

Pharmacy Regulations

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CONTENTS

CONTENTS2
2021 Pharmacy Regulations3
Pharmaceutical healthcare3
1. General3
2. Reimbursement of registered medicines5
3. List of preferred medicines6
4. Reimbursement of compounded medicines6
5. Medicines in Appendix 2 of the Dutch Health Insurance Regulations7

2021 Pharmacy Regulations

Pharmaceutical healthcare

The Dutch Ministry of Health, Welfare and Sport decides which kinds of pharmaceutical healthcare qualify for reimbursement, and on what conditions and medical grounds. 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. General

Pharmaceutical healthcare consists of the provision of medicine or advice and guidance as provided by pharmacists with respect to medicine and its responsible use. When dispensing medicines, the pharmacy will verify whether or not the medicine in question is compatible with any other medication you are already taking. The pharmacy will also check for contraindications for any illnesses or other conditions that you have to make sure you can safely take the medication. The first time you come to the pharmacy with a repeat prescription, the pharmacist or pharmacy assistant will ask you whether you have actually taken the medicine and whether it was satisfactory. This is an ideal opportunity to discuss the effectiveness of the medicine and any side effects with your pharmacist, although you can, of course, also do this at an earlier stage.

Pharmaceutical healthcare is made up of different aspects (services and support under the policy rule of the 'Nederlandse Zorgautoriteit' (Dutch Healthcare Authority, NZa)).

1. Dispensing with guidance

Additional guidance when the pharmacy dispenses a medicine that you have never taken before or that you have not taken for over 12 months. As part of such guidance when dispensing a new medicine, the pharmacist or pharmacy assistant will explain:

- the effect and possible side effects of the medicine;
- how and how often to take the medicine;
- whether there are any risks associated with using the medicine, such as whether it affects your ability to drive;
- and any other specifics, such as unusual storage instructions.

2. Patient instructions for medicine-related medical aids

If the medication you have been prescribed also requires the use of a medical aid, the pharmacist will have to explain to you how to use this medical aid in conjunction with the medicine, so as to ensure the medicine is as effective as possible for you. If you have any questions about the medical aid, it will be up to your healthcare provider to explain it again.

3. Pharmaceutical support during day treatment/visit to an outpatient clinic

This kind of support consists of updating and saving the details of the medication you are taking, as well

as instructions for medication prescribed after day treatment or a visit to an outpatient clinic. This is necessary to avoid mistakes:

- after consultation with you, the pharmacist will go over your current medicines with the prescribers at the day treatment facility/outpatient clinic and record this in the (electronic) patient record.
- after day treatment or a visit to an outpatient clinic, any changes to your medication must be reported to your general practitioner and pharmacist in writing. Aside from that, the pharmacist will provide instructions on how to take the (new) medicine at home.

4. Pharmaceutical support during hospitalisation/visit to an outpatient clinic

This kind of pharmaceutical support consists of recording, in writing, and providing further instructions regarding your current medicine use and your medication while you are in hospital or at the clinic. When you are admitted to hospital, it is important that you receive personalised guidance on your medicine use and that the medication that you are already taking is recorded in writing by the attending healthcare provider.

Conditions

1. if you are admitted to hospital, a personal consultation has taken place between you (or your representative) and the pharmacist or pharmacy assistant beforehand;
2. if you visit an outpatient clinic, a personal consultation has taken place between you (or your representative) and the pharmacist or pharmacy assistant beforehand and afterwards;
3. the pharmacist provides the support in compliance with the current protocol for the transfer of medication details in the supply chain ('Overdracht van medicatiegegevens in de keten') and updates your written or electronic patient record.

5. Pharmaceutical support following discharge from hospital

When you are discharged from hospital, any changes to your medication must be reported to your general practitioner and pharmacist in writing. Aside from that, the pharmacist will provide instructions on how to take the (new) medicine at home.

Conditions

You will only qualify for reimbursement of 'Pharmaceutical support following discharge from hospital' if the following conditions are met:

1. the pharmacist provides the support in compliance with the current protocol for the transfer of medication details in the chain ('Overdracht van medicatiegegevens in de keten') and updates your (electronic) patient record;
2. a personal consultation has taken place between you (or your representative) and the pharmacist or pharmacy assistant responsible for dispensing your regular or discharge medicine.

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

This 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.

You are also 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 with Parkinson's disease;
- 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.

In addition, you are insured for new conditional support services (or parts of these) that are developed during the term of your insurance and for which your pharmacist has made agreements with us.

2. Reimbursement of registered medicines

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

2.1 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.

2.2 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.

2.3 Preferred medicines

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.

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. For some ingredient names, we decide based on the price which medicine will be reimbursed.

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.

Our preferred medicines are specified on the list of preferred medicines ('Lijst voorkeursgeneesmiddelen') on our website.

You will only be entitled to an interchangeable medicine that is not among the preferred medicines if this medicine is the lowest-price medicine, or not more than 5% more expensive than the lowest-price medicine.

For medicines that do not appear on the list of preferred medicines, we will reimburse the lowest market price within a group of interchangeable medicines at the time (we refer to this as the Lowest Price Guarantee or Price Preference).

This is part of healthcare appropriate to the condition in question, see clause A.3.2 in the terms and conditions of insurance.

3. List of preferred medicines

Within a group of interchangeable medicines, we designate one or more medicines as preferred medicines, 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. The list of preferred medicines ('Lijst voorkeursgeneesmiddelen') 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.

4. 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.

PHARMACY REGULATIONS

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. Third-party compounds are allowed only in exceptional situations.

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.

5. 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).

For medicines from Appendix 2 to the Dutch Health Insurance Regulations ('Regeling zorgverzekering') that are listed below, we will assess whether the conditions are met. The table below shows for each medicine (active ingredient listed) what is needed for the assessment and who will conduct it. 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
Alirocumab	110	Doctor's statement	pharmacy

PHARMACY REGULATIONS

Medicine	No.	Assessment method*	Assessment by
Ambrisentan	28	Prescription will suffice	
Contraceptives (reimbursed under the general insurance policy up to the age of 21)	64	Medication check	health insurer
Apixaban	101	Prescription will suffice	
Asfotase alfa	119	Doctor's statement	pharmacy
Benzodiazepine receptor agonist with enteral administration	57	Note on prescription by prescriber (see pharmacy instructions)	pharmacy
Bosentan	28	Prescription will suffice	
Canagliflozin	93	Medication check with pharmacy instructions	pharmacy
Combination of basal insulin with GLP-1 agonist	112	Doctor's statement	pharmacy
Cladribine	76	Doctor's statement	pharmacy
Clopidogrel		Prescription will suffice	
Dabigatran	101	Prescription will suffice	pharmacy
Dapagliflozin	93	Medication check with pharmacy instructions	pharmacy
Darbepoetin alfa		Prescription will suffice	
Dietary preparations	1	Doctor's statement	health insurer
Dornase alfa		Prescription will suffice	
Dulaglutide	85	Doctor's statement	pharmacy
Edoxaban	103	Prescription will suffice	
Eliglustat		Prescription will suffice	
Eltrombopag	94	Prescription will suffice	
Empagliflozin	86	Medication check with pharmacy instructions	pharmacy
Epoprostenol IV	28	Application	health insurer
Ertugliflozin	117	Medication check with pharmacy instructions	pharmacy
Erythropoietin and analog		Prescription will suffice	
Everolimus	74	Medication check with pharmacy instructions	pharmacy
Evolocumab	106	Doctor's statement	pharmacy
Exenatide	58	Doctor's statement	pharmacy
Fampridine	122	Prescription will suffice	
Febuxostat	98	Prescription will suffice	
Fidaxomicin		Prescription will suffice	
Filgrastim. G-CSF i.e. Recombinant granulocyte-(macrophage-)colony stimulating factor		Prescription will suffice	
Fingolimod	118	Doctor's statement	pharmacy
Idebenone	115	Medication check with pharmacy instructions	pharmacy
Iloprost for inhalation	28	Application	health insurer
Imiglucerase		Prescription will suffice	
Interferon alfa		Prescription will suffice	
Ivabradine		Prescription will suffice	
Ivacaftor	100	Doctor's statement	pharmacy

PHARMACY REGULATIONS

Medicine	No.	Assessment method*	Assessment by
Leuprorelin	92	Medication check with pharmacy instructions	pharmacy
Linaclotide	102	Prescription will suffice	
Linagliptin	51	Medication check with pharmacy instructions	pharmacy
Liraglutide	58	Doctor's statement	pharmacy
Lixisenatide	85	Doctor's statement	pharmacy
Lumacaftor/ivacaftor	114	Doctor's statement	pharmacy
Proton-pump inhibitors	71	Medication check	pharmacy
Macitentan	28	Prescription will suffice	
Multicomponent meningococcal B vaccine	123	Prescription will suffice	
Miglustat		Prescription will suffice	
Nintedanib	104	Prescription will suffice	pharmacy
Patiromer	120	Doctor's statement	pharmacy
Pentosan polysulfate	125	Doctor's statement	pharmacy
Pirfenidone	90	Prescription will suffice	
rDNA interferon		Prescription will suffice	
Rifaximin	111	Doctor's statement	pharmacy
Riociguat	28	Prescription will suffice	
Rivaroxaban	95	Prescription will suffice	
Romiplostim	61	Prescription will suffice	
Sacubitril/Valsartan	109	Prescription will suffice	
Saxagliptin	51	Medication check with pharmacy instructions	pharmacy
Semaglutide	85	Doctor's statement	pharmacy
Sildenafil Viagra tablet and Revatio injections do not qualify for reimbursement	28	Doctor's statement	pharmacy
Sitagliptin	51	Medication check with pharmacy instructions	pharmacy
Statins (atorvastatin, fluvastatin, rosuvastatin, ezetimibe)		Prescription will suffice	
Tadalafil Cialis does not qualify for reimbursement	28	Doctor's statement	pharmacy
Tafamidis	78	Prescription will suffice	
Tezacaftor/ivacaftor	121	Doctor's statement	pharmacy
Ticagrelor	70	Doctor's statement	pharmacy
Treprostinil subcutaneous/IV	28	Application	health insurer
Trientine	124	Doctor's statement	pharmacy
Velaglucerase		Prescription will suffice	
Vildagliptin	51	Medication check with pharmacy instructions	pharmacy
Over-the-counter medicines: laxatives, allergy medication, diarrhoea medication, gastric emptying medication and dry eye medication.	35	Note on prescription by prescriber, medication check with pharmacy instructions	pharmacy

* All the latest information is available at www.znformulieren.nl (in Dutch).

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.