

Pharmacy Regulations

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2022 Pharmacy Regulations

Pharmaceutical healthcare

The Dutch Ministry of Health, Welfare and Sport decides which kinds of pharmaceutical healthcare qualify for reimbursement as well as under which conditions, and under which conditions certain medicines are eligible for reimbursement. This has been laid down in the Dutch Health Insurance Act ('Zorgverzekeringswet') and associated regulations. You can consult these regulations under 'regeling zorgverzekeringswet' (regulations under the health insurance act) on the government website www.wetten.overheid.nl (in Dutch). The legislation furthermore allows health insurers to set further prerequisites for reimbursement of pharmaceutical healthcare. These prerequisites are specified in these Pharmacy Regulations. These Pharmacy Regulations are part of your terms and conditions of insurance, relating to clause B.15.

The Regulations include lists that are subject to change. If we do proceed to change these lists, we will post the updated version of these Regulations with the amended lists online.

In these Regulations, the words 'medicine(s)' and 'medication' are used interchangeably.

1. Reimbursement of registered medicines

The Medicines Reimbursement System (GVS) contains both interchangeable medicines and non-interchangeable medicines.

1.1 Interchangeable medicines

These are medicines that are:

- administered in the same way; and
- prescribed on the same medical grounds; and
- intended for people in the same age bracket.

This gives a doctor two or more interchangeable medicines to choose from for a patient. For each group of interchangeable medicines, the government has set a maximum reimbursement (reimbursement limit). If the medicine you have been prescribed from this group is more expensive, you will have to pay the excess yourself as a personal contribution.

You will also have to pay this personal contribution if a pharmacy uses a more expensive medicine in a compounded medicine (prepared by the pharmacist himself/herself).

Visit www.medicijnkosten.nl (in Dutch) to check medicine prices and the associated personal contributions for medicines.

For medicines for which we do not designate a preferred medicine, and which are therefore not on our list of preferred medicines ('Lijst voorkeursmedicijnen') (see Article 1.3. Preferred medicines), we reimburse the price that does not deviate by more than 5% from the lowest market price. This concerns the market rate that applies at that time within a group of interchangeable medicines. We call this the Lowest Price Guarantee, which is one of the aspects of 'effective healthcare'.

1.2 Non-interchangeable medicines

Non-interchangeable medicines are the medicines listed in Appendix 1B (medicines not clustered on the basis of comparable therapeutic effect) that have different properties to those listed above, such as their effect and the medical grounds on which the medicine is prescribed. A personal contribution is not payable for these medicines; we will reimburse them in full.

1.3 Preferred medicines

The active ingredient in a medicine determines the medicine's effect. There are often multiple medicines with the same active ingredient, in the appropriate strength and with the same method of administration. These medicines differ in price, but have the same effect.

Within a group of interchangeable medicines (see clause B.15.1.b in the terms and conditions of insurance), we designate one or more medicines as preferred medicines, partly on the basis of the lowest price. Within this group, you are only entitled to these preferred medicines. There will always be at least one medicine available to you containing the prescribed active ingredient in the appropriate strength and with the appropriate method of administration. These medicines are on our list of preferred medicines ('Lijst voorkeursmedicijnen').

Having problems?

There may be cases where the same medicine with the appropriate strength, but from a different manufacturer, produces different side effects. This can happen due to the use of certain additions such as colouring agents or fillers. Such side effects may go away after a few days. If, after 15 days of use, unpleasant and unacceptable side effects have not disappeared, please contact your pharmacist. As soon as you have discussed the side effects with your pharmacist, he or she will contact your attending doctor, if necessary, to find a solution for you.

If the unacceptable side effects continue after you have tried the preferred medicine, your pharmacist will look into whether the preferred medicine is indeed medically inappropriate in your case, in consultation with your doctor if necessary. A medicine is considered to be medically inappropriate if treatment with the medicine we have selected is not advisable for verifiable medical reasons (see also Article 2.8, paragraphs 3 and 4 of the Dutch Health Insurance Decree ('Besluit zorgverzekering')). Together with your general practitioner or medical specialist, your pharmacist will assess whether there are medical reasons to switch you to a medicine from the Medicines Reimbursement System (GVS) other than the preferred medicine. If there are indeed medical reasons for it, you will be entitled to that other medicine with the same active ingredient, the appropriate strength and method of administration. This will generally not be the original branded medicine, as this other medicine must not be unnecessarily expensive.

The list of preferred medicines ('Lijst voorkeursmedicijnen') can be consulted separately on our website. We may amend the list from time to time, in which case will post a notice and the amended list of preferred medicines online.

2. Medication assessments in the event of chronic use of medicines

A medication assessment is a medically and pharmaceutically required regular evaluation. You are entitled to at least one such evaluation every 12 months.

Conditions

1. You use multiple medicines chronically; and
2. the medication assessment is conducted in consultation with you, your attending doctor, and the other healthcare providers involved; and
3. there must be a pharmaceutical need for it; and
4. when carrying out a medication assessment, the healthcare provider must follow the current performance description and the multidisciplinary guideline for geriatric polypharmacy ('Multidisciplinaire Richtlijn Polyfarmacie bij ouderen'); and
5. the medication assessment relates to medicines that meet the conditions specified in clause B.15.1 of the terms and conditions of insurance. If you also use medicines that do not meet these conditions, these will still have to be included in the medication assessment.

Depending on the agreements we have made with your pharmacy, you may also be insured for pharmaceutical self-management information for a patient group ('Voorlichting farmaceutisch

zelfmanagement voor patiëntengroep') and the conditional pharmaceutical support services ('facultatieve prestaties farmaceutische zorg') as described in the policy rule of the 'Nederlandse Zorgautoriteit' (Dutch Healthcare Authority, NZa):

- improving medications adherence of patients with asthma/COPD;
- medication optimisation and support for patients receiving complex pharmaceutical healthcare;
- guidance for chronic use of prescription only medicines (POMs);
- guidance for asthma and/or COPD medicines.

3. Reimbursement of compounded medicines

Compounded medicines: medicines prepared by the pharmacy

If the medicine you need is not marketed in the required form or appropriate strength, your doctor will prescribe a medicine that the pharmacy will prepare especially for you. This is what is referred to as a *compounded medicine*. Supplementary to clause B.15.4 of your terms and conditions of insurance, this section will provide further details of reimbursement of such compounded medicines.

Difference between a compounded medicine and 'third-party compounds'?

A compounded medicine is a medicine that the pharmacy makes especially for you. This can be necessary because the strength or form of an existing medicine is not suitable for you. A compound is a non-registered medicine, which means that it does not have marketing authorisation. If your pharmacy supplies the medicine it has prepared directly to you, marketing authorisation is not needed.

If your pharmacy does not prepare the medicine itself, but has another pharmacy do so on its behalf, this is known as a *'third-party compound'*. In the case, the medicine is not supplied to you by the pharmacy that prepared it.

Reimbursement for a compound

Under the Dutch Health Insurance Decree ('Besluit zorgverzekering'), compounded medicines qualify for reimbursement if used as part of rational pharmacotherapy. This means that the compound:

- must have a form that is suitable for the patient. For example, a liquid solution for a child that cannot swallow tablets yet;
- has been proven to be efficient and effective. This means that adequate scientific research has been conducted into the medicine, that it is effective in treating the symptom or illness and that the efficacy and effectiveness have been scientifically proven;
- must have the lowest price and be the most economical for the health insurer. It must, for example, not be more expensive than comparable medicines that are equally or more effective.

Situations in which compounds are not reimbursed

If the above conditions are not met, you will not be reimbursed for the compound.

A compound will not be reimbursed either if it is:

- a product that comes under the Dutch Commodities Act ('Warenwet'), which means that it is not actually a medicine, but rather a personal care product such as shampoo or hand cream;
- a medicine intended to prevent diseases while travelling, such as an adjusted dose of malaria tablets;
- a compound that is the same or nearly the same as a 'regular' registered medicine that does not qualify for reimbursement and that does not come under the exception as described in clause B.15.4. of the terms and conditions of insurance, e.g. paracetamol 500mg tablets for pain and fever. These are not included in the Medicines Reimbursement System (GVS) (see clause B.15.1 of the terms and conditions of insurance). A compound of capsules with paracetamol for pain and fever is therefore not reimbursed either.

For details of exclusions, refer to clause B.15.1.a of the terms and conditions of insurance.

4. Medicines in Appendix 2 of the Dutch Health Insurance Regulations

The Dutch government has formulated conditions for reimbursement of a number of medicines/groups of medicines. You will find these medicines and the respective conditions in Appendix 2 of the Dutch Health Insurance Regulations ('Regeling zorgverzekering'). The conditions for medicines listed in Appendix 2 are changed by the Ministry of Health, Welfare and Sport on a regular basis, while new medicines are also added to the list from time to time. You can consult the latest version of Appendix 2 online at www.wetten.overheid.nl (in Dutch. Type 'Regeling zorgverzekering' (Dutch Health Insurance Regulations) in the search window, click the link and find 'Hoofdstuk 8 Bijlage 2' (Chapter 8 Appendix 2) in the bottom left-hand corner).

The list below shows the medicines (active ingredients) that must be assessed by the health insurer (by us in other words). We may amend the list from time to time, in which case we will post the new Regulations with the amended list on our website.

Medicine	No.	Assessment method*	Assessment by
Epoprostenol IV	28	Application	health insurer
Iloprost for inhalation	28	Application	health insurer
Treprostinil subcutaneous/IV	28	Application	health insurer

* All the latest information on assessing the medicines is available at www.znformulieren.nl (in Dutch). This site also lists the medicines the pharmacy needs to assess.

Assessment

Formally, it is up to us to decide whether or not you are entitled to certain medication under the Dutch Health Insurance Act ('Zorgverzekeringswet'). In many cases, however, your pharmacist or provider can assess right away whether or not you are entitled to the medication in question based on a standard doctor's statement or a note on the prescription.

Doctor's statement

For many medicines, there are standard doctor's statements. The prescriber can find these by clicking 'Farmacie' (Pharmacy) on www.znformulieren.nl (in Dutch). The doctor who made the diagnosis will complete the doctor's statement in full and send it to your pharmacy along with the prescription. Your pharmacy will subsequently assess whether you qualify for reimbursement under the Dutch Health Insurance Act ('Zorgverzekeringswet'). For the pharmacy to be able to make this assessment, the issue date of the doctor's statement must not be more than one month from the date on which the medicine is dispensed.

Medication check

Your pharmacist checks whether the various medicines you use are compatible.

Application

For some medicines, we will assess compliance with the conditions ourselves. In that case, your attending doctor will send an application for reimbursement to our 'Medische Beoordelingen' (Medical Assessments) department. We will then send a response to you and your attending doctor.

Objection

If you do not want your pharmacist or supplier to make the assessment, you can send the statement completed by your prescriber to our 'Medische Beoordelingen' (Medical Assessments) department directly, stating your objection.

Conditions not met

If you have a condition that is not listed on the doctor's statement or that does not meet the other conditions, but the medicine you need is listed in the table above, the attending specialist can submit a substantiated application to us containing at least the following:

- the completed doctor's statement, even if you do not meet the conditions;
- the medical grounds on which the medicine has been prescribed;
- prevalence of this condition in the Netherlands;
- a specification of other medicines used to treat this condition and the results;
- the scientific literature on the basis of which this medicine has been selected.

We will then assess whether you may still be entitled to reimbursement for the medicine. We will let you know in writing.

Please note!

Submitting an application for reimbursement does not guarantee that we will issue an approval.