BELGIAN SITUATION

Policies and practices in dealing with high-priced medicines

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MORSE REPORT

Monitoring Of Reimbursement Significant Expenses

WHAT IT IS

MORSE Report

Comprehensive overview of expenditure on reimbursable medicines

Written by National Institute for Health and Disability Insurance (NIHDI)

Supports a shared understanding of spending trends

LATEST REPORT

2024 data · Published Jan 2026

REPORT AVAILABLE ONLINE

riziv.fgov.be · MORSE report 2024 (EN)



MORSE REPORT

Some numbers…

2024 EXPENDITURE

Gross expenditure reached €7.9bn (+9.6% vs. 2023)
After clawbacks and taxes, net expenditure was €5.6bn (+6.6%).

LONGER-TERM TREND

From 2019 to 2024, gross expenditure grew 51%, net expenditure 32% and patient contributions 10%.

PATIENT PROTECTION

The relative share paid by patients declined, supported by a.o. co-payment caps and maximum billing limits.

> Other pharmaceutical services such as medical nutrition and care pathways → represented €258m in 2024 (+6.7%).

Key Growth Drivers

Expenditures remain highly concentrated:
15 classes out of 164 account for 68% of total spending (ATC-3 level)

Price fluctuations, expanded indications, innovation, and increased volumes → explain most significant trends:

- L01F – Monoclonal antibodies: €1.3 billion, driven by indication extensions and broader use of next-generation molecules.
- L04A – Immunosuppressants: 0.99 billion, Largest category in community pharmacies and second overall
- L01E – Protein kinase inhibitors: €510 million, slight decrease in 2024 (–1%) but volumes rising through new indications
- A10B – Non-insulin antidiabetics: €275 million, tripled over 10 years, fueled by patient growth, expanded indications, and increased use of GLP-1 and SGLT2;

  control measures introduced in 2025 to address off-label use (weight loss)
- C10A/C10B – Lipid-lowering agents: strong growth since 2022 from PCSK9 inhibitors, inclisiran and combination therapy.
- Other rising classes: Immunoglobulins (J06B), innovative dermatology (dupilumab), anti-CGRP migraine treatments, nervous system drugs (tafamidis)

Key Growth Drivers

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ATC3	Name	Share of hospital budget	Share of budget for public pharmacies	Share of total budget	NIHDI expenditure 2024 in millions	% cumulative	Growth 2023/2022	Growth 2024/2023
L01F	Monoclonal Antibodies and Antibody Drug Conjugates (T) †	29.8%	0.0%	16.3%	1,298.46	16%	19.0%	8.6%
L04A	Immunosuppressants (T)	8.1%	17.7%	12.4%	987.21	28%	2.1%	4.9%
L01E	Protein Kinase Inhibitors (T) †	11.7%	0.2%	6.5%	517.35	35%	13.9%	-1.0%
N07X	Other Nervous System Drugs (T) †	8.5%	0.1%	4.7%	370.99	40%	55.9%	43.8%
B01A	Antithrombotic Agents (T)	0.8%	8.7%	4.4%	346.44	44%	2.7%	-1.9%
A10B	Blood Glucose Lowering Drugs, Excl. Insulins (T) †	0.0%	7.6%	3.5%	275.33	47%	20.3%	16.5%
J06B	Immunoglobulins (T) †	4.7%	0.4%	2.8%	218.64	50%	12.3%	44.7%
B02B	Vitamin K and Other Haemostatics (T)	2.2%	3.2%	2.7%	213.16	53%	8.5%	11.7%
J05A	Direct Acting Antivirals †	1.1%	4.5%	2.7%	210.56	56%	5.2%	7.2%
L02B	Hormone Antagonists and Related Agents (T)	4.1%	0.6%	2.5%	198.38	58%	-5.4%	23.3%
L01X	Other Antineoplastic Agents (T) †	4.2%	0.1%	2.3%	185.49	60%	12.7%	51.6%
R03A	Adrenergics, Inhalants	0.1%	4.7%	2.2%	175.91	62%	7.0%	8.6%
R07A	Other Respiratory System Products (T)	4.0%	0.0%	2.2%	175.48	64%	77.2%	0.7%
C10A	Lipid Modifying Agents, Plain (T) †	0.0%	4.8%	2.2%	173.87	66%	27.5%	23.2%
S01L	Ocular Vascular Disorder Agents (T)	3.0%	0.0%	1.6%	128.61	68%	-3.9%	10.7%

MORSE REPORT

CRM activity and managed entry agreements both expanded in 2024

CRM Files

532 dossiers processed (+23%), with more reimbursement-modality changes.

89% of Ministerial decisions followed CRM advice; 99% for positive opinions.

MEA PORTFOLIO

189 agreements in force in 2024, covering 149 molecules (+16% vs. 2023).

38 new agreements concluded in 2024: a new record

≈60% focused on oncology and immunomodulators.

MEA: FINANCIAL numbers

€2.9bn reported turnover across active agreements.

€1.8bn in 2024 clawbacks

45.4% cumulative clawback rate from 2015–2024.

Conclusion

The 2024 pattern is structural, not temporary.

CONCENTRATION

Rapid innovation, expanded indications and more intensive treatment are concentrating expenditure in hospitals and a limited number of high-impact classes.

COST MITIGATION

Managed entry agreements reduce net costs through clawbacks and risk sharing, while supporting access as evidence develops.

SUSTAINABILITY

The growing weight of MEAs and the concentration of expenditures on highly innovative classes pose a major challenge for financial sustainability and budgetary pressure.

OVERVIEW

Managing high-priced medicines at several levels

CHAPTER IV	Criteria for the individual patient
BUDGET EVALUATION	Budget evaluation during the reimbursement process
MANAGED ENTRY AGREEMENTS	Temporary reimbursement, evidence generation and budget safeguards
OTHER APPROACHES	Revisions, system readiness and international cooperation

From patient eligibility over MEA’s to broader system-level policy tools

CHAPTER IV

Background

Belgium has a 'positive' reimbursement list: only medicines on this list are reimbursed.

The list has several chapters.

CHAPTER I

Medicine is reimbursed for all patients, regardless of conditions.

CHAPTER IV

Specific reimbursement conditions must be met by the patient to receive reimbursement.

CHAPTER IV

The medicine is only reimbursed to patients who fulfil predefined conditions:

IV

→ Reimbursement only for the intended patients

WHO?	Diagnosis, severity, biomarker, prior treatment…
HOW?	Qualified prescriber, approved indication and treatment line, specialised setting…
HOW LONG?	Initial period, continuation criteria and renewal evidence…

Prescriber must check the conditions for each patient before reimbursement can be granted for that patient

Process : electronically, and partially automatically

CHAPTER IV

Implications

REIMBURSED INDICATIONS

Chapter IV criteria : define also reimbursed indications

- Can be stricter than the SPC
- New indications are not automatically reimbursed

→ Each new indication will be evaluated, assessed and, if applicable, negotiated upon (MEA)

OTHER ADVANTAGE

Chapter IV : implicitly leads to large data set

→ Information available e.g. on use of drug by indication

CHAPTER IV

Summary

Chapter IV supports budget control :

- Limiting reimbursement only for the intended patients

- Companies must file a new reimbursement file for each new indication. Which can mean a new price will be applicable for the medicine or a new acceptable cost will be negotiated for this new indication (MEA)

- Provides information on use by indication

BUT:

- Administrative burden, especially in the field

- Complicates matters

REIMBURSEMENT PROCESS

Budget as a criterion during the reimbursement process

FORMAL EVALUATION CRITERIA

Price and budget impact are assessed alongside therapeutic value and added clinical value for each new medicine and each new indication.

Cost-effectiveness is also assessed.

CRM proposal + reimbursement decision → ultimately based on these criteria.

RELATES TO ADDED VALUE

Claimed added value is part of the voting.

Higher price vs. comparator is only possible if added clinical value is accepted by the CRM.



MANAGED ENTRY AGREEMENTS

Temporary reimbursement

DURING TEMPORARY REIMBURSEMENT

Patients gain earlier access to the medicine.

The pharmaceutical company must collect information to address clinical, budgetary or combined uncertainties.

Confidential budgetary compensation helps align cost with therapeutic value while accounting for uncertainty.

PLACE IN THE PROCESS

Embedded in the national reimbursement process.

The HTA evaluation and the reimbursement commission’s proposal provide an important basis for negotiations.

FROM NEGOTIATION TO CONTRACT

Negotiation with the company → agreement → contract (under "Article 112", "111" or "113“)

MANAGED ENTRY AGREEMENTS

Adedicated process turns negotiations into a signed contract

PRACTICALITIES

Dedicated task force

Face-to-face meetings with companies.

Maximum 120 days to close the deal; otherwise, no contract is signed and the normal reimbursement process continues.

Agreement and stipulations are written into a contract signed by NIHDI and the company.

WHAT THE CONTRACT STIPULATES

Information gathering and uncertainty conditions

Confidential budgetary rules in an attachment

Other aspects: duration, list price, reimbursement modalities, payment deadlines....

Non-budgetary elements are non-confidential and publicly available.



MANAGED ENTRY AGREEMENTS

Budgetary compensation is defined in the contract attachment

CORE MECHANISMS

Refunds: for example, a percentage of turnover reimbursed afterwards.

Budgetary cap : if turnover exceeds an agreed amount, the overshoot is reimbursed.

Price Volume schemes

Other mechanisms

Pay for performance schemes: complicated.

IMPLEMENTATION DETAILS

Refund : almost always defined as part of turnover that the company must repay to NIHDI, often per 12-month period.

Calculation method : must be clear and not open to interpretation.

Budgetary compensation is confidential by law and detailed in an attachment to the agreement.

MANAGED ENTRY AGREEMENTS

Benefits and limitations should be considered together

BENEFITS

Faster access for patients

Budgetary containment

Improved budget forecast

Evidence generation can address uncertainties.

LIMITATIONS

Limited transparency and complexity

Workload and operational burden

Need for dedicated follow-up

Quid end of the MEA



Special casus: Class contracts

WHEN THEY CAN BE USED

Several new medicines with very similar target populations and indications arrive at the same time, while market shares are difficult to predict (competing medicines).

In this situation, individual budget caps might have less value.

GROUPED COMPENSATION MODEL

Principle: A class budgetary cap is applied. Each molecule refunds its share of any overshoot according to its net market share.

Benefit : more budgetary predictability.

Limitation : difficult to negotiate and complicated to follow up.

OTHER APPROACHES

Abroader policy mix can support access to high priced medecines

REVISIONS

Individual revision: limited options.

Group revision : not intended for new high-priced medicines; it can be used for an existing group, for example to streamline reimbursement criteria.

SYSTEM READINESS

Cost-saving measures: generally not focused on new innovative medicines, but can create space for innovation.

Open environment and communication: for example, a pre-hearing.

Preparation : horizon scanning through IHSI.

INTERNATIONAL COOPERATION

Reflect on strategies

Exchange information

Conduct joint negotiations

...

System preparedness and international collaboration complement medicine-specific reimbursement tools.


The End.