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):

A classification system developed and maintained by the World Health Organization (WHO) Collaborating Centre for Drug Statistics Methodology that 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:

A medicine derived from living organisms or from their cells, often made using biotechnology. Biologics are used to treat diseases and medical conditions including anemia, diabetes, inflammatory bowel disease, psoriasis, rheumatoid arthritis, hormone deficiency, and some forms of cancer. These medicines are generally larger and more complex than chemically produced pharmaceuticals. In Canada, biologics are listed in Schedule D of the *Food and Drugs Act*.[1]

Biosimilar:

A biologic medicine demonstrated to be similar to a brand name medicine already authorized for sale (known as the reference or originator biologic). Biosimilars may enter the market after the expiry of reference biologic 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 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:
The amount submitted by pharmacies and accepted towards reimbursement by a public plan, representing the fees charged for the dispensing of prescriptions. Dispensing costs are one of the two components of prescription drug expenditures, along with drug costs.

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.

Dosage form:
The pharmaceutical form in which the drug is supplied, e.g., tablet, capsule, or powder. A product can have more than one dosage form when it is a kit (e.g., tablet, capsule).[3]

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 amount 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.

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[3] Health Canada. Drug Product Database: Terminology, available at: https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database/terminology.html

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. [4]

Essential medicines:

Medicines that satisfy the priority health care needs of the population.[5]

Expensive drugs for rare diseases (EDRDs):

For the purposes of NPDUIS reports, these medicines are defined as having both an orphan designation from either the US Food and Drug Administration (FDA) or the European Medicines Agency (EMA) and a treatment cost exceeding $100,000 annually for non-oncology medicines or $7,500 per 28-day treatment for oncology medicines. There is no universal definition for EDRDs.

Generic:

A medicine equivalent to a brand-name or reference medicine 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.

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[4] 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

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

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 NASs.

Orphan medicine:
A medicine used to treat a rare disease or medical condition, as designated by a regulatory body, typically the US Food and Drug Administration (FDA) or the European Medicines Agency (EMA). 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.

Product listing agreement:

A confidential negotiated agreement between a pharmaceutical manufacturer and a drug plan intended to support the reimbursement of a product on the formulary. Agreements may be based on a number of factors including internal and external recommendations, clinical evidence, therapeutic need, and cost-effectiveness.[6] Also referred to as a managed entry agreement.

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:

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

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.

Unit:

A single physical unit of a medicine in the form sold, e.g., a tablet, vial, or capsule.

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[6] Ontario Ministry of Health and Long-Term Care, Improving Patient Access to Drugs, available at: http://www.health.gov.on.ca/en/pro/programs/drugs/plan_reform_ods/improv_except_access.aspx