How to apply for reimbursement in Lithuania?

Key steps and requirements for medicine reimbursement

Healthcare system

Lithuanian healthcare system is financed by the compulsory health insurance fund (CHIF). The fund is administered by the National Health Insurance Fund (NHIF). Reimbursable healthcare includes services provided by public and private entities that have contractual agreements with the NHIF. This includes preventive care, primary, secondary and tertiary healthcare services, medical rehabilitation and nursing care. It also includes medicines that are included in the list of reimbursable medicines.

The list of reimbursable medicines is updated when a new active substance is added or the indications for a prescription are changed. Additionally, a price list of reimbursable medicines is published twice a year. Further changes may also be made to the price list throughout the six months.

Pricing principles

- Lithuania uses external reference pricing. Drug prices are set based on the average of the three lowest prices in European Union (EU) countries. When adding a medicine to the price list of reimbursable medicines, its compliance with national patient co-payment requirements is also assessed.
- For each additional quality-adjusted life year gained through the use of a medicinal product, Lithuania can finance 1, 3 or 5 times the GDP per capita, depending on the severity of the disease.

Responsible institutions and working groups

Ministry of Health (MoH). Shapes the country's pharmaceutical policy, including reimbursement of medicines. The MoH coordinates the activities of the Reimbursement Commission, which decides on the inclusion of a medicine into the reimbursement system. Medicines are included in the reimbursement lists by an order of the Minister of Health and in accordance with the Pharmacy Law.

State Medicines Control Agency under the Ministry of Health (SMCA). Performs health technology assessments and provides recommendations to the Reimbursement Commission. The SMCA also provides HTA scientific and regulatory advice.

National Health Insurance Fund under the Ministry of Health (NHIF). Assesses the impact a medicinal product proposed for reimbursement would have on the CHIF budget and verifies its compliance with the benchmark average of the three lowest wholesale prices in the EU. The NHIF coordinates pricing negotiations, signs contracts with pharmaceutical companies and draws up the reimbursable medicines price list.

The MoH's Reimbursement Commission. It is responsible for making a decision on the inclusion of medicines in the list of reimbursable medicines.

Two representatives from the MoH, one from NHIF, two from university hospitals, two from patient organisations, two from general practitioners' organisations and two from scientific and academic institutions. SMCA representatives who have carried out the HTA, NHIF representatives who have carried out the budget assessment also attend the meetings. The applicant is given the opportunity to attend, too.

NHIF's Interinstitutional Negotiation Commission. It is responsible for conducting negotiations with the pharmaceutical company

One representative from the MoH, two from SMCA, two from NHIF, one from patient organisations, one from the Ministry of Economy and Innovation or its subordinate institutions, one from the Ministry of Defence and one from the Ministry of Energy.

Which medicinal products are eligible for reimbursement?

- Authorised. The medicinal product must be approved in Lithuania or the EU.
- Prescription-only.
- Those of appropriate price. The price of a medicine must be the same or lower than in EU countries

Is it an authorised medicine, but the reimbursement is sought for an unapproved indication?
Treatment for such indication must be scientifically based and established in guidelines, included in reimbursement systems in at least three EEA countries, there must be no other treatment alternatives, and there must be a registered generic analogue.

Has the medicine previously been centrally financed (centrally procured) and is life-saving or is a medicine included on the WHO Model List of Essential Medicines, with no other way to ensure treatment using reimbursable medicines?
In such cases, no application needs to be submitted and no state fee is payable; however, the medicine must meet the pricing requirements.

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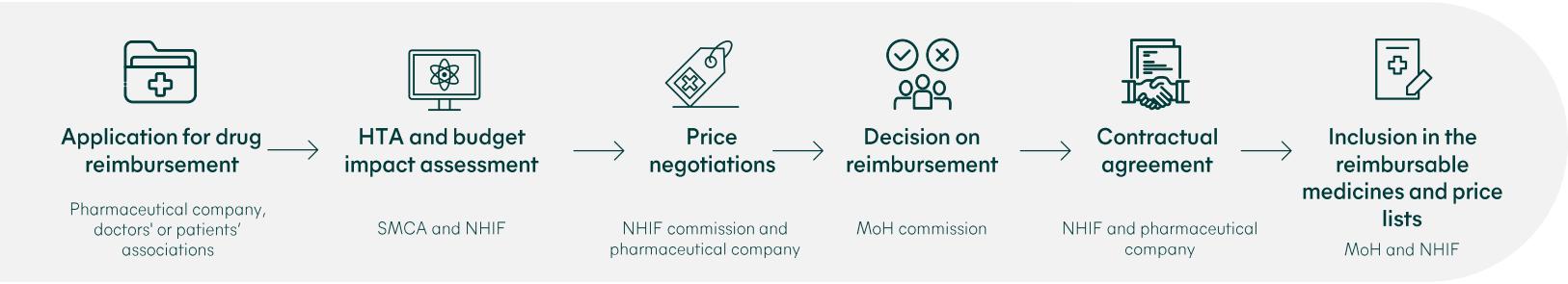

Submitting an application for reimbursement

Required documents

1. Application. Either a full or simplified application, covering clinical and economic assessment parts.

2. Estimated impact on the compulsory health insurance fund budget and the compliance of the declared prices with those in other EU countries.

3. Patient access scheme, optional.

4. Application submission form.

5. Proof of payment of the state fee.

Application types

Full:

- For original medicinal products.
- Generic or biosimilar medicinal products, where the aim is to demonstrate greater comparative effectiveness and cost-effectiveness.

Simplified:

- Generic or biosimilar medicinal products, where the aim is to include a new active substance in the list of reimbursable medicines.

Structure of the application

- Clinical assessment – medicinal product authorisation information, overview of suitability for the disease, comparative effectiveness and safety.
- Economic assessment – pharmacoeconomic analysis (for a full application, when seeking to demonstrate greater comparative effectiveness and cost-effectiveness), cost minimisation analysis (for simplified applications seeking to demonstrate the same comparative effectiveness and no increase in costs).

The requirements for each section of the application are described in and must be completed in accordance with the rules and methodology of the SMCA.

During the assessment, the SMCA may contact the applicant with additional questions. In such cases, questions and answers are submitted in writing.

Scientific and regulatory advice

- The SMCA offers consultations to help ensure compliance with HTA requirements in the clinical and/or pharmacoeconomic sections of the application. It can be used at various stages of drug development, authorisation and post-authorisation activities.
- The service is intended for medicinal product researchers, developers, marketing authorisation holders or their representatives

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Negotiations on price or terms of the contract

When can negotiations take place?

A. Before reimbursement decision:

- Comparative effectiveness is higher, but cost effectiveness does not meet the reference cost-effectiveness threshold, or
- Comparative effectiveness does not differ from the standard of care, but CHIF costs are less than 5% lower than those of the comparative treatment.

B. Before signing the contract:

- Disagreement with the terms of the contract, or
- Disagreement on the reimbursable price or discount amount.

Who can initiate negotiations?

- MoH, Reimbursement Commission, SMCA and NHIF.
- Marketing authorisation holder of a medicinal product or its importer.

Duration

If the company fails to provide the requested information within 30 calendar days, the negotiations are considered unsuccessful.

Within 2 working days from the end of negotiations, the Negotiation Commission provides the initiator with information on the negotiation outcome.

Subject matter: prices, applicable discounts, contract amounts or the repayable portion of the price.

How is the decision on drug reimbursement made?

The MoH's Reimbursement Commission makes its decision based on:

- SMCA health technology assessment conclusion and recommendation.
- Cost alignment with the reference cost-effectiveness threshold.
- The projected expenditure from the CHIF budget.
- Proposed measures to manage CHIF expenditures and to reduce patient co-payments.
- The availability of treatment for the disease, the nature of the disease, and the patient subgroup for whom the treatment will be provided.
- Opinions received from patients and healthcare professional organisations.
- If negotiations have taken place, whether a positive negotiation outcome has been achieved.

A positive health technology assessment recommendation is given in the following cases:

- Comparative effectiveness is superior to standard of care, and the cost effectiveness result meets the reference cost-effectiveness threshold, or
- Comparative effectiveness does not differ from the standard of care, but the CHIF costs are reduced by more than 5%.

The inclusion of a medicinal product in the reimbursement lists depends on the CHIF budget:

The medicine is included in the reimbursement list if:

- No additional CHIF funds are required, or
- The projected increase in reimbursement expenditure from the CHIF budget in the second year of reimbursement is equal to or less than 0.03% of the total CHIF expenditure on reimbursement of medicinal products in the previous year.

A medicinal product is included in the reserve list if:

- The medicine is considered eligible for reimbursement, but there are insufficient CHIF funds. The reserve list is reviewed at least twice a year.

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Useful information

Legal basis (in Lithuanian)

- Law on Pharmacy of the Republic of Lithuania.
  Defines the general requirements for the pricing of reimbursable medicinal products and their inclusion in the lists of reimbursable medicines.

- Order No. 159 of the Minister of Health of the Republic of Lithuania on the approval of the procedure for the inclusion of medicinal products and medical aids in reimbursement lists and their update.
  Defines the process of including medicinal products in the lists of reimbursable medicines, including general requirements, application and document requirements, health technology assessment and decision-making.

- Order No. V-326 of the Minister of Health of the Republic of Lithuania on the establishment of the Interinstitutional Negotiation Commission for the Pricing of Medicinal Products and Medical Devices and the approval of its rules of procedure.
  Defines the organisation and conduct of negotiations.

- Order No. V-726 of the Minister of Health of the Republic of Lithuania on the approval of the procedure for the conclusion and implementation of agreements between the State Health Insurance Fund under the Ministry of Health and medicinal product manufacturers on improving access to treatment and risk sharing.
  Defines the process for entering into contracts between the National Health Insurance Fund under the Ministry of Health and pharmaceutical manufacturers.

Ministry of Health information (in Lithuanian)

- English version of the MoH website

- Pharmaceutical and other related activities. The main page of the website, defining drug pricing and reimbursement, monitoring of availability.

- Commission for the Reimbursement of Medicinal Products and Medical Devices – activities, documents, composition and meetings.

- Reserve list of medicines

National Health Insurance Fund under the Ministry of Health information (in Lithuanian)

- English version of the NHIF website

- Reimbursable medicines and medical aids. The main page of the website, which provides key information on the preparation of the medicines price list, medicine prices, contracts, discounts on patient co-payments, and procedures for treatment of various conditions with reimbursable medicines.

- Interinstitutional Commission for Negotiations on the Pricing of Medicinal Products and Medical Devices – activities, documents, composition and meetings.

- Database for prices of medicinal products and medical devices.

State Medicines Control Agency under the Ministry of Health information (in Lithuanian and English)

- English version of the SMCA website.

- Health technology assessment home page. English and Lithuanian versions.

- Information for applicants on the application procedure, relevant documents for preparing an application, methodologies and information related to accessibility improvement schemes. English and Lithuanian versions.

- HTA assessments and recommendations by SMCA.

- Application assessment monitoring system.

- Scientific and regulatory advice.

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