



Pan-Canadian Oncology Drug Data Minimum Data Set

2018

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Cette publication est aussi disponible en français sous le titre *Fichier minimal de données pancanadiennes sur les médicaments oncologiques, 2018*.

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Preface

Background information

About the Canadian Institute for Health Information

The **Canadian Institute for Health Information (CIHI)** is an independent, not-for-profit organization that provides essential information on Canada's health systems and the health of Canadians. CIHI provides comparable and actionable data and information that are used to accelerate improvements in health care, health system performance and population health across Canada. Stakeholders use CIHI's broad range of health system databases, measurements and standards, together with evidence-based reports and analyses, in their decision-making processes. CIHI protects the privacy of Canadians by ensuring the confidentiality and integrity of the health care information it provides.

About the Canadian Partnership Against Cancer

The [Canadian Partnership Against Cancer \(CPAC\)](#) was created by the federal government in 2006 with funding through Health Canada to work with Canada's cancer community to reduce the incidence of cancer, lessen the likelihood of Canadians dying from cancer and enhance the quality of life of those affected by cancer.

Our collaboration

CIHI's foundational work related to oncology drug data harmonization, collection and sharing began in 2013 with a feasibility study on the collection of oncology drug data. In CPAC's work related to real-world evidence generation, comprehensive, pan-Canadian data on oncology drugs was identified as an important data need. Pan-Canadian data collection is currently limited to oncology drugs covered by federal/provincial/territorial drug programs in CIHI's National Prescription Drug Utilization Information System (NPDUIS).

This alignment of interest in more comprehensive oncology drug data led to a partnership between CIHI and CPAC to advance this work. The development of a data standard was considered an important first step to support the collection of more comprehensive oncology drug data. CPAC and CIHI co-chaired an in-person meeting in November 2016 that brought together experts, including clinicians, researchers and policy-makers from across Canada. A draft data standard was developed based on discussions that took place during that meeting and was then circulated to meeting attendees, as well as to additional content experts for a final review. Feedback from this review was incorporated into this version.

Acknowledgements

CIHI and CPAC wish to acknowledge and thank individuals from the following organizations for their contribution to the development of the *Pan-Canadian Oncology Drug Data Minimum Data Set, 2018*:

- BC Cancer Agency
- Canada Health Infoway Inc.
- Canadian Agency for Drugs and Technologies in Health (CADTH)
- Canadian Association of Provincial Cancer Agencies (CAPCA)
- CancerCare Manitoba
- Cancer Care Ontario
- Centre hospitalier de l'Université de Montréal (CHUM), Quebec
- Eastern Health, Newfoundland and Labrador
- Institute for Clinical Evaluative Sciences (ICES)
- Ministère de la Santé et des Services sociaux, Quebec
- New Brunswick Cancer Network
- Nova Scotia Department of Health and Wellness
- Ontario Institute for Cancer Research
- PEI Cancer Treatment Centre, Prince Edward Island
- Saskatchewan Cancer Agency
- Sunnybrook Odette Cancer Centre, Ontario
- Tom Baker Cancer Clinic, Alberta

Please note that the conclusions in this document do not necessarily reflect those of the organizations mentioned above.

Privacy and confidentiality

CIHI is committed to protecting the privacy of Canadians and ensuring the security of their personal health information. We have a comprehensive privacy program to protect the confidentiality and security of our Canadian health care data holdings. Part of this program is a set of strict privacy and security policies. These policies govern how we collect, store, analyze and disseminate data on Canada's health care systems.

Introduction

In recent years, stakeholders across the country, including provincial cancer agencies and ministries of health, have expressed an increasing interest in accessing comprehensive pan-Canadian oncology drug data. This data is integral to enabling the development of real-world evidence and applying it to drug funding decisions that affect the sustainability of the cancer control system. The data can also be used to monitor trends in oncology drug use.

This data can be used

- To provide consistent, comparable, essential information to a broad range of partners and stakeholders who have key roles in the use of oncology drug data;
- For post-market surveillance, to understand usage patterns for specific therapies;
- To support drug utilization trend analysis, outcomes research, evidence-based practice research and real-world effectiveness/cost-effectiveness research;
- To reduce manual effort on comparative analysis; and
- To understand and improve equity in access to cancer drugs across Canada (to fill an important gap toward the achievement of data for “all drugs, all people”).

Scope

CIHI currently collects oncology drug data for claims that are covered by federal/provincial/territorial drug programs in its NPDUIS. A data standard specific to drugs dispensed in the community is used to collect this data.

The data standard in this document was developed to support the collection of a broader scope of oncology drug data. Typically, these drugs are dispensed in settings other than community pharmacies (e.g., acute care facilities, cancer centres). Additional types of data that may be collected in these settings include

- Data on special access drug products and clinical trial drug products; and
- Clinical data related to the diagnosis for which the patient is receiving the drug therapy (e.g., diagnosis, staging).

The minimum data set

CIHI's Oncology Drug Data Minimum Data Set (MDS) is intended to provide consistent, essential information to a broad range of partners and stakeholders who have key roles in the collection and use of oncology drug data. The purposes of the MDS are to

- Identify and describe the specific data elements used to gather information on oncology drugs;
- Provide a rationale for including each data element;
- Codify the values that categorize the data element (where applicable); and
- Provide a guide for the use and collection of the data element.

Oncology drug data elements are classified as mandatory, optional or conditional. This classification is based on the consensus opinion of key stakeholders across the country. Data collected in the mandatory fields is considered essential to support the major uses of the data, including the development and application of real-world evidence. Optional data elements are not viewed as being less important, but they may be more difficult to obtain or they may not be relevant in all cases. Data providers are encouraged to make every effort to collect all relevant data elements.

The oncology drug data elements are grouped under the following information/data domains:

- **Health Service Event** — A past, current, planned or requested act;¹ a characterization of the event (e.g., dispense date/administration date)
- **Organization Information** — A group of persons with a common purpose or function¹ (organization ID, province, postal code)
- **Prescriber Information** — An individual who has delivered, is delivering or has the potential to deliver health care–related services or goods¹
- **Client/Patient Information** — A person who has received, is receiving or is eligible for health care–related services or goods¹
- **Disease Information** — Data related to the disease of the client/patient
- **Drug Information** — Data related to the drug(s) used in the treatment of the cancer

How to use this manual

This manual is designed to be a resource for the accurate and consistent coding of oncology drug data to support data collection by facilities and potential data submission to CIHI.

The MDS (e.g., data elements, coding values) will be further refined based on feedback collected during its use.

Appendix

The appendix provides a table listing the mandatory, optional and conditional data elements.

Contact information

For client support, or to provide feedback on the MDS, please send an email to drugs@cihi.ca.

Guidelines for coding and interpretation

This section provides detailed coding and interpretation guidelines for staff involved in assessing, coding and submitting data. These guidelines are also required for accurate interpretation of analysis and reports derived using the data.

This section provides a detailed description of each data element, including

- Rationale for each data domain;
- Data element definitions;
- Coding responses;
- Coding guidelines; and
- Reference/source documents.

1.0 Health Service Event

Definition

A past, current, planned or requested act¹

Rationale

Information provided in this domain will identify the timing of the event (e.g., drug dispense/administration date).

List of data elements

1.1 Service Date

1.1 Service Date

Definition

The date on which the prescription was dispensed

Assumptions

The administration date will be submitted (instead of the dispense date) if it is the only date collected. It is assumed that the administration date will provide a reasonable estimate for (and often be the same as) the dispense date for IV treatments.

Coding

YYYYMMDD

Guide for use

- Mandatory
- Input year, month and day

Reference/source documents

- NPDUIS = Service Date

2.0 Organization Information

Definition

A group of persons with a common purpose or function¹

Rationale

Information provided in this domain

- Uniquely identifies the facility where the oncology event took place;
- Allows the facility submitting data to be distinguished from other cancer centres; and
- Can be used to support geographic and related analysis (e.g., by health region, urban/rural).

List of data elements

- 2.1 Organization ID
- 2.2 Organization Province
- 2.3 Organization Postal Code

2.1 Organization ID

Definition

The CIHI identifier for the health care facility where the drug was dispensed/administered

Coding values

CIHI Institution Number (Discharge Abstract Database [DAD]/National Ambulatory Care Reporting System [NACRS])

Note: If submitting institutions do not have a CIHI Institution Number, CIHI will work with the jurisdiction to assign an appropriate code.

Guide for use

- Mandatory

Reference/source documents

- *CIHI Reference Data Model Toolkit¹*

2.2 Organization Province

Definition

The province or territory from the organization's physical address

Coding

Valid jurisdiction codes

Guide for use

- Mandatory

Reference/source documents

- *CIHI Reference Data Model Toolkit¹*

2.3 Organization Postal Code

Definition

The 6-digit postal code from the organization's physical address

Coding

Alphanumeric, ANANAN

Guide for use

- Mandatory

Reference/source documents

- *CIHI Reference Data Model Toolkit*¹

3.0 Prescriber Information

Definition

An individual who has delivered, is delivering or has the potential to deliver health care–related services or goods¹

Rationale

Information provided in this domain will

- Uniquely identify the health care professional so that oncology drug utilization can be linked to a health care provider;
- Identify the type of health care professional prescribing oncology medication;
- Identify the health care professional's practice location; and
- Help support prescriber-/specialty-related analysis (e.g., by health region, urban/rural).

List of data elements

3.1 Prescriber ID

3.2 Prescriber Specialty

3.3 Prescriber Province

3.4 Prescriber Postal Code

3.1 Prescriber ID

Definition

The identifier that uniquely identifies the prescribing health care professional

Coding

Alphanumeric

Guide for use

- The prescriber ID submitted by the jurisdiction
- Optional

Reference/source documents

- *CIHI Reference Data Model Toolkit¹*

3.2 Prescriber Specialty

Definition

A code that indicates the specialty of the prescribing health care professional

Coding

Alphanumeric

Note: A specific value set will be determined.

Guide for use

- Optional

Reference/source documents

- *CIHI Reference Data Model Toolkit¹*

3.3 Prescriber Province

Definition

The province or territory from the prescriber's physical address of practice

Coding

Valid jurisdiction codes

Guide for use

- Optional

Reference/source documents

- *CIHI Reference Data Model Toolkit*¹

3.4 Prescriber Postal Code

Definition

The 6-digit postal code from the prescriber's physical address of practice

Coding

Alphanumeric, ANANAN

Guide for use

- Optional

Reference/source documents

- *CIHI Reference Data Model Toolkit*¹

4.0 Client/Patient Information

Definition

A person who has received, is receiving or is eligible for health care–related services or goods¹

Rationale

Information provided will

- Uniquely identify the client/patient so that their oncology drug use can be tracked over time;
- Identify basic demographic information about the client/patient associated with the event (e.g., analysis by age, sex, health region, urban/rural); and
- Support data linkage to other health databases (e.g., on hospitalizations, physician/emergency department visits, community drug dispenses).

List of data elements

- 4.1 Client/Patient ID
- 4.2 Client/Patient Province
- 4.3 Client/Patient Postal Code
- 4.4 Client/Patient Gender

- 4.5 Client/Patient Date of Birth
- 4.6 Client/Patient Height
- 4.7 Client/Patient Weight
- 4.8 Client/Patient Body Surface Area
- 4.9 Body Surface Area Formula

4.1 Client/Patient ID

Definition

Unique identifier of the person for whom the prescription was filled (e.g., provincial health card number)

Coding

NNNNNNNN

Guide for use

- Mandatory

Reference/source documents

- *CIHI Reference Data Model Toolkit¹*

4.2 Client/Patient Province

Definition

The province or territory issuing the health card

Coding

Valid jurisdiction codes

Guide for use

- Mandatory

Reference/source documents

- *CIHI Reference Data Model Toolkit¹*

4.3 Client/Patient Postal Code

Definition

The 6-digit postal code from the client's/patient's physical address

Coding values

Alphanumeric, ANANAN

Guide for use

- Mandatory

Reference/source documents

- *CIHI Reference Data Model Toolkit¹*

4.4 Client/Patient Gender

Definition

A code used to indicate the gender or sex of a person

Coding values

Male

Female

Undifferentiated — the gender of a person could not be uniquely defined as male or female

Guide for use

- Mandatory

Reference/source documents

- *CIHI Reference Data Model Toolkit¹*

4.5 Client/Patient Date of Birth

Definition

The calendar date of birth of the client/patient involved in the event

Coding

YYYYMMDD

Guide for use

- Mandatory

Reference/source documents

- *CIHI Reference Data Model Toolkit¹*

4.6 Client/Patient Height

Definition

The height of the client/patient at the time of dispense

Coding values

Height: XX.X cm

Guide for use

- Optional

Reference/source documents

- Not applicable

4.7 Client/Patient Weight

Definition

The weight of the client/patient at the time of dispense

Coding values

Weight: XXX.X kg

Guide for use

- Optional

Reference/source documents

- Not applicable

4.8 Client/Patient Body Surface Area

Definition

The body surface area (BSA) of the client/patient involved in the event

Coding values

BSA: X.XX m²

Guide for use

- Optional

Reference/source documents

- Not applicable

4.9 Body Surface Area Formula

Definition

The formula used to calculate the BSA

Coding values (to be finalized)

- Mosteller
- Du Bois
- Haycock
- Gehan and George
- Boyd

Guide for use

- Mandatory if BSA is populated

Reference/source documents

- Not applicable

5.0 Disease Information

Definition

Data related to the disease of the client/patient

Rationale

Information provided will

- Allow activity reporting by disease site group;
- Allow incidence rate reporting by cancer type; and
- Allow original diagnosis to be used in historical analyses if necessary.

List of data elements

- 5.1 Diagnosis Code
- 5.2 Topography Code
- 5.3 Morphology Code
- 5.4 Topography/Morphology Code Version
- 5.5 Staging
- 5.6 Date of Initial Diagnosis

5.1 Diagnosis Code

Definition

The diagnosis of the neoplasm coded according to the International Classification of Diseases, 9th revision (or more recent version)

Coding values

4-digit code

Note: The ICD-9 cancer code is used to describe the site of the tumour; it must be supplemented with an ICD-O-2 histology code and an ICD-O-2 behaviour code.

Guide for use

- Mandatory
- Based on the International Classification of Diseases for Oncology (second or third edition)

Reference/source documents

- *Canadian Cancer Registry System Guide — 2015/2016 Edition*²

5.2 Topography Code

Definition

The site of origin of the neoplasm coded according to the International Classification of Diseases for Oncology (second or third edition) topography section

Coding values

4-digit code

Guide for use

- Mandatory
- Based on the International Classification of Diseases for Oncology (second or third edition)

Reference/source documents

- *Canadian Cancer Registry System Guide — 2015/2016 Edition*²

5.3 Morphology Code

Definition

- The histological description of the neoplasm, coded according to the International Classification of Diseases for Oncology (second or third edition) morphology section
- The behaviour associated with the histological description of the neoplasm

Coding values

ICD-O-2 histology: 4-digit code

ICD-O-2 behaviour: 1-digit code

Guide for use

- Mandatory
- Based on the International Classification of Diseases for Oncology (second or third edition) morphology section

Reference/source documents

- *Canadian Cancer Registry System Guide — 2015/2016 Edition*²

5.4 Topography/Morphology Code Version

Definition

The version of ICD-O that was used for the topography/morphology codes

Coding values

ICD-O-2

ICD-O-3

Guide for use

- Mandatory
- Based on the International Classification of Diseases for Oncology

Reference/source documents

- *Data Book, 2016–2017*³

5.5 Staging

Definition

Cancer staging is the process of determining the extent of the cancer based on the assessment of 3 components: tumour, node and metastasis (TNM).

Clinical staging/classification is based on evidence acquired before treatment. Such evidence arises from physical examination, imaging, endoscopy, biopsy, surgical exploration and other relevant examinations.⁴

Coding values

Valid values according to the TNM Classification of Malignant Tumours

Guide for use

- Mandatory

Reference/source documents

- *DAD Abstracting Manual, 2016–2017*⁴
- Description of TNM staging is taken from the *TNM Classification of Malignant Tumours, Fifth Edition*, developed by the International Union Against Cancer (UICC) pp. 6–7⁵

5.6 Date of Initial Diagnosis

Definition

Date of the initial pathological diagnosis of the tumour

Coding values

YYYYMMDD

Guide for use

- Mandatory

Reference/source documents

- *Canadian Cancer Registry System Guide — 2015/2016 Edition*²

6.0 Drug Information

Definition

Data related to the drug(s) used in the treatment of the cancer

Rationale

Collecting drug product information will

- Uniquely identify the drug product(s), including their strength, form and approved routes (drug identification number [DIN]);
- Inform/monitor trends in oncology drug use; and
- Provide information related to oncology drug spending.

List of data elements

- 6.1 Drug Product ID
- 6.2 Drug Product Name
- 6.3 Drug Product Strength

- 6.4 Drug Product Dosage Form
- 6.5 Regimen/Treatment Plan
- 6.6 Quantity Dispensed
- 6.7 Measurement Unit
- 6.8 Days Supply
- 6.9 Route of Administration
- 6.10 Drug Cost

6.1 Drug Product ID

Definition

Unique identifier for the drug product prescribed during an active course of treatment

Coding values

NNNNNNNN (Health Canada's DIN)

Guide for use

- Mandatory

Reference/source documents

- Not applicable

6.2 Drug Product Name

Definition

Name of the drug product prescribed during an active course of treatment

Coding values

Free-text field

Guide for use

- Mandatory if DIN cannot be provided (e.g., clinical trial drug)

Reference/source documents

- Not applicable

6.3 Drug Product Strength

Definition

Strength of the drug product prescribed during an active course of treatment

Coding values

Free-text field

Guide for use

- Mandatory if DIN cannot be provided (e.g., clinical trial drug)

Reference/source documents

- Not applicable

6.4 Drug Product Dosage Form

Definition

Dosage form of the drug product prescribed during an active course of treatment

Coding values

List of values from Health Canada's Drug Product Database

Guide for use

- Mandatory if DIN cannot be provided (e.g., clinical trial drug)

Reference/source documents

- Drug Product Database⁶

6.5 Regimen/Treatment Plan

Definition

A set of anti-cancer (and supportive) medications given during an active course of systemic chemotherapy

Coding values

Provincial formulary regimen code lists

Guide for use

- Optional

Reference/source documents

- Not applicable

6.6 Quantity Dispensed

Definition

The quantity of drug dispensed per visit

Coding values

NNNNN.NN

Guide for use

- Mandatory
- Injectables: dose per treatment/visit
- Oral medication: collect the quantity prescribed for 1 prescription fill
- See **6.8 Days Supply** to record the number of days' supply corresponding to the quantity dispensed.

Reference/source documents

- Not applicable

6.7 Measurement Unit

Definition

International standard units of measurement for the drug (e.g., milligram)

Coding values

List of values from Health Canada's Drug Product Database

Guide for use

- Optional

Reference/source documents

- Drug Product Database⁶

6.8 Days Supply

Definition

The total number of days' supply dispensed/administered

Coding values

XXX

Guide for use

- Optional

Reference/source documents

- *CIHI Reference Data Model Toolkit*¹

6.9 Route of Administration

Definition

The part of the body on which, through which or into which the drug was introduced⁷

Coding values

List of values from Health Canada's Drug Product Database

Guide for use

- Optional

Reference/source documents

- Drug Product Database⁶
- Drug Product Database — Terminology⁷

6.10 Drug Cost

Definition

Total cost of the drug product dispensed/administered

Coding values

Dollar value of total quantity of drug dispensed/administered. If actual price is not available, cost will be calculated based on manufacturer's list price.

Guide for use

- Optional

Reference/source documents

- Not applicable

Appendix: List of data elements

Data element	Status (M = mandatory; O = optional; C = conditional)
Health Service Event	
Service Date	M
Organization Information	
Organization ID	M
Organization Province	M
Organization Postal Code	M
Prescriber Information	
Prescriber ID	O
Prescriber Specialty	O
Prescriber Province	O
Prescriber Postal Code	O
Client/Patient Information	
Client/Patient ID	M
Client/Patient Province	M
Client/Patient Postal Code	M
Client/Patient Gender	M
Client/Patient Date of Birth	M
Client/Patient Height	O
Client/Patient Weight	O
Client/Patient Body Surface Area	O
Body Surface Area Formula	C
Disease Information	
Diagnosis Code	M
Topography Code	M
Morphology Code	M

Data element	Status (M = mandatory; O = optional; C = conditional)
Topography/Morphology Code Version	M
Staging	M
Date of Initial Diagnosis	M
Drug Information	
Drug Product ID or Drug Product Name	One is mandatory
Drug Product Strength	C
Drug Product Dosage Form	C
Regimen/Treatment Plan	O
Quantity Dispensed	M
Measurement Unit	O
Days Supply	O
Route of Administration	O
Drug Cost	O

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1. Canadian Institute for Health Information. [CIHI Reference Data Model Toolkit](#). 2016.
2. Statistics Canada. *Canadian Cancer Registry System Guide — 2015/2016 Edition*. 2015.
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