College voor zorgverzekeringen

Subject:	**Efficacy of interspinous implants**
Summary:	In this outcome of assessment, CVZ assessed whether the use of interspinous implants to treat: 1) patients with neurogenic claudicatio intermittens (NCI) and no more than grade I spondylolisthesis 2) patients with spondylosis and rontgenologically demonstrated spinal stenosis, but without classic neurogenic claudication symptoms 3) patients indicated for the prevention of postoperative back complaints after a spinal stenosis operation in connection with NCI can be regarded as an insured provision as defined in the Health Insurance Act (*Zorgverzekeringswet,* Zvw). The main question discussed in this outcome of assessment is whether treating spinal stenosis with interspinous implants complies with the established medical science and medical practice criterion, which would mean this intervention could be regarded as insured care. CVZ's reply to this question is negative: the treatment of spinal stenosis with interspinous implants does not comply with the established medical science and medical practice criterion. No care-activity currently exists within the framework of the DBC-system for treatment involving interspinous implants. Partly in response to advice from an interested party, CVZ feels it is important that the DBC-system should provide a separate care-activity for this treatment that is colour-coded red (not insured basic care). This is to avoid invoices being submitted under an existing care-activity that is not colour-coded and which is not intended for this purpose ('as if' coding).
Type of ruling:	SpZ = Zvw outcome of assessment
Date:	30-10-2012
Issued to:	DCC NOV NVVN ZN knowledge-centre DBCs NPCF
Care form:	Medical specialist care

The full text is as follows.

Outcome of assessment	**Efficacy of interspinous implants**
	Date: 30-10-2012
Publication	College voor zorgverzekeringen Postbus 320 1110 AH Diemen Fax (020) 797 85 00 E-mail info@cvz.nl Internet www.cvz.nl
Series number ***Department*** ***Authors***	2012099592 ZORG-ZA Dr. I.B. de Groot, Dr. G. Ligtenberg
Telephone number	Tel. +31 (0) 20 797 85 55

Contents

Summary

In this outcome of assessment, CVZ has assessed the use of interspinous implants to treat:

4) patients with neurogenic claudicatio intermittens (NCI) and no more than grade I spondylolisthesis
5) patients with spondylosis and rontgenologically proven spinal stenosis, but without the classic neurogenic claudication symptoms
6) patients indicated for the prevention of postoperative back-pain after a spinal stenosis operation in connection with NCI

can be included among the insured provisions as described in the *Zorgverzekeringswet* (Health Insurance Act, Zvw).

This assessment was occasioned by an SKGZ-dispute.

The main question behind this outcome of assessment is whether using interspinous implants to treat spinal stenosis complies with the established medical science and medical practice criterion which would mean that this intervention can be regarded as insured care for the above-mentioned indications.

CVZ's reply to this question is negative: the use of interspinous implants to treat spinal stenosis does not comply with the established medical science and medical practice criterion.

At the moment, within the framework of the DBC-system, no care-activity exists for treatment using interspinous implants. Partly in response to advice from an interested party, CVZ feels it is important that the DBC-system should provide a separate care-activity for this treatment that is colour-coded red (not insured basic care). This is to avoid invoices being submitted under a currently existing care-activity that is not colour-coded and which is not intended for this purpose ('as if' coding).

1. Introduction

1.a. Reason

One of CVZ's tasks is to assess whether care is covered by the basic insurance. This takes place by means of an outcome of assessment. The current assessment was occasioned by an SKGZ-dispute. This is a dispute between an insured client and a health insurer. The SKGZ plays an authoritative role in disputes and has requested advice in a dispute about medical-specialist care.

1.b. Principle question

The main question behind this outcome of assessment is whether using interspinous implants to treat spinal stenosis complies with the established medical science and medical practice criterion, which would mean that this indication/intervention combination can be regarded as insured care.

1.c. Reading instructions

Section 2 describes the general criteria a care-form must fulfil in order to be included in the basic insurance. Section 3 describes that the care requirement for symptoms relating to the legs, walking and a patient's back is an insured risk. This is followed by a discussion about whether the use of interspinous implants to treat spinal stenosis complies with the established medical science and medical practice criterion. Section 4 discusses the reactions received during consultations with the scientific associations in the field. Section 5 is about the conclusion and finally, section 6 discusses possible consequences for implementation in practice.

2. When is a care-form deemed an insured provision and how does CVZ assess this?

2.a. What criteria apply?

A care-form is only insured care if it complies with the following criteria: the care-form must fulfil a medical care requirement (the indication) and evidence must exist that the care-form (the intervention) is effective.

Article 10 of the Zvw describes the first criterion: it sums up the risks that must be covered by insurance. It describes these risks as 'the need for medical care, etc'. The care-form being assessed is only regarded as an insured provision if it covers (one of) these risks.

Article 2.1, second paragraph, of the Health Insurance Decree describes the second criterion: a care-form can only be regarded as an insured provision if the care is regarded as effective according to established medical science and medical practice.

2.b. How does CVZ carry out its assessment?

Once CVZ has established that a given care-form does cover (one of) the risks mentioned in article 10 of the Zvw, CVZ then establishes whether it fulfils the established medical science and medical practice criterion.

CVZ described its methods for determining what constitutes established medical science and medical practice in its report *Assessing established medical science and medical practice*. CVZ examines whether scientific evidence exists for the efficacy of the care-form. In doing this CVZ adheres to the principles of evidence-based medicine (EBM). The EBM-method focuses on 'the meticulous, explicit and discerning use of the best evidential material currently available.' Furthermore, CVZ's general point of departure is that the highest possible level of evidence must be available for a positive decision on the medical-scientific data relating to efficacy. If such data are not available than CVZ may decide to depart from this requirement, indicating its motives, and be satisfied with data that has a lower level of evidence.

3. Does the care-form fulfil the criteria?

As care for legs, walking and back-pain is insured care (article 10, paragraph a), this outcome of assessment is only about the question of whether placing an interspinous implant in the treatment of spinal stenosis complies with the established medical science and medical practice criterion.

3.a. Which indication is involved?

This report discusses a number of indications for the placement of interspinous implants:

- Patients with neurogenic claudicatio intermittens (NCI) and no more than grade I spondylolisthesis
- Patients with spondylosis and rontgenologically proven spinal stenosis, but without the classic neurogenic claudication symptoms
- Patients indicated for the prevention of postoperative back-pain after a spinal stenosis operation in connection with NCI

3.b. Does the care-form comply with the established medical science and medical practice criterion for these indications?

This outcome of assessment is about the placement of interspinous implants to treat spinal stenosis. In May 2012 the Dutch Cochrane Centre carried out a literature study to assess whether the use of interspinous implants to treat spinal stenosis in cases involving the above-mentioned indications complies with the established medical science and medical practice criterion. That report is enclosed as background information. The following is a summary.

What is the standard treatment?

Standard treatment of spinal stenosis is physical therapy and pain relief (conservative therapy) and – where this fails – a laminectomy, with or without spondylodesis (surgery).

What is the new treatment?

A less invasive treatment is to place a 'spacer' (in the form of an implant) between the processi spinosi of two vertebrae. This can be done at one – or at most – two levels. Distraction of the posterior structures in this way creates more space in the vertebral canal and in the foramina, the nerve exit points. This reduces pressure on the nerve tissue ('decompression').

Which studies did CVZ examine?

Symptoms relating to the legs, walking and the back that are associated with constriction of the spinal column are not rare. This assessment included prospective, randomised (RCT) and non-randomised (CCT), controlled trials in which the treatment of spinal stenosis with interspinous implants in patients with spinal stenosis was compared with conservative or surgical treatment. In CVZ's opinion there are no arguments for accepting a lower level of evidence than the level of comparative studies. CVZ examined not only whether the

studies showed that the treatment was effective for the indication concerned, but also the chance of complications. The studies involved were also expected to provide a complete picture of the results.

Which studies were found?

Below are the results of the literature study carried out by the Dutch Cochrane Centre, specified according to indication.

Indication: NCI
Three studies examined the efficacy of interspinous implants for the indication NCI. In one RCT the placement of an interspinous implant was compared with conservative treatment and in another RCT an interspinous implant was compared with surgical treatment (spondylodesis with pedicular screws). One CCT compared an implant with surgery (laminectomy) (table 1).

Indication: spondylosis and rontgenologically proven spinal stenosis, but without the classic neurogenic claudication symptoms
Not a single prospective, comparative study was found for this indication.

Indication: preventing back-pain after a spinal stenosis operation in connection with NCI
Two CCTs examined the efficacy of interspinous implants for the prevention of back-pain after a laminectomy in connection with NCI (table 1). The number of patients included in the studies varied between 36 and 191 patients.
Maximum follow-up was two years.

What was the methodological quality of the studies found?

The methodological quality of the studies was assessed based on the "Cochrane Risk of Bias tool".
The methodological quality of the RCTs was poor. For example, the RCTs did not provide an exact description of the randomisation procedures. One study did involve sufficient blinding regarding the allocation of treatment. It was not mentioned in the other studies. Not one study reported the blind status of the patients and/or assessors. The CCTs also had methodological flaws. CCTs have a greater risk of biased results because the intervention allocation has not been randomised. This can lead to a bias in the results due to differences between the groups.
These differences were not corrected (or not described) in the CCTs).

What was the quality of the evidence?

The quality of the evidence was assessed according to the GRADE system. This involved assessing, per outcome (category), confidence in the effect found, i.e., the degree of confidence that the (pooled) effect agrees with the actual effect. A high level of confidence increases the quality of the evidence found (table 1).

What was the efficacy according to the studies?

Indication: NCI

Implant in comparison with conservative treatment

The efficacy of interspinous implants versus conservative therapy for the indication NCI was only demonstrated in one RCT. In comparison with conservative treatment, a large statistically significant improvement in patients' pain symptoms and satisfaction was measured two years after placing an implant. The group that received the interspinous implant also required operations significantly less frequently subsequent to their treatment. The quality of the evidence was low. The results therefore need to be confirmed in more studies with less bias.

Implant in comparison with surgery

In comparison with surgical treatment, symptoms were reduced in both the intervention group and the control group, whereby the patients with an implant reported slightly more improvement than the patients in the control group.
The difference could not be statistically verified due to the lack of standard deviations. The opposite was the case for a different type of implant, though these differences were not statistically significant. This means that the efficacy of treatment with interspinous implants versus surgical treatment for cases of NCI has not been proven.
The quality of the evidence was extremely low.

Indication: back-pain after a spinal stenosis operation in connection with NCI

In both studies the symptoms improved in both the intervention group and the control group. In general, patients with interspinous implants reported a slightly larger – though not statistically significant or clinically relevant – improvement than patients in the control group. The added value of placing an interspinous implant after a laminectomy in order to prevent back-pain has not been demonstrated in an RCT. The quality of the evidence was extremely low.

Did the studies take complications into account?

Relatively few complications (such as leakage of cerebrospinal fluid, infection and nerve damage) occurred during the two-year follow-up and no more frequently in the people treated with interspinous implants. This applies to all the indications studied.

Table 1. Summary of studies included

Name first author, year	Study design	Treatment Number of patients (n)	Indication	Follow-up Improvement	GRADE assessment
Zucherman, 2005	RCT	Interspinous implant vs. conservative N = 191	NCI	2 years Significant improvement	low
Azzazi, 2010	RCT	Interspinous implant vs. surgery N = 60	NCI	2 years No significant difference	extremely low
Sobottke, 2010	CCT	Interspinous implant vs. surgery N = 36	NCI	1 year No significant difference	
Richter, 2010	CCT	Surgery +/- Interspinous implant N = 60	Prevention of back-pain after spinal stenosis operation due to NCI	1 year No significant difference	extremely low
Ryu, 2010	CCT	Surgery +/- Interspinous implant N = 36	Prevention of back-pain after spinal stenosis operation due to NCI	Average: Surgery + interspinous implant 21.4 months vs. surgery 22.8 months Only different in back-pain	

RCT: randomised controlled trial, CCT = non-randomised comparative study, NCI = neurogenic claudicatio intermittens

What was the overall quality of the evidence?

Due to limitations in the study design and lack of precision in the estimated effects, the overall quality of the evidence varies from low to extremely low. This means that the accuracy of the effects measured is too uncertain. Furthermore, long-term outcomes (2-5 years) are lacking, so we do not know whether the results following an intervention will be lasting. This applies in particular to the chance of long-term complications.

Were the outcomes of the studies complete?

No protocol for any of the studies was found in a trial register. This meant that CVZ was unable to fully assess the published outcomes. For the rest, the trial register shows that eight trials into the use of interspinous implants are either still on-going or have not been published. Most of these (n = 5) are for the indication NCI.

3.c. Conclusion on the established medical science and medical practice criterion

Not established medical science and medical practice

Based on the available studies, CVZ concludes that using interspinous implants to treat spinal stenosis cannot yet be regarded as effective.

4. Consultation regarding contents

CVZ consulted the following scientific associations: The Dutch Orthopaedic Association [*de Nederlandse Orthopedie Vereniging,* NOV], the Dutch Association for Neurosurgery [*de Nederlandse Vereniging voor Neurochirurgie,* NVvN] and the Dutch Spine Society (DSS). These three associations have indicated their agreement with the conclusion that, based on the current literature, the indication/intervention combination cannot be regarded as effective and should therefore not be deemed insured care.

The quality commission of the NVvN stated that measures needed to be taken to prevent invoicing under a non-applicable care-activity. CVZ therefore suggests that the DBC system should include a care-activity for this treatment, one that is colour-coded red. This has been included in the section regarding consequences.

The content of the comments have been incorporated into the report.

5. Conclusion in relation to insured care: Outcome of assessment

CVZ's literature study shows that using interspinous implants to treat spinal stenosis does not currently comply with established medical science and medical practice. This means that the treatment is not an insured provision.

Once the results of current studies become available, CVZ will examine whether there is reason to reconsider this outcome of assessment.

6. Consequences for daily practice

No care-activity currently exists for treatment with interspinous implants within the framework of the DBC-system. Partly in response to the advice of an interested party, CVZ feels it is important that the DBC-system should provide a separate care-activity for this treatment which is colour-coded red (not insured basic care). This is to avoid invoices being submitted under a currently existing care-activity that is not colour-coded and which is not intended for this purpose ('as if' coding).