



GLOSSARY OF TERMS: NPDUIS ANALYTICAL REPORTS

This glossary is included for the convenience of the reader. It does not have the force of law and is not binding on the PMPRB. Some exceptions to these general definitions may apply to individual analyses; if so, this will be clearly stated in the methodology of the report.

Active beneficiary:

An individual with at least one claim accepted for reimbursement by a drug plan or program.

Anatomical Therapeutic Chemical (ATC):

The Anatomical Therapeutic Chemical (ATC) classification system, developed and maintained by the World Health Organization (WHO) Collaborating Centre for Drug Statistics Methodology, divides drugs into five increasingly granular levels of classification according to their site of action and therapeutic and chemical characteristics. Levels 1 and 2 reflect the main anatomical and therapeutic groups, respectively.

Biologic:

Biologic drugs come from living organisms or from their cells, and are often made using biotechnology. They are used to treat diseases and medical conditions including anemia, diabetes, inflammatory bowel disease, psoriasis, rheumatoid arthritis, hormone deficiency and some forms of cancer. Biologic drugs are generally larger and more complex than chemically produced pharmaceutical drugs. In Canada, biologic drugs are listed in Schedule D of the Food and Drugs Act.¹

Biosimilar:

A biosimilar biologic drug, or biosimilar, is a biologic drug demonstrated to be similar to a brand name drug already authorized for sale (known as the reference biologic drug). Biosimilars may enter the market after the expiry of reference biologic drug patents and data protections.²

¹ Health Canada, Fact Sheet: Biosimilars, available at: <https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/applications-submissions/guidance-documents/fact-sheet-biosimilars.html>

² Health Canada, Biosimilar biologic drugs, available at: <https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/biosimilar-biologic-drugs.html>

Co-payment:

The portion of the prescription drug expenditure that individuals must pay each time they make a claim. This may be a fixed amount, a percentage of the prescription drug expenditure, or a component of it (e.g., dispensing cost).

Cost driver:

A factor that puts an upward or downward pressure on the cost levels, such as a change in the size and age of the beneficiary population.

Deductible:

The amount of total prescription drug expenditure an individual must pay in a defined time period (normally a year) before any part of their drug costs will be paid by a drug program. A deductible may be a fixed amount or a percentage of income (income-based deductible).

Dispensing cost:

A component of prescription drug expenditure that refers to the amount spent on dispensing fees.

Dispensing fee:

A professional fee charged by a pharmacist for the dispensing of a prescription and accepted for reimbursement by a drug plan, if applicable.

Drug:

A medicinal ingredient that comes in a certain form, strength, and/or is associated with a certain trade name, and/or pertains to a Drug Identification Number (DIN) issued by Health Canada.

Drug cost:

The amounts submitted by a pharmacy and accepted towards reimbursement by a public plan, representing the pharmacy's acquisition cost for the drug (including the wholesale upcharges) and the pharmacy markups.

Drug Identification Number (DIN):

A computer-generated eight-digit number assigned by Health Canada to a drug product prior to being marketed in Canada. A DIN uniquely identifies the following product characteristics: manufacturer; product name; active ingredient(s); strength(s) of active ingredient(s); pharmaceutical form; and route of administration.³

³ Health Canada, Drug Identification Number (DIN), available at: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/fact-sheets/drug-identification-number.html>

Essential medicines:

Medicines that satisfy the priority health care needs of the population.⁴

Generic:

A drug equivalent to a brand-name or reference drug in medicinal ingredient(s), strength, dosage form and route of administration, generally sold under the name of the active ingredient.

For NPDUIS analytical studies the term “generic” encompasses both patented and unpatented generics, unless otherwise stated.

High-cost drug or medicine:

A drug or medicine with an annual treatment cost exceeding \$10,000 or, in the case of oncology, a 28-day course of treatment exceeding \$5,000. The treatment cost may be calculated based on either assumed dosage regimens or the average treatment cost observed in public and/or private plans.

Markup (pharmacy):

The additional amount a pharmacy may charge for a drug above the acquisition cost. This may represent a flat fee or a percentage of the cost of the drug itself. Depending on the data source and the analysis, this amount may be reported separately or as part of the overall drug cost.

Medicinal ingredient:

A chemical or biological substance responsible for the claimed pharmacologic effect of a drug. Sometimes referred to as a molecule or active substance.

Multi-source drug or medicine:

A drug or medicine that is available under multiple trade names, including the original brand-name drug and/or its generic equivalent(s).

New medicine:

A medicinal ingredient contained in a drug that has not previously received market authorization by a regulator. Past NPDUIS studies have referred to new medicines as new active substances, or NASSs.

⁴ WHO, Essential medicines, available at: http://www.who.int/topics/essential_medicines/en/

Orphan drug:

A drug used to treat a rare disease or medical condition. The prevalence rate used to define the term “rare disease” varies by jurisdiction/country. In the US, it is defined as a disease that affects fewer than 200,000 Americans; in the European Union, a disease is defined as rare when it affects fewer than 1 in 2,000 people.

Patented medicine:

A medicine with one or more patents issued by the Commissioner of Patents. A patent may be assigned to the medicinal ingredient, to a manufacturing process, or to another aspect such as a timed-release coating or inhaler mechanism. A patent provides its holder with a monopoly or market exclusivity over the invention for a limited time.

Plan-paid:

An amount that a public drug plan reimburses an eligible beneficiary towards the prescription drug expenditure. The plan-paid amount reflects the cost-sharing structure specific to each plan.

Prescription drug expenditure:

The total amount accepted for reimbursement by a drug plan including drug costs, with associated markups, and dispensing costs. This reflects both the plan-paid and beneficiary-paid portions of prescription costs, such as co-payments and deductibles.

Prescription size:

The physical quantity of a drug or the number of days’ supply for which the prescribed drug was dispensed to an eligible beneficiary.

Public drug plan:

A general term used to describe drug plans that are administered by the provincial, territorial or federal governments. Each public drug plan establishes eligibility requirements and cost-sharing structures, as well as drugs and prices accepted for reimbursement.

Rate of change:

The percent change from one year to another. The annual rate of change is calculated over two consecutive years as follows:

$$[(\text{Value in year 1})/(\text{Value in year 0})] - 1$$

The **compound annual rate of change** is calculated over three or more consecutive years as follows:

$$\left[\frac{\text{Value in year } n}{\text{Value in year } 0}\right]^{1/n} - 1$$

Single-source drug or medicine:

A drug or a medicine that is available under one single trade name. With a few exceptions, patented medicines are single-source. Some generic drugs are also single-source as there may be insufficient demand for more than one drug in a given therapeutic area.

Trade name:

The name under which a drug is marketed; this includes the brand name and, in some cases, other names assigned by generic manufacturers.