Report

Assessment of the reimbursement criterion

"current medical science and practice"

The text in this report is an English summary of the following report:
Beoordeling stand van de wetenschap en praktijk. Rapport nr 254. College voor Zorgverzekeringen. Diemen, 2007.
For the full text we refer to the Dutch version of the report.

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Documentnumber 2012076657 (27071300 Dutch version)
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A draft version of the Dutch report was sent for assessment to a number of external referees. We would like to take this opportunity of sincerely thanking them for their critical comments. These referees are as follows:
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Summary

Maintaining the basic health insurance package

CVZ is responsible for maintaining the basic health insurance package within the framework of the Health Care Insurance Act (*Zorgverzekeringswet,* Zvw) and the Exceptional Medical Expenses Act (*Algemene Wet Bijzondere Ziektekosten,* AWBZ).

Definition of the basic insurance package

One of CVZ's tasks is to define the insurance package in accordance with current laws and legislation. Within this framework CVZ assesses what forms of care will be included in the basic insurance package. One of the core elements of the Zvw is that whether health care is covered by the health insurance is determined in part by the criterion 'current medical science and practice'. This criterion applies since the introduction of the Zvw (as of 1st January 2006). Since the introduction of the Zvw, the criterion ('current medical science and practice') applies to all forms of care[1]. This requires an assessment framework that is consistent for all forms of care.

Zvw criterion: 'current medical science and practice'

Consistent assessment framework

In this report CVZ elaborates on how the criterion 'current medical science and practice' will be assessed. The framework is based on the principles of evidence-based medicine (EBM).
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Principles of EBM

The EBM method focuses on the "careful, explicit and judicious use of the best evidence" . The evidence-based requirement does not imply that all medical interventions are expected to be based on firm evidence or firm outcome indicators, but that the available evidence has been systematically selected and in a structured format has been weighed and used. Central to the method is that a certain level of evidence is allocated to the medical-scientific information selected, thereby creating a hierarchy of evidence. Furthermore, in principle, stronger evidence outweighs weaker evidence.

Steps in the EBM-method

When making an assessment, CVZ follows the steps of the EBM method. Important steps, as indicated above, are systematically searching for, assessing and classifying medical-scientific literature. CVZ subsequently adopts a decision over the question of whether the care is according to 'current medical science and practice'. The basic requirement for a positive decision is that medical-scientific data with the highest level of evidence should be available. In case of

CVZ decision-making

Basic requirement: evidence of the highest level

	plausible, profound arguments for the lack of evidence of the highest level. evidence of a lower level can be sufficient as well. However, it is essential that CVZ justifies the reason for accepting a lower level of evidence. In this report CVZ describes a number of situations in which medical-scientific data with a lower level of evidence can be regarded sufficient to conclude that the care is according to 'current medical science and practice'.
Knowledge and expertise	Carrying out the assessment requires adequate knowledge and expertise. CVZ is capable of this, but if necessary input from external experts on specific matters will be asked (in particular the scientific associations of the various professional groups).
Experience, particularly with med. spec. care	The experience that CVZ already has in the assessment of medical-scientific research is mainly in the field of care provided by medical specialists. The introduction of the Zvw means that the criterion 'current medical science and practice' now also applies to other forms of care. CVZ still has to obtain experience with certain interventions. CVZ has set itself the goal of developing and refining their assessment task even further. A transparent and verifiable method of work is vital to this.
Further development/completion of the assessment task	

Introduction

Maintaining the basic health insurance package

CVZ fulfils the function of maintaining the basic health insurance package within the framework of the Health Care Insurance Act and the AWBZ. In brief, this means that CVZ assesses what is in the insured package, advises about the question of what should and should not be in the package (advice on additions and removals) and advises on the legislative system.

Criterion: 'current medical science and practice'

One of the core aspects of the Zvw is that the question of whether care falls under health insurance coverage is partly determined according to 'current medical science and practice'. This criterion applies since the introduction of the Zvw (as of 1st January 2006) and it has taken the place of the Sickness Fund Act criterion of what is considered usual care. CVZ already has years of experience in examining care according to that criterion. At the time emphasis was on assessing care provided by medical specialists. Since the introduction of the Zvw, the criterion ('current medical science and practice') also applies to other forms of care. This means that a consistent assessment framework needs to be applied to all forms of care. In connection with the desired transparency and verifiability, CVZ feels it is important to define how it will carry out verification of the criterion 'current medical science and practice'.

Consistent assessment framework

Relevant to health insurers

The method described here is also relevant to health insurers. After all, in individual cases they will have to make a decision, on the basis of a person's insurance, about the question of whether a form of care is covered by the insurance. As stated above, this will partly be determined by the criterion 'current medical science and practice'. Health insurers will be able to use the method described here as guidance for their assessment. It is also important that care-providers clearly understand the assessment method. They – particularly if they have been contracted to provide care by a health insurer – have to inform patients/insured persons about whether an

and for care-providers

intervention being offered is according to ‘current medical science and practice’ (and therefore – as long as the other conditions have been fulfilled – covered by the insurance)[2].

Statutory framework

Risks to be insured

Article10 of the Zvw contains a summary of the insurable risks. It is a global description of the provisions that have to be included in the basic health insurance[3]. These are the following insurable risks, in particular the need of:

a. medical care;
b. dental care;
c. pharmaceutic care;
d. medical aids;
e. nursing;
f. welfare;
g. residence in relation to medical care;
h. transport.

Translation into insured provisions

The basic insurance package is stipulated in article 11 of the Zvw. The article regulates which provisions should be provided by health insurance and obliges health insurers to include these provisions in the health insurance and to translate them into insured provisions. The health insurance agreement (policy) that insured persons have with a health care insurer provides them either with the right to care or the right to the reimbursement of the costs of care.

Bvz provides detailed regulation on content/quantity

Article 11, third paragraph of the Zvw determines that the content and quantity of insurable provisions (which the health insurers must translate into insured provisions) are stipulated in further detail by means of a governmental decree (Order in Council). In this case the Health Insurance Decision (Bzv) . Article 2.1, first paragraph of the Bzv, refers to articles 2.4 up to and including 2.15 for care to which insured persons have a right. These articles regulate successively medical care (including G.P. care, care by medical specialists, obstetric care, paramedical care and cure-oriented mental health care [GGZ][4]), dental care, pharmaceutic care, medical aids, nursing, welfare (including maternity care), residence and transport. The legislators define some forms of care in more general terms. This applies for example to GP care and care provided by medical specialists[5]. Other forms of care are regulated in more

General description	detail and sometimes one can even speak of a restrictive list[6].
Detailed description	This applies for example to medical aids and extramural pharmaceutic care. A restrictive list at category level applies to medical aids and a restrictive list at product level applies to extramural pharmaceutic care.
'current medical science and practice' applies to all forms of care	For all forms of care – even for the forms of care that are regulated in (more) detail – the content and quantity of care is partly determined by 'current medical science and practice' and – where this is not established – by whatever is regarded in the relevant field as responsible and adequate care and services (article 2.1, second para, Bzv). For provisions defined at product level, which applies to extramural medicines, this verification with respect to 'current medical science and practice'[7] has already taken place, i.e., before a medicine is included in the restrictive enumeration. In This means that if a medicine is indicated by the Minister (i.e., it has been included in the restricted list), then fulfilment of the criterion of 'current medical science and practice' has already been established[8].

Method for assessing the 'current medical science and practice'

Evidence-based medicine (EBM)

Using the best evidence available

As indicated, the EBM-method focuses on "the careful, explicit and judicious use of current best evidence". Evidence-based does not mean that firm evidence has to exist for all medical interventions, but it does mean that the available evidence has been systematically selected, weighted and used. Furthermore, it is important to emphasise that EBM does not mean that attention will be given only to 'hard' end-points, such as morbidity and mortality. Other end-points, such as quality of life, patient satisfaction and the experience of patients and care-providers, will also be included in the assessment. Obviously, here also, research and reports must have been carried out in a scientifically responsible manner. In this way experience-based practice is also involved in the assessment[9].

Allocating "levels of evidence"

The core of the EBM-method is that a level of evidence is allocated to the selected medical-scientific information, which results in a hierarchy of evidence. Making this hierarchy transparent is a transparent way of indicating the strength of the scientific evidence. Furthermore, strong evidence outweighs weaker evidence.

The EBM follows these four steps :

EBM steps:

Formulating the question

- ***Formulating the question to be answered.*** It must be formulated so that relevant literature can actually be identified and irrelevant literature is not selected[10]. This is an initial selection, which can be further refined if necessary;

Literature search

- ***Structured search for literature.*** A large number of databases are available. Important ones are the databases of Medline/Pubmed and the Cochrane Library and

EMbase[11]. In addition, it is relevant to be acquainted with national and international guidelines, such as those of the CBO or as found in the Guidelines International Network (GIN) and in the Guideline Clearing House of the Agency for Healthcare Research and Quality;

Selecting literature

- ***Selecting the literature found.*** A (detailed) selection of relevant studies takes place according to various criteria, which must have been properly and transparently defined prior to the selection. Examples of criteria are the follow-up duration, the degree of relevance of the end-points and the composition of the study population.

Assessing literature

- ***Assessing the selected literature***. The assessment of the study described can be divided into:
  - the (internal) validity[12];
  - its importance (both the size and the relevance of the effect)[13];
  - its applicability[14];

Classifying literature

- ***Classifying the literature assessed.*** On the basis of the final assessment, each study is classified according to the level of evidence, using the following classification (reproduced here only for therapeutic interventions):

  A1: systematic review of at least two A2-level studies carried out independently of one another;
  A2: sufficiently large, high quality randomised double-blind comparative clinical study (RCT);
  B : comparative study, though not with all A2 characteristics;
  C : non-comparative study;
  D : experts' opinion.

Formulating conclusion(s)

- ***Formulating one or more conclusions.*** This step is about having to determine which conclusion(s) can be drawn based on the literature that has been assessed and classified[15].
  The (methodological) quality of the studies was

determined for all levels of evidence (from A1 up to and including D). This is weighted in decision-making. It is also possible that more than one systematic review has been published for a given intervention, with differing conclusions. In that case the quality of the reviews will be the deciding factor[16].

Basic considerations for the assessment

In determining whether care fulfils the 'current medical science and practice' criterion, CVZ keeps to the steps described in brief above. The following basic considerations are applicable:

Comparing standard/usual treatment

- CVZ assesses the intervention to be examined in comparison with the standard or usual treatment[17], including efficacy, effectiveness, and side effects or other undesired effects in the comparison. Experience, applicability and ease of use can also be included in the assessment[18].

Systematic reviews

- Where possible CVZ will use or expand upon qualitatively good systematic reviews of randomised studies on the subject. Such reviews have the highest level of evidence. If a systematic review is available that fulfils the quality requirements, then it is sufficient to check whether other additional studies have appeared since carrying out the literature search for the review. The studies included in the review and the additional studies are then assessed jointly.

Peer-reviewed publications

- In principle, for their assessment of 'current medical science and practice', CVZ uses only published and peer-reviewed literature[19].

Specific regulations for assessing

- The Health Insurance Regulation includes rules for the assessment of medicines (assessment of replaceability and therapeutic value). For example, article 2.39 of the Health

medicines

Insurance Regulation provides a summary of the data to which attention will exclusively be given for medicines. This is explained in more detail in the brochure "Procedures for the assessment of extramural medicines"[20]. For example, it indicates that in principle, when assessing medicines, no attention will be given to: 1) opinions of experts consulted by the registration-holder and 2) "expert reports" used during registration, unless no EPAR/NPAR is available[21].

EBM-guidelines

- Where possible, CVZ makes use of existing (international) EBM-guidelines. It is important to determine the quality, the possibility of being outdated and the independence of these guidelines.

Insurance status abroad

- Where possible, CVZ considers the insurance status abroad of the care being assessed[22]. After all, in legal decisions about the usual practice criterion (current criterion: 'current medical science and practice'), the question of whether the form of care is included in other member states' social insurance package is significant. Decision-making on the package will always be based on current Dutch legislation. Extensive additional legislation applies to forms of care with a positive list, such as, for example, pharmaceutical care. Comparison with the situation abroad is less relevant in this case.

Decision-making regarding 'current medical science and practice'

Health care provisions based on established medical science/medical practice

CVZ gives its opinion on the question of whether care (for certain indications) is according to 'current medical science and practice'. The answer is either positive or negative. Unlike guidelines, CVZ does not make any recommendations.

Equivalence or added value

The intervention that is to be assessed should be equivalent to the standard or usual treatment or it should have added value. This applies both to effectiveness and to undesired effects. If the conclusion of "equivalence" or "added value" is based on

the data assessed, then the care is according to 'current medical science and practice'. If the conclusion is that the assessed intervention is not at least equivalent, then the care does not fulfil the 'current medical science and practice' requirement.

Evidence of higher level outweighs evidence of a lower level.

If studies have the same outcome indicators, in principle evidence of a higher level outweighs lower level evidence. However: reports of severe side effects in particular may have a lower level of evidence (case reports). This evidence should not be ignored, but included in weighing up whether there is a proper balance between effectiveness and side effects.

CVZ's approach can be described as follows:

Concordant results: unequivocal decision

- The availability of one A1-level[23] study or at least two A2-level studies with concordant results is, in principle, sufficient for an unambiguous decision (according/not according to 'current medical science and practice'). One should always check for the presence of conflicting evidence of a lower level and the possible reasons for this. This is particularly important for severe side effects.

In the event of discordant results

If several equivalent systematic reviews or RCTs with discordant results are available, then an unambiguous decision cannot be taken. In this case the presence of evidence of lower level that supports the results of one or more of the discordant reviews/RCTs may form the deciding factor.

Involve evidence of a lower level in assessment

- Where no A1 level study or (completed) studies A2-level studies have been published, CVZ will include evidence of a lower level (B, C and D-level studies) in their assessment. As indicated above, EBM is not limited to randomised trials, meta-analyses or systematic reviews; a positive decision can also be made based on evidence of a lower level. In that case a number of conditions/comments apply:

Conditions

- the results of relevant studies and sources must be

consistent and up-to-date;
- it is important to find out why no higher level evidence is available;
- there must be plausible, profound reasons why there is no evidence of the highest level. Only then can the conclusion based on evidence of a lower level be drawn, that the care under assessment is according to 'current medical science and practice'. Below CVZ provides examples of arguments.

An illustrative example:

No arguments for lack of RCTs

In 2006 CVZ assessed the intervention "endovenous laser treatment of varicose veins"[24]. At that moment there were no RCTs comparing the effectiveness of this intervention with the standard treatment over a long-term period. Nevertheless, the intervention was already used on a large scale, partly due to more rapid recovery and cosmetically improved results for patients. CVZ was unable to find any arguments as to why RCTs should not be demanded in this case, and for this reason decided that this intervention was not yet according to 'current medical science and practice'. The results of an RCT are currently expected. As soon as they have been published in a peer-reviewed journal, CVZ will re-assess the intervention.

Evidence of a lower level

Positive decision based on evidence of lower level

In the following situations, a positive decision can be made based on evidence of a lower level. These are situations in which it has been established that no (additional) RCTs can be demanded and for which the evidence of a lower level is so convincing (consistent and up-to-date) that the conclusion can be drawn that the care being assessed is according to the 'current medical science and practice'.

Demanding a RCT is not ethical

These are the following situations:

- interventions for which it would not be ethically responsible to carry out (randomised) research. This applies to interventions involving persons unable to give their informed

consent (children, people suffering from dementia, the mentally handicapped) and for interventions that have to be carried out in ICU's and in acute life-threatening situations.

An illustrative example:

Rare disorder: RCTs not required

In 2006 CVZ assessed the intervention "early intensive neurorevalidation in children with a vegetative or low level of consciousness"[25]. This was a relatively short-term intervention both diagnostically and therapeutically. Due to the small number of patients (± 40 per year), the fact that they were unable to give consent and the fact that this was an extremely serious disorder, CVZ decided that randomised studies could not be demanded. Descriptive studies were available for a cohort of patients, and comparison took place with historic controls. CVZ deemed this sufficient to decide that this care is according to 'current medical science and practice'.

Blinding is not possible

- interventions for which blinding is impossible. This is often the case for surgical interventions. For medical aids also, it is not always possible to fulfil all the requirements of an RCT. In particular the "double blinding" requirement is often not feasible. In that case, unblinded, open RCT is the highest possible study design.

Low prevalence

- interventions involving an indication group with an extremely low prevalence (rare disorders).

Starting RCT outdated

- interventions for which it seems too late to start an RCT. This is the case, for example, when an intervention has already become well established, so that patients can be expected to refuse to co-operate in randomisation. In such cases neither will researchers generally be motivated to start up (an) RCT/RCTs.

Interventions that have existed for longer

- interventions that have been in use for a long period of time and for which international consensus exists about their effectiveness, but for which no randomised studies have been

done in the past. The international consensus is based on lower level evidence.

An illustrative example:

Intervention established: starting RCT unrealistic

In 2007 CVZ assessed the metal-on-metal hip resurfacing arthroplasty (MoM HRA hip prosthesis)[26]. This hip replacement method has been applied widely during recent years. In spite of the fact that only 1 RCT has been published, CVZ decided that this intervention is according to 'current medical science and practice'. They had two reasons for this: many other studies were available, in particular non-randomised comparative studies and large cohort studies with a long follow-up. On the grounds of this evidence, the professional groups, both national and international, had started placing such prostheses on a large scale. On the grounds of these data, CVZ assessed that to initiate a new RCT would be an unrealistic demand.

Comparison with foreign social insurance systems

Insurance situation abroad

CVZ indicated above that, where possible, their assessment will involve the insurance status of the intervention in other countries. In such a case, CVZ's position is that the mere fact that a (new) treatment was provided in accordance with the legislation of the country where the treatment in question took place, without any evidence, is insufficient to consider the care to be according to 'current medical science and practice'.

Considerations abroad sometimes relevant

As some other social health insurance systems also use (among other things) 'current medical science and practice' as a factor to determine the content and size of the package, in a specific case it may be important to investigate which (medical) considerations played a role in the package decision in the country concerned. This could be relevant in situations in which, though evidence was available, it was not of the highest level.

Relevant knowledge and expertise

The examples provided show that the assessment of whether a care intervention is according to 'current medical science and

practice' is not a simple exercise but must be assessed on its merits and this demands sufficient relevant knowledge and expertise. This is in particular care-related expertise and insight into clinical epidemiology. CVZ has this knowledge and expertise and is continuously working towards further improvement[27]. Nevertheless it may be desirable to ask for external input, in particular from experts on specific subjects. CVZ discusses this in more detail below.

Care-related knowledge and expertise required

Consultation of experts

Quality assessment and support

In order to increase the quality of CVZ's assessment, and also to create support from health care providers, it can be desirable to obtain relevant and practical knowledge from the relevant Dutch scientific associations. Due to their specific expertise and experience in practice, they are able to supplement any relevant information and literature that may be missing or they may assist in the technical interpretation of data. Furthermore, where applicable, they can provide (additional) information about (reasons for) the absence of scientific evidence at the highest level. After all, the professional group will usually be aware if publication bias is involved.

Seeking knowledge among professional groups

CVZ will typically approach the scientific associations with this type of question, rather than individual experts. After all, this will help realise input that is broadly supported. CVZ comments that the aim is to gain input of an association from a scientific perspective. Comments relating to the promotion of professional interests – another task fulfilled by scientific associations – should therefore be excluded from consideration.

Transparent and verifiable decision-making

Elaborate on decision

CVZ will elaborate its decision on the 'current medical science and practice'.

Verification/

In brief, the following matters will be included:

- the question posed;

evaluation of method

- the criteria that play a role in the literature search and selection (relevant outcomes, follow-up, patient population), followed by the results;
- the criteria that play a role in the assessment (effectiveness, cost-effectiveness, side effects/undesired effects) followed by the results (quantitative and qualitative);
- the arguments that support the conclusion based on the above-described approach.

This working method will obviously be examined and assessed regularly.

Specific matters for (possible) discussion during assessment

Technical variant or innovation

Technical variant/innovation

Ruling on medical science/medical practice necessary?

CVZ is sometimes faced with the question of whether there is or is not any reason to make a statement on 'current medical science and practice'. This happens in cases of a technical variation as part of care that has already been included in the package, for example, an implant in back surgery which has been altered (in details), or a new type of hip prosthesis. A new treatment technique may also be involved. For example, the recent introduction of endoscopic surgery.

Assessment per case

Assessment necessary in case of relevant consequences

CVZ determines per case whether assessment of the intervention, including the technical variant/innovation is required or not. The basic consideration adopted by CVZ is that if the alteration can be assumed to have (possible) consequences for the efficacy, effectiveness, safety or general applicability of the intervention, there is reason to assess the altered intervention and make a statement about 'current medical science and practice'. Indications of the involvement of one or more of the mentioned consequences are:

- the professional group is researching or has already researched the matter involved;
- a current guideline is paying particular attention to the technical variant/innovation and expressed considerations in relation thereto;

- the technical variation/innovation has financial consequences or could form a reason for determining a separate tariff.

Consultation professional group

Here also, consultation with the professional group can lead to clarity regarding the above-mentioned points.

For the rest, this could occur for any forms of care and each time CVZ will have to answer the question of whether it really is an innovation or just an inconsequential variation. Drawing up the package agenda also involves such questions. CVZ is currently busy elaborating upon the points of departure for determining agenda points and priorities.

Technical variation in medical aids (me-too products)

No central assessment

CVZ does not carry out a (central) assessment for so-called me-too products. Me-too products are products with the same working mechanism and the same treatment goal as products that fall under the medical aids category mentioned in the Health Insurance Regulation and which fulfil the criterion 'current medical science and practice'. As the working mechanisms and treatment goals of these new products are (largely) comparable with products already included in health insurance, they are not subjected to a separate, central assessment by CVZ. It is then up to the health insurers to determine whether they will supply or reimburse these newer versions. Where there is doubt as to whether a me-too product is involved, the manufacturer can contact CVZ and/or the health insurer can consult CVZ by submitting an application for advice. CVZ will then issue a statement on the question of whether a me-too product is involved[28].

Up to the health insurers

Difference in level of evidence with a patient group with the same diagnosis

Lack of cost-effectiveness data

If there are (as yet) no – or relatively few – data on long(er)-term cost-effectiveness data for a given intervention, then this will generally result in the conclusion that the intervention cannot be regarded as at least equivalent with the standard treatment. However, it may be the case that an intervention is

Health care according to status quo re medical science/medical practice for sub-group

Motivate difference in approach

conform 'current medical science and practice' for a sub-group of patients with the same diagnosis. This could be the case for a sub-group of patients who do not benefit from the standard treatment (contraindication) and for whom nothing else is available except the intervention concerned. The limited efficacy evidence will be deemed acceptable for that sub-group. There must be sufficient grounds for the difference in approach within the patient group, for example, using arguments (provided by the professional group) based on the pathophysiology of the disorder.

An illustrative example:

Implantable insulin pump only health care in accordance with medical science/medical practice for diabetes sub-group

Insulin can be administered to diabetes patients intraperitoneally instead of subcutaneously, using implanted insulin pumps. Limited research has been carried out with this method of administration: in short-term studies it proved capable of regulating the diabetes properly. However, there are no long-term studies to prove that this method of administration is just as effective as the usual one in respect of prevention/delaying the complications of diabetes mellitus. Furthermore, there are reports of complications, such as infections and material failure. For this reason CVZ has concluded that intraperitoneal administration by means of an implanted pump is an insured provisions only for patients for whom subcutaneous administration of insulin is no longer possible. In this case, therefore, data with a lower level of evidence are considered sufficient because these are patients for whom there is no other means for administering insulin[29].

Cost-effectiveness data

Cost-effectiveness data

Purchasing by health insurers

Supply by care-providers

In principle, cost-effectiveness data do not play a role in assessing 'current medical science and practice'. For example, two interventions may exist for a single disorder. If both are just as effective, then both fulfil the norm 'current medical science and practice'. In principle, it is up to the health insurer to purchase the most effective care (the Zvw is designed so that health insurers can make such a selection, thereby encouraging care-providers to work as efficiently as possible). If proper cost-efficacy analyses are carried out, then care-providers themselves will probably make a choice, and the

intervention with the least favourable cost-efficacy ratio will eventually become obsolete. Over the course of time, that care will eventually no longer fulfil the norm 'current medical science and practice'.

An illustrative example:

Percutaneous angioplasty versus bypass operation

In the general population, due to efficacy and cost-effectiveness aspects, percutaneous angioplasty (PTCA) is preferred to a bypass operation for certain forms of coronary disease. However, in the long term percutaneous angioplasty is less effective for patients who suffer from coronary disease and diabetes, and a bypass operation is recommended. In other words, a generally less effective intervention can be indicated for a sub-group of patients. Preferably, this should be substantiated by pathophysiological mechanisms.

Organisational aspects of health care

Organisational aspects

In principle, assessing the criterion 'current medical science and practice' does not involve organisational aspects of care (such as, e.g., logistics in operating theatres). Improved logistics in operating theatres can increase efficiency in the deployment of personnel, funds, etc., but they will generally have no effect on the prognosis for the patient. However, situations are imaginable in which this is the case. For example, setting up an acute stroke unit in a hospital. Improved procedures for patients with a CVA can lead to improved prognosis, fewer admissions to nursing homes, etc.

Sometimes integrated in medical science/practice

Demonstrating this with proper comparative study is a reason to regard such organisational aspects as 'current medical science and practice'. After all, in this case the maximum efficacy of treatment is inextricably linked to an optimal procedures set-up.

References and notes:

[1] There are two exceptions. The criterion established medical science and medical practice does not apply to seated medical transport or welfare-related aids. See also section 4.

[2] See the explanation of articles included in article 2.1 of the Health Insurance Decree (Bull. Acts & Decrees. 2005, 389).

[3] See note 6 of the article by Groot GRJ de. Established medical science and medical practice. Tijdschr Gezondheidsrecht 2006; 30(5): 326-50 [in Dutch].

[4] The GGZ, which focuses on healing, will be transferred from the AWBZ to the Zvw as of 1st January 2008.

[5] One can also refer to an open definition of the provision to be insured. This means, for example, that a new care form which is effective (fulfils the established medical science and medical practice criterion) and which is care as normally provided by medical-specialists (and which is not explicitly excluded), should, in principle, be included among the provisions to be insured. In other words, new care forms, as long as they fulfil the statutory requirements, are automatically included in the package. Treatments that have clearly become obsolete will automatically be dropped from the package.

[6] In that case one can also speak of a closed system of provisions to be insured.

[7] When assessing pharmaceutic care, this is also referred to as: testing the therapeutic value.

[8] See the pleading notes of Prof. G.R.J. de Groot dated 4th July 2007 (cause list no. 2007/01755) concerning CVZ/NESS Nederland B.V. : "If provisions are defined at product level, as in the case of medicines, there is no room for application of the established medical science and medical practice criterion. A medicine is either included on the limited list of insured medicines, or it is not."

[9] The CBO has started structured patient participation in the development of guidelines. See the CBO website.

[10] An aid to translating the question in a method for searching international literature is the PICO-method. This stands for:
P = patient population
I = Intervention or diagnostic test
C = control intervention or reference test
O= outcome.
In addition to the PICO, filters can be used: for example, the year from which the search applies (if an addition is required to a systematic review that is several years old). Both free text words and controlled thesaurus terms are possible (e.g. MeSH = Medical Subject Headings, Medline's thesaurus with controlled terminology).

[11] The most frequently used databases for literature searches are: Medline via Pubmed, the Cochrane Library, Embase drugs and pharmacology, INAHTA, CBO and Clinical Evidence. For information on current trials one tends to use: Clinicaltrials.gov. Sites for information in the field of foreign policy are: NICE, AETNA, CIGNA, Regence Group and Medicaid (CMS).

[12] *Validity* means that the study actually did measure the effect of the intervention. Did randomisation take place, and if so, did it go well, was it a blind study and if so, who was blind (patient, treating physician, person assessing the effects?), who complete was the follow-up, was (in cases of controlled studies) the intervention the only variable in the study legs?

[13] The *importance* of a study is reflected by the size and the relevance of the effect and the precision of the estimation of the effect (e.g. a difference score, the relative risk [RR], the odds-ratio [OR], and the reliability interval). In assessing diagnostic tests, the terms used are sensitivity and specificity.

[14] The *applicability* of study results depend on the similarities between the study population and the patient population, the advantages and disadvantages of treatment for the patient and medical ethical aspects.

[15] For an extensive description of the EBM method, CVZ suggests the EBRO-instructions (Evidence-Based Guideline Development, Manual for members of working groups, November 2006). This manual can be found on www.cbo.nl. CVZ also suggests the book written by M. Offringa, W.J.J. Assendelft en R.J.P.M. Scholten. Introduction to evidence-based medicine. 2nd revision, Dr. Houten: Bohn Stafleu van Loghum, 2007.

[16] See, for example Jadad AR, Cook DJ, Browman GP. A guide to interpreting discordant systematic reviews. CMAJ 1997; 156: 1411-6.

[17] Standard treatment is the treatment that is regarded in daily practice as first choice treatment, the efficacy of which has been established. Usual treatment exists when it is used in practice on a substantial number of patients with the indication concerned (taken from: *Farmacotherapeutisch Kompas* 2007).

[18] See the *Farmacotherapeutisch Kompas* 2007. Diemen: CVZ, 2007.

[19] This relates to literature that has only been accepted by a scientific journal after a critical assessment by peers.

[20] This concerns a joint publication by the Ministry of VWS and CVZ. It can be found on CVZ's website.

[21] See paragraph 12 of the Procedures for assessing extramural medicines.

[22] Places for finding information in the field of foreign policy include the following sites: NICE, AETNA, CIGNA, Regence Group and Medicaid (CMS).

[23] The qualification A1 can also be sub-divided into A1+ and A1-. The reference indicates that the internal validity of a systematic review is acceptable, for example, if publication bias has been taken into account by also involving unpublished data in the review.

[24] CVZ 20th November 2006, no. 26073455, RZA 2007/12.

[25] Appendix 1.k. of the Package Advice 2007. Diemen, CVZ, 2007: 61-3. Publication no. 248.

[26] CVZ 23rd July 2007, no. 27024808 and no. 27041039.

[27] CVZ provides regular (refresher) courses for their employees who test interventions according to the criterion established medical science and medical practice and those who are involved with the development of the framework for assessment. If first-class specialist knowledge is required, such as for example HTA-expertise, CVZ purchases it.

[28] The term me-too also exists in pharmaceutic care. A me-too medicine is a medicine that is chemically as good as identical to the first product from a given group, but which only differs in one or more chemical sub-groups. Me-too medicines are also assessed by CVZ. Furthermore, such a product is only subject to the insurance if the Minister has designated the product as such.

[29] CVZ 21st May 2007, no. 27013933.