quality and the generalisability of the conclusions. CVZ feels that the two double-blind RCTs have, at the very least, raised serious doubts about the efficacy of VP and BK, and that research of a similar level is needed in order to refute these conclusions if possible.</p>
Current state of affairs	<p>In August 2010 CVZ carried out a supplementary study of the literature, using the same search terms as in the period starting in November 2009. We found no additional publications of studies with the highest level of evidence (level A; double-blind, randomised trials). Very recently, an article appeared in the <i>Lancet</i> (online on 10 August 2010) about the Vertos II trials; a non-blinded RCT (level of evidence B) in which vertebroplasty was compared with conservative treatment of patients with a vertebral compression fracture. The Dutch Association for Radiology had already granted CVZ access to this study, which at that moment had not yet been published nor accepted. Despite the positive outcomes of this study for vertebroplasty, CVZ sees no reason to alter its conclusion on the basis of established medical science and medical practice. Evidence of a higher level will, at the very least, also cast serious doubt on this trial.</p>
Outcome of assessment	<p>CVZ's conclusion is that VP and BK do not comply with the criterion 'established medical science and medical practice', which means they are not regarded as insured care under the <i>Zorgverzekeringswet</i>.</p>
Type of ruling:	SpZ = Outcome of Assessment Zvw

Date:	30 August 2010
Issued to:	Health insurer Care-provider insurer Healthcare Authority
Care form:	Medical devices

For further information, please contact: JDerksen@cvz.nl

*The original text of this **Outcome of Assessment** of CVZ was in Dutch. Although great care was taken in translating the text from Dutch to English, the translation may nevertheless have resulted in discrepancies. Rights may only be derived on the basis of the Dutch version of CVZ's Outcome of Assessment.  
Furthermore, CVZ points out that only the summary of this report was translated. A proper understanding of all relevant considerations and facts would require familiarity with the Dutch version of this report, including all appendices.*