Framework for assessing medical aids

This document is a translation of het CVZ-report 'Beoordelingskader hulpmiddelenzorg'. As this report dates back to 2008, we recently decided that an update of this report is necessary. The most important reason for this update is a change in the legislation for the reimbursement of medical devices. In 2008, the legislation contained a 'closed list of medical devices', while nowadays we work with a more 'open system'. In this open system the legislation is described from the perspective of a functioning problem rather than evaluating each medical device individually. This has implications for the way in which we evaluate medical devices and also for the timing of when we evaluate medical devices. We will start drafting in the beginning of 2013.

4.a. Introduction

The CVZ reports, "Package management in practice" and "Assessment of established medical science and medical practice", together with the final report of the RIVM, have led to the elaboration of a framework for assessing medical aids. The criteria relevant to medical aids were classified within the package principles of CVZ that apply to the whole range of health care: necessity, effectiveness, cost-effectiveness and feasibility. In this section, for each principle, CVZ addresses the various criteria that play a role in assessing medical aids.

Greater detail

In particular CVZ elaborates upon a number of criteria for medical aids in greater depth than in the report "Package management in practice". In paragraph 4.f CVZ describes the points of departure when assessing medical aids.

4.b. Necessity

For this principle, in "Package management in practice', CVZ assesses whether the disease or the required care justify a claim on solidarity, in view of the cultural context.

In order to evaluate the package with respect to 'necessity', CVZ makes use of, among other things, the following criteria that apply to the whole range of health care: disease burden, care needs and the costs of the intervention on an individual basis. After all, the idea behind insurance is that it should cover costs that we as individuals are unable to bear. Preferably, disease burden should be expressed in measurable, comparable units. For the criterion 'care requirement', CVZ pictures the demand for care by a group of patients with a given disorder.

As CVZ state in the report "Package management in practice", package management is work in progress. CVZ is currently working on specifying and refining the package principles. The following is a refined definition of the principle necessity for medical aids. CVZ looks at whether this definition could also apply to other forms of care, and if so, in what way.

History

Up till now, when assessing medical aids, CVZ made use of these two preparatory questions:

- Is the medical aid in general use?
- Does the medical aid involve substantial costs?

These criteria are now part of the package principle necessity,

whereby the term substantial costs has been replaced by financial accessibility. The reason for applying this criteria is that medical aids often involve an adaptation of a product that people without handicaps also purchase at their own expense. An example of this is a watch that has been adapted for the blind.

Operationalisation

On the basis of the RIVM report, CVZ has further operationalised these two criteria for durable medical aids. The following is an elaboration of this.

4.b.1. Assessment of general use

In order to determine whether a medical aid is in general use, CVZ addresses the following questions:

- Is the medical aid especially intended for people with a functioning problem?
- Is the medical aid (almost) only on sale in medical specialist shops and does the fitting require specific (medical) expertise?

CVZ provides clarification per question below, with one or more examples.

- *Is the medical aid especially intended for people with a functioning problem?*

Functioning problem

A therapeutic elastic stocking is especially intended for people with a functioning problem. This medical aid compensates the loss of function of veins in transporting blood and the loss of function of the lymphatic system in transporting lymph.
A television is an aid to the provision of information and is not specially intended for people with a functioning problem.

- *Is the medical aid (almost) only on sale in medical specialist shops and does the fitting require specific (medical) expertise?*

(medical) expertise

This criterion refers to the degree of expertise required in order to customise the aid for an individual. This has an effect on the adequate use of the aid.
A hearing aid is an example of an aid that is sold (almost) only in medical specialist shops and which requires specific expertise for the fitting.

In the package advice 2007, CVZ decided that no specific expertise was required for 'the fitting' of a rollator (no more than for a bicycle). It is the supplier's responsibility to provide proper information about the use of an aid and it is the user's responsibility to ensure he/she is properly informed.

4.2.b. Assessment of financial accessibility

In order to determine whether a medical aid is financially accessible, CVZ addresses the following questions:

- Is the medical aid a substitute for an object in general use?
- Are the costs (or the added costs in connection with a model adapted to a handicap) so high that the medical aid becomes financially inaccessible?
  - Does it involve a problem in functioning with a high

incidence that is predictabel?
- Is the medical aid related to another insurable provision, so that savings or quality aspects may play a role?

Here also, for the sake of clarification, CVZ provides one or more examples per question.

Substitution

- *Is the medical aid a substitute for an object in general use?*

The question here is whether the medical aid replaces an object that is purchased by a large proportion of the population. Adapted cutlery substitutes normal cutlery, and a motor-assisted bicycle substitutes a 'normal' bicycle. If substitution is involved, then CVZ also considers the following questions.

Costs involved

- *Are the costs (or the added costs in connection with a model adapted to a handicap) so high that the medical aid becomes financially inaccessible?*

What costs does the medical aid involve or what are the added costs in connection with adapting an object to the handicap, if this is a case of substitution of an object in general use.
CVZ is of the opinion that no fixed financial limit can be indicated here. On the one hand because this could have a price-inflating effect. For example, if the limit were to be €100, there is the danger than the (added) costs for the medical aid would by definition amount to €101. On the other hand, because many factors play a role in determining such a financial limit. Will a medical aid last one year or ten years? If a medical aid costs €100, but a person needs to purchase a new one each year, then considerations will differ when a medical aid of the same price last ten years.
In making the considerations, CVZ will also take into account the variety of the range and the price variations.
For this reason CVZ applies a broad financial range and in the advice they will indicate the motives for why they consider the (added) costs of a medical aid are financially accessible or not.

Degree of 'predictability'

° *A sub-criterion for CVZ is the question 'Does it involve a problem in functioning with a high incidence that is predictabel?'.*
This is about the degree to which the occurrence of a functioning problem is predictable during the normal course of a life. A normal course of life is one without congenital or contracted diseases. Thus if a person born blind this sub-criterion does not apply. CVZ feels that if a disorder is 'to be expected', a higher limit can be applied for the sum that should be at one's own expense than in a case with an 'unexpected' disorder. After all, citizens cannot be expected to anticipate 'unexpected' events, though citizens have the own responsibility for matters that can be 'anticipated'.

Age-related deterioration in hearing is also a predictable functioning problem with a high incidence. However, this does not imply that a hearing aid for elderly people should not be

designated as an insurable provision, as the costs should also be taken into account, as well as the fact that specific expertise is required for the fitting. On the other hand, reading glasses are also intended to compensate for a predictable functioning problem with a high incidence. But the costs are relatively low, even though specific expertise may be necessary for the fitting. Weighing these factors leads to the conclusion that reading glasses do not need to be designated as an insurable provision.

- *Is the medical aid related to another insurable provision, so that* savings *or quality aspects may play a role?*

Different insurable provision

A medical aid can be a part of a chain of care. CVZ examines not only the medical aid but also its relationship to other insurable provisions. This might lead CVZ to advise designating a relatively cheap medical aid as an insurable provision in a case where this leads to savings elsewhere in health care or to an improvement in the quality of care.
An example of this is the aid for pulling up therapeutic elastic stockings. Simple aids such as these are available from about €25. Such a sum could remain a personal expense. However, using such an aid promotes independence, therapy compliance, contributes to retaining the quality of the stocking and saves on the costs of Home Care. In other words, it involves both savings and quality aspects, by which a relatively cheap medical aid can be included as an insurable provision.

4.b.3. Functioning problem burden

Functioning problem

In this project we chose to refer to 'functioning problem burden' instead of 'disease burden'. How large is the burden (reduced quality of life) of the functioning problem for which the medical aid is intended to help. The term functioning problem refers to disorders, limitations and participation problems, according to the interpretation of the 'International Classification of Functioning, Disability and Health'. No evaluation reviews exist for these, such as those for 'disease burden'. Until such time that such a list for evaluating functioning problems is available, CVZ will assess this criterion pragmatically.

4.b.4 Total assessment of necessity

Context

CVZ emphasises that all aspects within the criteria general use and financial accessibility are always weighed up within the context. No single aspect will be of deciding importance. This means, for example, that the fact that a medical aid is for a

Deciding factor

predictable functioning problem with a high incidence does not necessarily lead to the conclusion that such an aid should not (/no longer) be regarded as an insurable provision. The purchasing costs (or additional costs related to handicap-customisation) of a medical aid are just as important in decision-making, as is the specific (medical) expertise that may be required for 'the fitting' of the aid. This also applies when addressing the question of whether the medical aid is related to another insurable provision by which possible quality

aspects or savings are relevant. This illustrates how CVZ scales the consequences of possibility not reimbursing a medical aid at the expense of the statutory insurance.

4.b.5. Accumulation of costs

Solidarity

Examining the package in relation to these criteria is relevant in order of retaining solidarity. Items that are in general use and financially accessible, and which could therefore be at one's own expense, should not put pressure on this solidarity between the young and the elderly, those who are sick and those who are healthy, the wealthy and the less prosperous. The Zvw is a statutory insurance for everyone and not an instrument for income policy.

Accumulation and personal expense

CVZ realises that by concluding that a certain medical aid can be at the expense of citizens may lead to problems if these citizens are confronted with an accumulation of personal contributions and personal payments.

Safety net

CVZ notes that in order to apply the criteria general use and financial accessibility a safety net is required. Only then will CVZ be able to examine the package responsibly with respect to the criteria "in general use" and "financially accessible".

Various regulations

Various regulations can be called upon in order to avoid that necessary and effective care becomes financially inaccessible for individuals, such as:

- exceptional assistance;
- deductible exceptional burdens;
- a subsidy on the grounds of the Exceptional Expenses Subsidy Regulation (TBU).

Depending on a person's individual situation, one may be eligible for one or more of the above-mentioned regulations if the costs of care that remain at one's own expense are too high in relation to one's income. This may also apply when costs that are at one's own expense start to accumulate. There are plans to revise the fiscal regulations. It is important that this revision ensures that citizens still have a safety net, so that care that is actually necessary remains financially accessible.

4.c. Effectiveness

'Package management in practice'

In '*Package Management in Practice'* CVZ examined whether an intervention or form of care was actually doing what was expected of it. This basic question can be interpreted either narrowly or broadly. Effectiveness can vary from realising a clinical effect to achieving the intended result. A broader interpretation of effectiveness also involves matters such as safety, side effects, quality of life and ease of use.

Method of work

In order to assess effectiveness, CVZ sets to work in the same way in which they assessed established medical science and medical practice (see paragraph 3.a). After all, if one fails to establish that the requirement 'care is in accordance with established medical science and medical practice', one also fails to fulfil the package principle "effectiveness". It is highly unlikely that inclusion in the package will be recommended.

In the following paragraphs, CVZ will elaborate on the determination of the effectiveness of medical aids. For the level of evidence, CVZ distinguishes between health-related medical aids and welfare-related medical aids.

4.c.1. Health-related medical aids

Medical aids for treatment

Health-related medical aids often involve products for the treatment or products that are closely related to the treatment. In terms of the ICF, health-related medical aids have an effect at the level of the disorder, and the aim is:

- to partially or entirely relieve a disorder;
- to prevent or delay exacerbation of the disorder;
- to reduce the physical symptoms that result from a disorder;
- to replace an entire or partial lack of a body part or a bodily function.

The ICF defines a disorder as a defect or loss of functions or anatomical properties.
Medical aids that are worn on or about the body often exert an effect on a disorder (e.g., therapeutic elastic stockings, orthoses, hearing aids).

Level of evidence

Published studies

For these medical aids CVZ requires a minimum of two scientific studies, that have been published in peer-reviewed journals. The quality of the scientific studies is relevant to the assessment. Different study set-ups can be classified according to a hierarchy of level of evidence, whereby, for example, a randomised clinical trial (RCT) constitutes a high level of evidence while a non-comparative study has a low level of evidence. The point of departure for CVZ is that 'a strong level of evidence takes precedence over a weaker level of evidence'.

RCT

If substantiating the efficacy of a medical aid is based on a minimum of two qualitatively well-implemented RCTs, then a medical aid has a better chance of receiving a positive assessment than, for example, if no comparative studies have been carried out. This means there is no obligation to submit RCTs, but the chance of a positive assessment increases if substantiation is based on qualitatively good RCTs. CVZ also includes foreign studies in the assessment. Obviously, CVZ does examine whether such a study is representative for the population and the health situation in the Netherlands.

What is an RCT?

Why an RCT

The reason why CVZ values an RCT so highly is that this study method keeps the distortion of results to a minimum. The aim is to measure the effect of the treatment. For this reason it is important to ensure that the results are influenced by as little confounding factors as possible.

Randomisation

In order to ensure that no difference occurs between the two groups that could affect the effectiveness of the treatment, the allocation of patients between intervention group and control group, should be determined at random. By randomisation

selection bias may be prevented.

Blind studies

Single-blind studies avoid:

- a conscious or unconscious increased compliance with the protocol;
- effects on the resulting measurements due to treatment preferences.

Double-blind studies ensure:

- that doctors-in-charge exude a degree of enthusiasm;
- a varying degree to which they adhere to the guidelines of the study protocol (for example, by offering supplementary treatment to the placebo group).

Blinding the persons assessing the results avoids:

- differences in assessing the effects of the intervention and the control treatment.[1]

Other study designs lead to increased bias and as a result to greater uncertainty as to whether the effects found really do result from the intervention.

Blind studies difficult for medical aids

CVZ is aware that medical aids cannot always comply with the double-blind requirement. In that case, the following characteristics of an RCT can be implemented:

- control group that undergoes the standard treatment;
- randomisation of test persons over the intervention group and the control group;
- sufficient test persons;
- sufficiently long study duration;
- relevant outcome measurements.

Outcome measurements

Quality of life

Significant versus clinically relevant

CVZ should point out that a significant improvement does not always automatically lead to a positive assessment. Before starting the assessment CVZ determines what the relevant outcome measurements will be. Obviously, these will also include outcome measurements that are relevant to the patient, such as quality of life. CVZ subsequently determines whether a significant improvement in a relevant outcome measurement is also a clinically relevant improvement. For example, if speed of walking is a relevant outcome measurement and this is found to be significantly improved, but the improvement is only small, then this could still lead to a negative assessment if CVZ feels that this effect is not clinically relevant.

Lower level of evidence

Lower level of evidence

The report "Assessment of established medical science and medical practice" states that in some situations a positive decision is determined on the grounds of lower evidence. These involve situations in which it is established that no (additional) RCTs can be demanded and when the lower evidence is so convincing (consistent and up-to-date), that one can conclude that the care being assessed fulfils the

[1] Introduction in evidence-based medicine (Offringa et al., 2007).

requirement of established medical science and medical practice.

This applies to the following situations:

Ethical
- Interventions whereby it would be ethically irresponsible to carry out a (randomised) study. This applies to interventions on persons unable to give informed consent (children, persons suffering from dementia, the mentally handicapped) and for interventions that take place in ICs and in life-threatening, acute situations. Exceptions to this are therapeutic research whereby the study could benefit the test persons themselves, and non-therapeutic, group-related research. This is the case if the study could not be carried out without the participation of the group to which the test persons belong, the level is admissible and the risks for the test persons are negligible.

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

Blind implementation
- interventions whereby blind (patients and/or carers) implementation is impossible. This is often the case with surgical interventions. Even with medical aid care, it is not always possible to fulfil all the requirements of an RCT. In particular, the 'double blind' requirement is often not feasible.

Out of date
- interventions for which it is too late to start an RCT. This is the case, for example, when an intervention has already become pretty much established, so that patients could not be expected to want to participate in randomisation. In this case the researchers would not be motivated to start up an RCT either.

International consensus
- interventions that have been used for some time and for which international consensus exists over its efficacy, but for which no randomised research was carried out in the past. Such international consensus has been realised on the basis of lower evidence.

Grounds for CVZ

Moreover, with respect to the above, CVZ comments that the applicable point of departure is that a positive decision will require the existence of medical-scientific data with the highest possible strength of evidence, but that a departure from this requirement can be argued. In particular it will involve showing CVZ grounds for accepting evidence of a lower level.

4.c.2. Welfare-related medical aids

Participation in society

Welfare-related medical aids are aids that promote participation in society, such as aids to communication, mobility aids and design elements for homes. In terms of ICF, these medical aids are deployed not at the level of the disorder, but in order to reduce the consequences of a disorder:

- a person's limitations as a consequence of a disorder

or;
- a person's participation problem as a consequence of a disorder;

The medical aid acts not at the level of the disorder but on the limitation or participation problem.

Level of evidence

Not worn on or around the body

In general these are medical aids that are not worn on or around the body. Though it is true that scientific evidence is not relevant to these medical aids, one should be able to determine whether the care is capable of doing that which it is supposed to do and whether safety and ease of use are guaranteed. For example, these questions can be answered using a practical evaluation and/or consumer research. This research should preferably have been published. This year CVZ will publish a guideline regarding practical evaluations.

Guideline for practical evaluations

4.c.3. Outcome measurements

Prior to starting the evaluation, CVZ will determine which outcome measurements are relevant on the basis of the manufacturer's claim and (scientific) literature. CVZ will include both clinical outcome measurements and patient-related outcome measurements, such as quality of life and pain. For outcome measurements such as quality of life and pain, it is important that the measuring instruments used are validated and reliable.

4.d. Cost effectiveness

In "Package management in practice", for this principle CVZ asks whether the relationship between the costs and the advantages, in the broadest sense of the word, is acceptable. CVZ will base themselves, preferably, on a cost-utility analysis. What are the costs of the care provided per life-year gained, corrected for quality (Quality-adjusted Life-Year/QALY). CVZ is aware that a cost-utility analysis is not always available and nor can it be applied for all forms of care. Other methods of cost analysis can be relevant, for example, a cost effectiveness analysis (CEA) or a budget-impact analysis.

QALY

CEA and budget-impact

If no data on cost effectiveness are available, an indication of the costs of this provision can be given in relation to the supposed benefits:

- the number of patients eligible for the form of care (prevalence and incidence);
- a prognosis of the number of patients to be treated;
- the costs of the intervention.

CVZ has a broad interpretation of the term 'benefits', i.e., both within and beyond the field of health care (perspective of society).

CVZ also applies these criteria when assessing the cost effectiveness of medical aids.

4.e. Feasibility

Feasible and tenable

In "Package management in practice" this principle is about the question of whether admission to – or exclusion from – the package, now and in the future, is feasible and tenable. An important element within each recommendation made is financial feasibility. Financial feasibility is not synonymous with cost effectiveness. Financial feasibility is about the financial consequences of a recommendation on a macro-level, now and in the future. Having favourable cost effectiveness does not necessarily imply that including a form of care in the package is also financially feasible. For example, the benefits could be mainly external to health care or the cost effectiveness could be favourable in the long term, but could involve an immediate financial claim that is (too) excessive. Cost effectiveness may depend on the indication for the intervention. Financial feasibility will then require that the indication requirements can and are adhered to during implementation, without this leading to an enormous administrative burden. An outflow of care can lead to unwanted substitution by more expensive forms of care. This might be substitution within health care, but also external to it. For health insurers, the administrative burden that results from the inflow and outflow is an important point. This is why CVZ the advice explicitly includes the consequences for the administrative burden.

Substitution

Administrative burden

CVZ also uses these criteria when assessing the feasibility of advice on inflow and outflow in the field of medical aids.

Budgetary Framework for health care

The minister has indicated the importance of avoiding uncontrolled growth in collective expenditure on health care. For this reason, the budgetary frameworks in health care should help determine the direction of decision-making with respect to decisions regarding the package. The Budgetary Framework for Health Care is, in principle, the precondition within which decisions on the package are made. CVZ takes this into account when they issue the advice. This means that CVZ makes proposals not only for expanding the package but also for limiting it. The current package advice and the sub-report on Medical Aid Care already show that CVZ is issuing proposals for removing forms of care and medical aids. CVZ will pay attention to this aspect in future positive advice.

4.f. Points of departure

During the project it proved difficult to develop a fixed decision-making structure. This is why CVZ makes use of the following points of departure:

4.f.1. Principle coherence

Single principle

CVZ always considers the principles as a coherent whole, unless it is possible to suffice with a single principle. For example, if a medical aid is not necessary or its efficacy is unproven, then the assessment of other principles will not take place. If a medical aid is ineffective, then by definition it is also not cost-effective. For this reason, CVZ starts the assessment of medical aids with the principles of necessity and efficacy.

Sequence of

4.f.2. Me-too products

No central assessment

CVZ does not carry out a central assessment for the so-called me-too products. These are products with the same working mechanism and the same treatment goal as products that fall under a category of medical aids mentioned in the Regulation and that fulfil the assessment of established medical science and medical practice. As these medical aids are comparable with products that are already subject to the cover of health insurance, it is up to the health insurers to determine whether they want to provide or reimburse a newer version. This is, in fact, a decision based on appropriateness. Health insurers also take quality aspects into consideration.

Where there is a lack of clarity as to whether a me-too product is involved, a manufacturer or health insurer can ask CVZ to adopt a standpoint.

4.g. Process

Once annually

Once per year the minister alters (if necessary) the Regulation's paragraph on medical aid care. This alteration comes into force as of 1st January, but the Minister's decision must have been taken on 1st July of the preceding year. The reason for this is that health insurers need time to draw up the model policies and medical aid regulations and inform the insured clients about the insured package in good time.

Policies

Period of assessment

CVZ tries to round off assessment requests from manufacturers within four months. This period starts at the moment an application has been submitted in its entirety. If there is an accumulation of manufacturer's files, then CVZ informs the applicants in cases where they suspect the target deadline will not be reached. CVZ sends the applicant confirmation of receipt, assesses the documents submitted, carries out a literature search and assesses the relevant literature.

CVZ attempts to include applications received in next advice on the package (sub-report Medical Aid Care). In order to do so, it is important that the manufacturer's file has been submitted in its entirety by the latest four months prior to sending the draft report to the parties in the field. If this is not the case, CVZ will be unable to guarantee inclusion in the following advice on the package (sub-report Medical Aid Care). CVZ sends the draft sub-report Medical Aid Care on package advice to the relevant parties mid-December.

Consultation

The applicant receives a draft assessment and can respond to it. CVZ will incorporate this response in drawing up the draft of the sub-report Medical Aid Care. CVZ sends these draft recommendations, for consultation, to interested parties mid-December. Approval of the sub-report Medical Aid Care of the package advice takes place annually in March, simultaneously with the package advice for all forms of care. The

recommendations on medical aids (summarised) are also included in the package advice for all forms of care.

CVZ places these assessment procedures on the website and also include the process in the guide to manufacturer's files.

Appendix 2

Guide to manufacturers' files on medical aid care

Guide for applications for advising the minister on including a medial aid as an insurable provision within the paragraph on medical aid care of the Health Insurance Regulation

Introduction

This guide is intended for manufacturers who want to submit an application for assessment to CVZ that they should advise inclusion of the medical aid as an insurable provision within the medical aid care paragraph of the Health Insurance Regulation, or inclusion of the medical aid in the insured package.

The guide provides applicants pointers about the information CVZ would like to receive. An application that is drawn up uniformly provides CVZ with rapid insight into the availability of data. CVZ understands that not all data will always be available. This will not necessarily lead to the rejection of an application. CVZ refers to the highest possible goals. When crucial data are lacking, CVZ will not be able to issue positive advice to the Minister.

In the event of a so-called 'me-too product' (with the same working mechanism and the same treatment goal as medical aids that are included in the medical aid care paragraph of the Health Insurance Regulation), it will automatically be incorporated in the Health Insurance Regulation. In that case no central assessment by CVZ will take place. Manufacturers can contact CVZ in order to find out whether a 'me-too product' is involved. Insurance organisations can also consult CVZ by submitting an application for advice. In such cases CVZ will determine whether a me-too product is involved that is eligible for reimbursement.

No rights can be derived on the basis of this guide.

Instructions for the manufacturer

You are expected to complete the application form and reply to the questions mentioned in this guide. An explanation is provided per question. **The substantiation and motivation of your replies is extremely important**. If data are not available, please state this. Where they are available, please quote published information, such as scientific studies and enclose this information as an appendix. You may also enclose Information on, for example, current studies, so these can be incorporated into the assessment of your application.
Substantiate your application according to the lay-out of this guide and keep to the same sequence and numeration.

Description of a medical aid

1. Provide a general description of the medical aid.

Apart form the physical description, also refer to the (general) name, any classification code, a schematic drawing/photograph. You can also enclose an information folder, where available. Mention an inspection hallmark, if the product has received one. If you do mention a hallmark, then explain which requirements the medical aid has fulfilled.

2. **What is the aim of the medical aid**

Describe the intended use. Which functioning problem (disorder, limitation, participation problem) is being treated or compensated? What is your claim? Are there any contraindications?

3. **For whom is the medical aid intended? How large is this group of people?**

Define the target group/users. Provide information on the number of people with the functioning problem(s) who require the medical aid. Provide information on the number of new persons per year who will become eligible for using the medical aid. It is also important to know how many people per year will stop using the medical aid. If no exact figures are available, provide the best

possible estimate and substantiate your reply as far as possible. Use, where available, scientific literature and enclose them with this document.

4. How will you distribute the medical aid
Via which distribution channel will the medical aid be provided?

If a durable medical aid is involved, then complete question 5a. If it is a consumable medical aid, then complete question 5b.

5a. What is the average life-span of the medical aid?
The Medical Aid Guideline states the following with regard to life-span: Characteristics and performance may not be damaged to such a degree that the clinical state and safety of the patient – and where applicable, other persons – are endangered during the life of the medical aid as indicated by the manufacturer when it is subjected to the stress of normal use.

5b. What is the average frequency of use during a given period?

6. Is there an alternative available for the same problem(s)? If so, what?
An alternative could be a medical aid or a different method of treatment. Describe this alternative medical aid/method of treatment. An alternative is not a reason for excluding something, but makes it possible to draw a comparison with current care and to carry out an efficiency analysis.

Effectiveness
7. Provide information about the efficacy of the medical aid.
The (desired) result for the user is most important. This result is reducing the burden of the functioning problem in many variants: retaining state of health, prevention or inhibition of deterioration, possibilities for participation, compensating limitations. Show by means of published data that the claim mentioned under question 1a actually takes place in the user.
Evaluating this takes place preferably by means of an analysis of effectiveness ('Does it help?' in daily practice). Secondarily, attention is paid to efficacy ('Does it work?' under controlled, optimal conditions). The duration of the disorder (is severity reduced) should also be taken into consideration. Attention should also be given to the extent to which the reported outcome measurement is relevant for (/has a relationship with) the desired (or claimed) clinical effect.
Provide, if possible, information about:
- *alterations in the quality of life of the user of the medical aid as a result of the medical aid and*
- *provide information about user satisfaction and therapy compliance.*

Substantiate the information provided where possible. Show that you have taken all relevant data into consideration. Provide as complete a summary as possible of (literature) studies, articles and authoritative published opinions/views about the medical aid at home and abroad. CVZ will ask, where possible, for a minimum of two scientific studies. This studies should have been published in peer-reviewed journals (preferably journals included in Pubmed; http://www.ncbi.nlm.nih.gov/entrez/query.fcagi?CMD=Search&DB=PubMed).
Include the full journal articles with your application.
The quality of the study you use to substantiate your replies is important for the assessment. Various study set-ups can be classified in a hierarchy of evidential value (see www.cbo.nl). Strong evidence takes precedence over weak evidence. If relevant Randomized Clinical Trials (RCTs) have been found, then it is not necessary to search any further for studies with weaker evidential value (for example, case control study). It is important that the RCTs are of a high quality. For a more detailed explanation, CVZ refers you to the report 'Assessment of established medical science and medical practice' which can be downloaded from the site, www.cvz.nl. CVZ is aware that it is not always possible to carry out an RCT for medical aid care. In particular it is often not feasible to fulfil the demand for a 'double-blind' set-up (neither the researcher nor the test person know whether the test person has undergone the intervention or is in the control group). In some cases

RCTs are unnecessary, unsuitable, impossible or inadequate. In CVZ's opinion, the following characteristics of an RCT can be implemented:
Studies should at least involve a control group receiving the standard treatment, have sufficient test persons and cover a sufficiently long period of time. Test persons should be randomised over the intervention group and the control group. If there is no standard treatment for solving the problem, the control group should receive no treatment.
International studies can and will be incorporated in the assessment. CVZ assesses the degree to which the study is representative for the Dutch situation. For example, is the study population representative for users in the Netherlands?
CVZ will distinguish between health-related medical aids and welfare-related medical aids. Health-related medical aids are often medical aids for treatment or which are associated with treatment. In terms of the ICF, medical-related medical aids have an effect on the disorder itself, whereby the aim is:

- *to counteract a disorder entirely or partially;*
- *to prevent or reduce exacerbation of the disorder;*
- *to reduce physical symptoms resulting from the disorder;*
- *to replace the entire or partial lack of a body part or bodily function.*

The ICF defines a disorder as a defect in or loss of function or anatomical properties. Medical aids that are worn on or about the body often act on a disorder (e.g., therapeutic elastic stockings, ortheses, hearing aids).

Welfare-related medical aids are medical aids that promote participation in society, such as medical aids for communication, medical aids for mobility and design elements in the home. In terms of the ICF, these medical aids are not deployed at the level of the disorder itself, but are deployed for reducing the consequences of a disorder:

- the limitations that a person has as a consequence of the disorder;
- the participation problem that a person has as a consequence of the disorder;

The medical aid does not intervene on the disorder but on the limitation or the participation problem. *In the last case, CVZ will be satisfied with studies with a different set-up from an RCT, for example, a practical evaluation. Though not strictly necessary, CVZ does set store by published data. A guide relating to practical evaluation is currently being developed.*

Costs

8. Provide information about the annual costs of the medical aid.
This is about obtaining insight into the financial consequences if a medical aid is included in the Regulation. The idea is to multiply the annual costs of the medical aid (the purchase price, including VAT, also including use of materials, accessories, check-ups and providing instruction) by the number of users. Any substitution costs and future costs can be subtracted. If substitution costs cannot be determined, then it is useful to provide a description.
Convert the costs into annual costs. Provide a minimum and maximum estimate of the costs. Indicate clearly how the costs were calculated. For durable medical aids it is necessary to take into account the average life (see question 5). The time horizon should make it possible for the analysis to include the cost consequences for the entire duration of use. In the case of consumable articles, you should estimate how many are required on average in one year.

9. Does the medical aid saves on other costs?
Does substitution takes place, i.e., does a medical aid replace a different medical aid or treatment and does this reduce costs? Or will costs be reduced in the future? Future costs are costs that could occur in the future is a medical aid is not used. If you feel that such economies exist, how large are they? Explain how you arrived at this sum.
For example, if nursing care is no longer required due to use of the medical aid, indicate the number of nursing hours saved, the costs of nursing per hour and multiply these numbers. Substantiate your answer as far as possible with scientific literature and calculations and enclose these with this document.

Efficiency/cost-effectiveness

10. What added value does the medical aid have in comparison with the alternative?

Compare the expected added value and the costs of this medical aid with the standard treatment (for example a different medical aid or form of care for the same functioning problem). In other words: describe the costs and effects (not in monetary terms) of the new medical aid (new method of working) in comparison with the costs and effects of the old medical aid/form of care (standard method of working). CVZ prefers such a comparison. Substitution will not always exist. If these data are not available, then you can supply cost-effectiveness data of a medical aid in comparison with doing nothing. Substantiate your reply as far as possible with scientific literature and enclose these with this document.

Additional data

11. What developments or studies are still in progress in relation to this subject?

Refer to developments and/or current studies that, in your opinion, are important for CVZ's advice and indicate when they will be complete. If there are no developments/studies, then enter 'not applicable'.

12. Are relevant additions to be expected from the professional groups and/or patient associations?

Are there any guidelines/protocols from the professional group that prescribes the medical aid? Have any opinions been published by the professional group and/or patient organisations?

13. Is the medical aid marketed in other countries? If so, in which countries and is it reimbursed there?

Indicate in which countries the medical aid is sold and in which of those countries it is reimbursed. If the medical aid is reimbursed in other countries, provide the assessment report if it is available. If a new medical aid is reimbursed according to the regulations of a given country, without the existence of evidence, this is insufficient to reach the viewpoint that a medical aid fulfils the criterion of established medical science and medical practice. However, if established medical science and medical practice is a factor that influences the content and size of the package in other social health insurance systems, then it may be important to find out which considerations played a role in the package decision in that case.

Check list

No.	Subject	Completed /described	No. of pages in appendix	Title of appendix or reference
-	Application form			
1	Description			
2	Aim			
3	Target group			
4	Sales address			
5	Life cycle/ frequency of use			
6	Alternative			
7	Effectiveness			
8	Economies			
9	Annual costs			
10	Added value			
11	Developments			
12	Professional groups			

13	Other countries			

Process:
Once a year the Minister amends (if necessary) the medical aid paragraph in the Health Insurance Regulation. This amendment comes into force as of 1st January, but the decision made by the Minister must have been taken before 1st July in the preceding year. The reason for this is that health insurers need time to draw up the model policies and medical aid regulations and to inform the insured clients about the insured package.

CVZ tries to complete assessment requests from manufacturers in four months. This period commences from the moment the application is submitted in full. In the event of an accumulation of manufacturers' files, CVZ will inform applicants if they surmise being unable to keep to the target time. CVZ sends the applicant confirmation of receipt, assesses the documents submitted and carried out a literature search.

CVZ tries to include the applications received in the next package advice. In order to achieve this goal, it is important that the manufacturer's file is submitted in full at the latest 4 months before it is sent to the parties in the field. If this is not the case, CVZ does its best to include the application, but will be unable to guarantee inclusion in the next package advice on medical aids. CVZ sends the draft Medical Aids sub-report of the Package Advice to the relevant parties in the middle of December.

The applicant receives a draft assessment and can respond to it. CVZ incorporates that response when drawing up the draft Medical Aids sub-report. In the middle of December CVZ sends this draft advice to interested parties for (administrative) consultation. Approval of the Package advice and the Medical Aids sub-report takes place annually in March. The medical aids advice is also included (summarised) in the Package Advice that applies to the whole range of health care.