

How Drugs Get Covered in Canada

WHO'S INVOLVED?

Health Canada

A federal agency that reviews new drugs to check for safety, efficacy, and quality.ⁱ

pCPA

The pan-Canadian Pharmaceutical Alliance negotiates prices on behalf of all of Canada's provincial, territorial, and federal drug plans.^{iv}

CDA & L'INESSS

Canada's Drug Agency performs health technology assessments for all provinces and territories except Quebec.ⁱⁱ

L'Institut national d'excellence en santé et en services sociaux is a Quebec-based agency who performs health technology assessments for Quebec only.ⁱⁱⁱ

Drug Plan Owners

Decide whether to cover a medicine.^v

- *Public drug plans* are run by the federal, provincial, or territorial governments
- *Private drug plans* are usually offered through workplaces or personal insurance

Each plan has its own list (formulary) of approved medicines.

MILESTONES ON THE PATH TO PUBLIC COVERAGE

The process of getting a drug publicly funded in Canada is complex and lengthy.^{vi} The process has many steps, and there can be exceptions. It's not always straightforward, or fully transparent.

New Drug Submission

Before a medicine can be sold in Canada, manufacturers must submit a new drug submission to Health Canada, even when medicines are already available for sale in other parts of the world.

Approved For Sale in Canada

A medicine can only be sold in Canada once Health Canada has reviewed it and found it to be safe, effective, and good quality.

Health Canada is the only organization authorized to approve a drug for sale in Canada. Once approved, the medicine can be marketed, but that doesn't mean it will be covered by drug plans.^{vii}

Drug Reimbursement Review

After Health Canada approves a drug, each province and territory decides whether their public drug plan will help cover the cost.

This decision often involves a drug reimbursement review, which looks at how well the drugs work, how much it costs, and how it compares to existing treatments.^{viii} This review is also called a Health Technology Assessment (HTA).^{ix}

HTAs help guide price negotiations and inform whether a drug should be covered by public drug plans. The review is optional, but it's often used because it plays an important role in access to public funding.

In Canada, HTAs are conducted by:

- Canada's Drug Agency (CDA): For most provinces and territories
- Institut national d'excellence en santé et en services sociaux (INESSS): For Quebec

Only drug manufacturers or public drug plans can request an HTA. This can be done either before or after the medicine is approved for sale.^x

Price Negotiation

Before a medicine is listed on a drug formulary, the drug plan owner can negotiate the cost with the manufacturer.^{xi}

Since 2016, the pan-Canadian Pharmaceutical Alliance (pCPA) has negotiated drug prices on behalf of all of Canada's provincial, territorial, and federal drug plans.^{xii}

Drug Listed on Public Formularies

After price negotiations have finished, public drug plans may choose to list the medicine on their formulary.

Even though the pCPA negotiates on behalf of all public plans in Canada, each province and territory makes its own decision about whether to cover the drug. This means a medicine is **not automatically** added to public formularies after negotiations, and coverage often varies across the country.^{xiii}

REFERENCES

ⁱ [How Drugs are Reviewed in Canada](#)

ⁱⁱ [CDA's Reimbursement Review](#)

ⁱⁱⁱ [About INESSS](#)

^{iv} [About pCPA](#)

^v [Prescription drug insurance coverage](#)

^{vi} [Access and Time to Patient: Prescription Drugs in Canada—January 2024](#)

^{vii} [What are the steps in the review process for a drug?](#)

^{viii} [An overview of the Drug Reimbursement Reviews](#)

^{ix} [Health Technology Review](#)

^x [New Target Zero Initiative Aims to Help Improve Access to New Drugs](#)

^{xi} [Payers' experiences with confidential pharmaceutical price discounts: A survey of public and statutory health systems in North America, Europe, and Australasia](#)

^{xii} [About pCPA](#)

^{xiii} [Access and Time to Patient Prescription Drugs in Canada](#)