Systemic Anti-Cancer Therapy Regimen Data Standard

HISO 10080:2021

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Te Aho o Te Kahu, the Cancer Control Agency is an independent departmental agency that was established to lead and unite efforts to deliver better cancer outcomes for Aotearoa.

Te Aho o Te Kahu develops and publishes cancer-specific data standards in partnership with the Health Information Standards Organisation (HISO).

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# Purpose

This document is a standard for the accurate and consistent identification and description of systemic anti-cancer therapy regimens in New Zealand.

Systemic anti-cancer therapy (SACT) refers to all drug treatments for cancer. This includes chemotherapy, targeted therapies, hormones and other drug therapies.

The standard originates from the project called SACT NZ at its launch in late 2018, which sets out to develop a detailed database of information on patients receiving systemic anti-cancer therapy across New Zealand, aiming to identify and reduce variation, enhance equity of access and support resource planning.

In 2020 the project was renamed [ACT-NOW](https://teaho.govt.nz/about/our-work/act-now-programme) which stands for Anti-Cancer Therapy – Nationally Organised Workstreams. The project, in its first phase, requires the development of national data and regimen definitions to create a solid foundation for the subsequent capture of meaningful and comparable data at a national level.

# Scope

The data standard covers treatment regimens for adult solid or haematological cancers developed under the auspices of the ACT-NOW project and software systems used to develop and manage those regimens.

This document identifies the mandatory data elements and code sets required to construct consistent, accessible and accurate SACT regimen definitions.

The standard does not cover:

* Adolescent and young adult cancer patients (AYA)
* Non-malignant bloods
* Clinical trials

While the standard currently excludes treatment regimens for paediatric cancers of all types and one-off regimens developed by individual clinicians, it is expected that any regimens eventually developed for these situations will comply with the standard.

# Background

The[**New Zealand Cancer Action Plan | Te Mahere mō te Mate Pukupuku o Aotearoa 2019-2029**](https://www.health.govt.nz/publication/new-zealand-cancer-action-plan-2019-2029)provides a pathway to improve cancer outcomes for all New Zealanders with the objectives of building a system that delivers consistent and modern cancer care, equitable cancer outcomes, fewer cancers and better cancer survival, supportive care and end of life care.

[Te Aho o Te Kahu (Cancer Control Agency)](https://teaho.govt.nz/about/our-work/act-now-programme) is the independent departmental agency, reporting directly to the Minister of Health, charged with providing strong central leadership and oversight of cancer control in New Zealand.

The [Anti-Cancer Therapy – Nationally Organised Workstreams (ACT-NOW)](https://teaho.govt.nz/about/our-work/act-now-programme) programme was launched in late 2018 to develop a detailed database of information on patients receiving systemic anti-cancer therapy across New Zealand and work with the medical oncology, haematology, pharmacist and nursing communities to identify and reduce variation, enhance equity of access and support resource planning.

The first phase of the ACT-NOW project requires the development of national data and regimen definitions to create a solid foundation for the subsequent capture of meaningful and comparable data at the national level. Linking this project with [Whakamaua – Māori Health Action Plan 2020-25](https://www.health.govt.nz/publication/whakamaua-maori-health-action-plan-2020-2025) will enable Te Aho o Te Kahu to coordinate action to achieve the aims of [He Korowai Oranga – Māori Health Strategy](https://www.health.govt.nz/our-work/populations/maori-health/he-korowai-oranga).

The [Cancer Health Information Strategy 2015](https://www.health.govt.nz/publication/new-zealand-cancer-health-information-strategy) endorsed SNOMED CT as the required system of terminology for point of care applications. SNOMED CT must be the clinical terminology used to capture cancer health information at point of care.

All systems with medicines management functions are required to adhere to [**HISO 10024.1:2018 New Zealand Universal List of Medicines and New Zealand Formulary**](https://www.health.govt.nz/publication/hiso-1002412018-new-zealand-universal-list-medicines-and-new-zealand-formulary) in order to be properly functional and interoperable in the digital health ecosystem.

## Definitions

| **Term** | **Definition** |
| --- | --- |
| Tumour group or stream | A group of similar or related cancers, usually categorised according to the bodily system or organ they are associated with (eg, bowel, gynaecological, breast). |
| SNOMED CT | Systematized Nomenclature of Medicine – Clinical Terms is a systematic, computer-processable collection of medical terms that provide definitions and synonyms that cover anatomy, diseases, findings, procedures, microorganisms, substances and so on. It is a consistent way to store, retrieve and aggregate medical data across specialties and sites of care. |

## Legislation and regulations

The following legislation and regulations are relevant to this standard:

* [Medicines Act 1981 and Medicines Regulations 1984](https://www.health.govt.nz/our-work/regulation-health-and-disability-system/medicines-act-1981).

ACT-NOW regimens contain information about medicines. Clinical systems that use ACT-NOW regimens will record health information about individual people and the medicines administered to them during their care.

## Related specifications

The following documents have been used to develop or are referenced in this standard.

* [New Zealand Cancer Health Information Strategy. Wellington: Ministry of Health](https://www.health.govt.nz/publication/new-zealand-cancer-health-information-strategy)
* [New Zealand Cancer Plan: Better, faster cancer care 2015–2018. Wellington: Ministry of Health](https://www.health.govt.nz/publication/new-zealand-cancer-plan-better-faster-cancer-care-2015-2018)
* [New Zealand Cancer Action Plan 2019–2029 – Te Mahere mō te Mate Pukupuku o Aotearoa 2019–2029.](https://www.health.govt.nz/publication/new-zealand-cancer-action-plan-2019-2029) Revised January 2020. Wellington: Ministry of Health
* [**HISO 10013:2015 HL7 Standards Endorsement**](https://www.health.govt.nz/publication/hiso-100132015-hl7-standards-endorsement)
* [**HISO 10038.3 National Cancer Core Data Standard**](https://www.health.govt.nz/publication/hiso-1003832011-interim-national-cancer-core-data-definitions-standard)
* [**HISO 10042 Medication Charting and Medicine Reconciliation Standards**](https://www.health.govt.nz/publication/hiso-10042-medication-charting-and-medicine-reconciliation-standards)
* [**HISO 10063:2017 GS1 Standards Endorsement**](https://www.health.govt.nz/publication/hiso-10063-gs1-standards)
* [**HISO 10083:2020 Interoperability Roadmap**](https://www.health.govt.nz/publication/hiso-100832020-interoperability-roadmap)

# Requirements

## SNOMED CT

#### Clinical terminology standard

Coded data elements in ACT-NOW regimens use by default the SNOMED CT terminology for clinical information. The concepts making up each value domain are denoted by either the preferred term or a clinically agreed term and are linked to entries in the [SNOMED CT browser](http://browser.snomedtools.org/). The SNOMED CT concept identifier (SCTID) can be viewed by hovering over the link.

Some data elements are restricted to a definite set of SNOMED CT concepts, while others are more open-ended and allow the user to select from a wider set of concepts, usually within a certain hierarchy or sub-hierarchy eg, the set of all disease concepts.

See the [SNOMED CT Search and Data Entry Guide](https://confluence.ihtsdotools.org/display/DOCSEARCH/SNOMED%2BCT%2BSearch%2Band%2BData%2BEntry%2BGuide) for a guide to building a user-friendly search across the terminology.

Systems should display the SNOMED preferred or clinically agreed term and capture the SNOMED concept identifier accordingly.

The [SNOMED NZ Edition](https://www.health.govt.nz/nz-health-statistics/classification-and-terminology/new-zealand-snomed-ct-national-release-centre/snomed-ct-subsets-and-maps), incorporating the SNOMED CT International Edition and released in April and October every year, is the standard distribution. SNOMED CT is free to use in New Zealand and easy to implement. Download and install each release from the [Member Licensing and Distribution Service](https://mlds.ihtsdotools.org/#/landing/NZ?lang=en) or integrate your software with the [SNOMED CT terminology service](https://www.health.govt.nz/our-work/digital-health/digital-health-sector-architecture-standards-and-governance/health-information-standards-0/snomed-ct-terminology-service) provided by the Ministry of Health.

## Character sets

Text data elements must accommodate macrons for te reo Māori and diacritic characters for other commonly used languages. By default, this means using the Unicode Basic Latin, Latin-1 Supplement and Latin Extended A character sets.

[ISO/IEC 10646:2017 Information technology – Universal Coded Character Set (UCS)](https://www.iso.org/standard/69119.html) is the recognised standard. UTF-8 is the recommended character encoding.

## Medicine concept specification

ACT-NOW cancer regimens specify medicines using the New Zealand Medicines Terminology (NZMT) Medicinal Product (MP) concept SCTID and Tall Man lettering[[1]](#footnote-1) preferred term.

Where the MP concept models a medicine that either:

* meets the requirements of the Health Quality & Safety Commission (HQSC) Medication Safety Expert Advisory Group’s [Specify Brand Advice Guidance](https://www.hqsc.govt.nz/our-programmes/medication-safety/publications-and-resources/publication/3421/) or
* the working group has objective evidence that available presentations of the medicine are not interchangeable in oncology practice.

The human readable format displayed to users in software systems will be «MP preferred term» «(Brand Name)».

## Data element template

Data element specifications in this standard conform to the requirements of ISO/IEC 11179 Information Technology – Metadata Registries (MDR).[[2]](#footnote-2)

|  |  |
| --- | --- |
| **Definition** | A statement that expresses the essential nature of the data element and its differentiation from other elements in the data set. |
| **Source standards** | Established data definitions or guidelines relating to the data element. |
| **Data type** | Alphabetic (A)DateDate/timeNumeric (N)Alphanumeric (X)Boolean | **Representational class** | Code, free text, value or identifier.For date and time data types, use full date or partial date. |
| **Field size** | Maximum number of characters | **Representational layout** | The formatted arrangement of characters in alphanumeric elements, for example:* X(50) for a 50-character alphanumeric string
* NNN for a 3-digit number
* NNAAAA for a formatted alphanumeric identifier.
 |
| **Value domain** | The named, enumerated or described set of valid values or codes that are acceptable for the data element.Each coded data element has a specified code set. |
| **Obligation** | Indicates if the data element is mandatory or optional in the context, or whether its appearance is conditional. |
| **Guide for use** | Additional guidance to inform the use of the data element. |
| **Verification rules** | Quality control mechanisms that preclude invalid values. |

#  Data elements

## Regimen value set taxonomy

The value set taxonomy for ACT-NOW regimens is:



## Regimen value sets

### Cancer type

Note: Two values in the proposed list of permissible cancer types, being ‘marrow transplant’ and ‘blood and marrow transplant’ are terms from the SNOMED CT Procedure hierarchy. Work is currently underway to support collecting the relevant cancer types that would represent these two terms.

|  |  |
| --- | --- |
| **Definition** | The taxonomy level that defines the body system group of cancers the regimen treats. |
| **Source standards** | SNOMED New Zealand Edition |
| **Data type** | Numeric  | **Representational class** | Code |
| **Field size** | 18 | **Representational layout** | N(18) |
| **Value domain** |

|  |  |
| --- | --- |
|  |  |
| **SCTID** | **Display name** |
| ~~234336002~~ | ~~Blood and marrow transplant~~ |
| 254837009  | Breast  |
| 781382000  | Colorectal  |
| 363514001  | Gynaecological  |
| 255056009 | Head and neck  |
| 93143009  | Leukaemias  |
| 118600007  | Lymphoma  |
| ~~23719005~~ | ~~Marrow transplant~~ |
| 109989006  | Multiple myeloma  |
| 372063002  | Neurological  |
| 449096009  | Respiratory  |
| 424413001  | Sarcoma  |
| 372130007 | Skin cancer |
| 61331000210103  | Upper gastrointestinal  |
| 271468000 | Urogenital  |
|  |  |

 |
| **Obligation** | Mandatory |
| **Guide for use** | The permissible codes for cancer type in ACT-NOW regimens are derived from the malignant neoplastic disease branch of the SNOMED CT disease hierarchy. |

### Cancer subtype

|  |  |
| --- | --- |
| **Definition** | The taxonomy level that defines the discrete cancer type from the body system group of cancers that the regimen treats. |
| **Source standards** | SNOMED New Zealand Edition |
| **Data type** | Numeric  | **Representational class** | Code |
| **Field size** | 18 | **Representational layout** | N(18) |
| **Value domain** |

| **SCTID** | **Display name** |
| --- | --- |
| 91857003 | Acute lymphoblastic leukaemia |
| 91861009 | Acute myeloid leukaemia |
| 110004001 | Acute promyelocytic leukaemia |
| 363490009  | Anal  |
| 254701007 | Basal cell |
| 363415003  | Biliary  |
| 399326009  | Bladder  |
| 448710000  | Bone sarcoma  |
| 118617000 | Burkitt lymphoma |
| 363354003  | Cervical  |
| 92814006 | Chronic lymphocytic leukaemia |
| 92818009 | Chronic myeloid leukaemia |
| 93781006  | Endometrial  |
| 363349007  | Gastric  |
| 420120006  | Gastrointestinal stromal cell tumours  |
| 416402001  | Gestational trophoblastic disease  |
| 393564001  | Glioma  |
| 118613001 | Hairy cell leukaemia |
| 93870000  | Hepatic  |
| 118599009 | Hodgkin lymphoma |
| 443487006 | Mantle cell lymphoma |
| 372244006 | Melanoma |
| 253001006 | Merkel Cell |
| 109378008  | Mesothelioma  |
| 109995007 | Myelodysplastic disorders |
| 187692001  | Nasopharyngeal  |
| 133531000119104  | Neuroendocrine  |
| 254637007  | Non-small cell lung cancer  |
| 118601006 | Non-Hodgkin lymphoma |
| 363402007  | Oesophageal  |
| 363443007  | Ovarian  |
| 363418001  | Pancreas  |
| 307649006 | Primary CNS lymphoma |
| 399068003  | Prostate  |
| 363351006  | Rectal  |
| 363518003  | Renal  |
| 255072001  | Salivary gland  |
| 254632001  | Small cell lung cancer  |
| 424952003  | Soft tissue sarcoma  |
| 402815007 | Squamous cell |
| 363449006  | Testicular  |
| 363478007  | Thyroid  |
| 94125001  | Urothelial  |
| 363367000  | Vulval  |
| 190818004 | Waldenstrom macroglobulinaemia |
|  |  |

 |
| **Obligation** | Mandatory |
| **Guide for use** | The permissible values for cancer subtype in ACT-NOW regimens are derived from the neoplastic disease branch of the SNOMED CT disease hierarchy. |

### Cancer subordinate subtype

|  |  |
| --- | --- |
| **Definition** | The taxonomy level that further defines the discrete cancer type from the body system group of cancers that the regimen treats according to cancer tissue characteristics or the cancer’s response to treatment. |
| **Source standards** | SNOMED New Zealand Edition |
| **Data type** | Numeric | **Representational class** | Code |
| **Field size** | 18 | **Representational layout** | N(18) |
| **Value domain** |

| **SCTID** | **Display name** |
| --- | --- |
| 427492003 | Castration resistant |
| 722103009 | Castration sensitive |
| 396198006 | Small cell prostate cancer |
|  |  |

 |
| **Obligation** | Optional. Inclusion of the cancer subordinate subtype in the regimen description is conditional. |
| **Guide for use** | The permissible values for cancer subordinate subtypes in ACT-NOW regimens are derived from the malignant neoplastic disease branch of the SNOMED CT disorder hierarchy. |

### Treatment intent

Note: The proposed list of permissible values for capturing treatment intent is currently under review.

|  |  |
| --- | --- |
| **Definition** | The value set characterises the nature of treatment the regimen or the expectation of whether treatment is curative or palliative. |
| **Source standards** | SNOMED New Zealand Edition |
| **Data type** | Numeric  | **Representational class** | Code |
| **Field size** | 18 | **Representational layout** | N(18) |
| **Value domain** |

| **SCTID** | **Display name** |
| --- | --- |
| 57251000210103 | Allogeneic conditioning protocol |
| 60551000210105 | Allogeneic intermediate intensity conditioning protocol |
| 60571000210102 | Allogeneic myeloablative conditioning protocol |
| 60581000210100 | Allogeneic non myeloablative conditioning protocol |
| 60611000210105 | Allogeneic reduced intensity conditioning protocol |
| 60561000210108 | Autologous conditioning protocol |
| 57241000210101 | Conditioning protocol |
| 816151001 | Consolidation |
| 703423002  | Definitive chemoradiation  |
| 450827009  | Induction chemotherapy  |
| 56671000210106 | Maintenance |
| TBA  | Metastatic  |
| TBA | Mobilisation |
| TBA | Neoadjuvant  |
| TBA | Non–metastatic |
| 60591000210103 | Peripheral blood stem cell mobilisation protocol |
| 394935005  | Post operative chemoradiation  |
| TBA | Recurrent or metastatic  |
| 60601000210108 | Reduced intensity conditioning protocol |

 |
| **Obligation** | Optional. Inclusion of treatment intent in the regimen description is conditional. |
| **Guide for use** | The permissible values for cancer subordinate subtypes in ACT-NOW regimens are derived from the malignant neoplastic disease branch of the SNOMED CT disorder hierarchy. |

### Dose form

|  |  |
| --- | --- |
| **Definition** | The value set defines the physical form of the medicine the regimen requires to be administered to the patient. |
| **Source standards** | SNOMED New Zealand Edition |
| **Data type** | Numeric  | **Representational class** | Code |
| **Field size** | 18 | **Representational layout** | N(18) |
| **Value domain** | *Note: A suitable list of values will be determined once the New Zealand common pharmaceutical dose form reference set has been reviewed.*

| **SCTID** | **Display name** |
| --- | --- |
|  |  |
|  |  |
|  |  |
|  |  |

 |
| **Obligation** | Mandatory |
| **Guide for use** | The permissible values for Dose form in ACT-NOW regimens are derived from the New Zealand common pharmaceutical dose form reference set in the SNOMED New Zealand Edition. |

### Dose unit

|  |  |
| --- | --- |
| **Definition** |  The value set defines the unit of measure used to define how much medicine the regimen requires to be administered to the patient.  |
| **Source standards** | SNOMED New Zealand Edition |
| **Data type** | Numeric  | **Representational class** | Code |
| **Field size** | 18 | **Representational layout** | N(18) |
| **Value domain** |

| **SCTID** | **Display name** |
| --- | --- |
| 413573002 | AUC (area under the curve) |
| 258682000 | gram flat dosing\* |
| 258997004 | international unit flat dosing\* |
| 414524001 | international unit/square metre |
| 258684004 | milligram flat dosing |
| 396163008 | milligram/kg |
| 258685003 | microgram flat dosing\* |
| 258803005 | microgram/kg |
| 404216004 | milligram/square metre |
| 396186001 | million unit flat dosing\* |
| 414745006 | million unit/square metre |

 |
| **Obligation** | Mandatory |
| **Guide for use** | \* **Flat dosing** refers to medication doses that are not defined in terms of the patient’s weight, surface area or body mass index (BMI). It is a concept used to enhance patient safety that is specific to oncology practice.The permissible values for dose unit in ACT-NOW regimens are derived from the SNOMED CT Unit of measure hierarchy. This list is also a subset of the New Zealand common pharmaceutical dose unit reference set in the SNOMED New Zealand Edition. |

### Administration frequency

|  |  |
| --- | --- |
| **Definition** | The value set defines the frequency that the regimen specifies a medicine is to be administered to patients. |
| **Source standards** | SNOMED New Zealand Edition |
| **Data type** | Numeric  | **Representational class** | Code |
| **Field size** | 18 | **Representational layout** | N(18) |
| **Value domain** |

|  |  |
| --- | --- |
| **SCTID** | **Display name** |
| 307443002 | Eight times daily |
| 225756002 | Every four hours |
| 225768006 | Every hour |
| 225753005 | Every three hours |
| 225750008 | Every two hours |
| 307440004 | Five times daily |
| 307439001 | Four times daily |
| 229797004 | Once daily |
| 307486002 | Once per one time |
| 307442007 | Seven times daily |
| 307441000 | Six times daily |
| 229798009 | Three times daily |
| 229799001 | Twice daily |

 |
| **Obligation** | Mandatory |
| **Guide for use** | The permissible values for administration frequency in ACT-NOW regimens are derived from the SNOMED CT Frequencies hierarchy. This list is also a subset of the New Zealand common pharmaceutical frequency reference set in the SNOMED New Zealand Edition. |

### Route of administration

|  |  |
| --- | --- |
| **Definition** | The value set the route by which the regimen specifies a medicine is administered to the patient. |
| **Source standards** | SNOMED New Zealand Edition |
| **Data type** | Numeric  | **Representational class** | Code |
| **Field size** | 18 | **Representational layout** | N(18) |
| **Value domain** |

|  |  |
| --- | --- |
| **SCTID** | **Display name** |
| 386356001 | intramuscular injection |
| 81633002 | intraperitoneal injection |
| 406188003 | intrathecal injection |
| 386358000 | intravenous injection |
| 431464005 | intravesical administration |
| 386359008 | oral administration |
| 386362006 | subcutaneous injection |
|  |  |

 |
| **Obligation** | Mandatory |
| **Guide for use** | The permissible values for route of administration are drawn from the Introduction procedure branch of the SNOMED CT Procedures hierarchy. |

### Supportive care

The permissible value set codes for supportive care dimensions in ACT-NOW regimens are:

#### Antifungal prophylaxis

|  |  |
| --- | --- |
| **Definition** | The value set identifies whether the patient should receive antifungal prophylaxis as part of the regimen. |
| **Source standards** | SNOMED New Zealand Edition |
| **Data type** | Numeric  | **Representational class** | Code |
| **Field size** | 18 | **Representational layout** | N(18) |
| **Value domain** |

| **SCTID** | **Display name** |
| --- | --- |
| 897021009 | Routine antifungal prophylaxis **not** recommended |
| 897020005 | Routine antifungal prophylaxis recommended |
|  |  |

 |
| **Obligation** | Optional |
| **Guide for use** |  |

#### Antiviral prophylaxis

|  |  |
| --- | --- |
| **Definition** | The value set identifies whether the patient should receive antiviral prophylaxis as part of the regimen. |
| **Source standards** | SNOMED New Zealand Edition |
| **Data type** | Numeric  | **Representational class** | Code |
| **Field size** | 18 | **Representational layout** | N(18) |
| **Value domain** |

| **SCTID** | **Display name** |
| --- | --- |
| 897022002 | Routine antiviral prophylaxis **not** recommended |
| 897019004 | Routine antiviral prophylaxis recommended |
|  |  |

 |
| **Obligation** | Optional |
| **Guide for use** |  |

#### Diarrhoea risk

|  |  |
| --- | --- |
| **Definition** | The value set identifies the level of risk of diarrhoea occurring during therapy with the regimen and advises whether anti-diarrhoeal medicines should be prescribed with this regimen |
| **Source standards** | SNOMED New Zealand Edition |
| **Data type** | Numeric  | **Representational class** | Code |
| **Field size** | 18 | **Representational layout** | N(18) |
| **Value domain** |

|  |  |
| --- | --- |
| **SCTID** | **Display name** |
| 723509005 | **High risk** (anti-diarrhoeals are usually prescribed with this treatment)  |
| 723505004 | **Low risk**(anti-diarrhoeals are not usually prescribed with this treatment) |
|  |  |

 |
| **Obligation** | Optional |
| **Guide for use** |  |

#### Emetogenicity

|  |  |
| --- | --- |
| **Definition** | The value set identifies the level of risk of nausea, vomiting or retching occurring with the regimen. |
| **Source standards** | SNOMED New Zealand Edition |
| **Data type** | Numeric  | **Representational class** | Code |
| **Field size** | 18 | **Representational layout** | N(18) |
| **Value domain** |

| **SCTID** | **Display name** |
| --- | --- |
| 723509005 | **High risk**   |
| 723505004 | **Low risk** |
| TBA | Variable |
| TBA | Minimal |

 |
| **Obligation** | Optional |
| **Guide for use** |  |

#### Growth factor support

|  |  |
| --- | --- |
| **Definition** | The value set identifies whether patients receiving the regimen will need growth factor medication to be prescribed with therapy. |
| **Source standards** | SNOMED New Zealand Edition |
| **Data type** | Numeric  | **Representational class** | Code |
| **Field size** | 18 | **Representational layout** | N(18) |
| **Value domain** |

| **SNOMED CT code** | **Display name** |
| --- | --- |
| 54361000210104 | Recommended for **primary** prophylaxis |
| 54371000210105 | Recommended for **secondary** prophylaxis |
|  |  |

 |
| **Obligation** | Optional |
| **Guide for use** |  |

#### Hydration

|  |  |
| --- | --- |
| **Definition** | The value set identifies whether patients receiving the regimen will need routine hydration to be administered with therapy. |
| **Source standards** | SNOMED New Zealand Edition |
| **Data type** | Numeric  | **Representational class** | Code |
| **Field size** | 18 | **Representational layout** | N(18) |
| **Value domain** |

| **SNOMED CT code** | **Display name** |
| --- | --- |
| 54271000210101 | Routine hydration **not** recommended |
| 54261000210107 | Routine hydration recommended |
|  |  |

 |
| **Obligation** | Optional |
| **Guide for use** |  |

#### Hypersensitivity/infusion related reaction risk

|  |  |
| --- | --- |
| **Definition** | The value set identifies the level of risk of a hypersensitivity infusion related reaction occurring with the regimen and advises whether routine premedication is recommended. |
| **Source standards** | SNOMED New Zealand Edition |
| **Data type** | Numeric  | **Representational class** | Code |
| **Field size** | 18 | **Representational layout** | N(18) |
| **Value domain** |

|  |  |
| --- | --- |
| **SCTID** | **Display name** |
| 723509005 | **High risk** (routine premedication recommended)  |
| 723505004 | **Low risk**(routine premedication **not** recommended) |
|  |  |

 |
| **Obligation** | Optional |
| **Guide for use** |  |

#### Irradiation blood components

|  |  |
| --- | --- |
| **Definition** | The value set identifies whether irradiation of blood components is recommended for patients receiving the regimen. |
| **Source standards** | SNOMED New Zealand Edition |
| **Data type** | Numeric  | **Representational class** | Code |
| **Field size** | 18 | **Representational layout** | N(18) |
| **Value domain** |

| **SCTID** | **Display name** |
| --- | --- |
| 54311000210101 | Irradiation of blood components is **not** recommended |
| 54301000210103 | Irradiation of blood components is recommended |
|  |  |

 |
| **Obligation** | Optional |
| **Guide for use** |  |

#### Constipation risk

|  |  |
| --- | --- |
| **Definition** | The value set identifies the level of risk of constipation occurring during therapy with the regimen and advises whether laxative medicines should be prescribed with this regimen |
| **Source standards** | SNOMED New Zealand Edition |
| **Data type** | Numeric  | **Representational class** | Code |
| **Field size** | 18 | **Representational layout** | N(18) |
| **Value domain** |

| **SCTID** | **Display name** |
| --- | --- |
| 723509005 | **High risk** (laxatives are usually prescribed with this treatment)  |
| 723505004 | **Low risk**(laxatives are not usually prescribed with this treatment) |
|  |  |

 |
| **Obligation** | Optional |
| **Guide for use** |  |

#### Ocular toxicity risk

|  |  |
| --- | --- |
| **Definition** | The value set identifies the level of risk of ocular toxicity occurring with the regimen and advises whether corticosteroid eye drops should be prescribed with the regimen. |
| **Source standards** | SNOMED New Zealand Edition |
| **Data type** | Numeric  | **Representational class** | Code |
| **Field size** | 18 | **Representational layout** | N(18) |
| **Value domain** |

| **SNOMED CT code** | **Display name** |
| --- | --- |
| 723509005 | **High risk**(administer corticosteroid eyedrops to minimise corneal toxicity) |
| 723505004 | **Low risk** |
|  |  |

 |
| **Obligation** | Optional |
| **Guide for use** |  |

#### Pneumocystis jiroveci pneumonia (PJP) prophylaxis

|  |  |
| --- | --- |
| **Definition** | The value set identifies whether the patient should receive Pneumocystis jiroveci prophylaxis as part of the regimen |
| **Source standards** | SNOMED New Zealand Edition |
| **Data type** | Numeric  | **Representational class** | Code |
| **Field size** | 18 | **Representational layout** | N(18) |
| **Value domain** |

| **SCTID** | **Display name** |
| --- | --- |
| 391159000 | Routine antibiotic prophylaxis not recommended |
| 413555000 | Routine antibiotic prophylaxis recommended |
|  |  |

 |
| **Obligation** | Optional |
| **Guide for use** |  |

#### Mesna uroprotection

|  |  |
| --- | --- |
| **Definition** | The value set identifies whether the patient should receive mesna uroprotective medicines as part of the regimen.  |
| **Source standards** | SNOMED New Zealand Edition |
| **Data type** | Numeric  | **Representational class** | Code |
| **Field size** | 18 | **Representational layout** | N(18) |
| **Value domain** |

| **SCTID** | **Display name** |
| --- | --- |
| 54291000210102 | Routine mesna uroprotection not recommended |
| 54281000210104 | Routine mesna uroprotection recommended  |
|  |  |

 |
| **Obligation** | Optional |
| **Guide for use** |  |

### Future value set additions

When new values need to be added to the value set collection, these principles apply:

* Where a suitable SNOMED CT concept exists in the SNOMED CT International Edition it will be used
* If a suitable concept in the SNOMED CT International Edition does not exist, a new concept will be created in the SNOMED CT New Zealand Extension.

## Regimen naming convention

Selecting and applying value set components to the regimen in the regimen editor, the software sets up the structure of the regimen name.

Each regimen has two names:

* The Full Name which is a unique description for a cancer regimen that defines the regimen in detail
* The Clinical Name which is a human readable description of a regimen name that is displayed in clinical software and documents accessed by clinicians. The clinical name contains abbreviations of the cancer type and other regimen parameters to improve its readability.

### Name structure

The general structure for full regimen names will be:

* **«cancer type» - «cancer subtype» «treatment intent» [«cancer subordinate subtype»] «regimen name suffix»**

### Regimen name suffix content

The regimen name suffix further describes the regimen and differentiates it from other, similar regimens. Where the regimen is derived from a clinical trial or an internationally recognised publication, the suffix will draw on the naming convention established by the triallists or the authors of the publication rather than creating a new identifier for the regimen. For example, the name for the FOLFOX6 regimen includes the word FOLFOX6 rather than the names leucovorin, fluorouracil and oxaliplatin. If the working group decides to modify an internationally recognised regimen the change will be indicated by placing a lower case «m» in front of the internationally accepted regimen name.

The constraints applying to this convention are:

1. If the regimen can be used to treat tumours in more than one cancer type group, new regimens duplicating the regimen content are created for each cancer type.

2. No more than two cancer subtypes may be allocated to the same regimen within a cancer type group. If the regimen can be used to treat more than two cancer subtypes in a cancer type group, duplicate regimens will be created.

3. Regimen value set information is not included in the regimen suffix.

Working groups are expected to follow the direction laid down by [International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10)](https://icd.who.int/browse10/2010/en) (and any successor document) where possible in defining regimen name suffixes.

The sequence for the suffix content is:

1. Time

2. Manner

3. Place

Any of these suffix components can be omitted if not required.

### Use of Tall Man lettering in medicine names

Tall Man lettering reduces the risk of look-alike and sound-alike medicine name confusion and errors.

Tall Man lettering will be used for all medicine names used in the Full Name and the Clinical Name where the current Aotearoa New Zealand Tall Man lettering list defines a Tall Man variant for either the medicine’s generic or brand name.

### Use of medicine brand names in regimen names

Regimen names will not include references to medicine brand names. Where a working group decides a medicine name is to be included in the regimen name, the generic name will be used.

The only exception to this requirement is where the various brands of a generic medicine are regarded as not being clinically interchangeable. In this situation the medicine will be referred to as «generic name (required brand)» to ensure users can identify the brand to be administered to the patient.

This exception will only be applied if either:

1. The generic medicine meets the requirements of the Medication Safety Expert Advisory Group’s Specify Brand Advice Guidance or
2. A generic medicine does not meet Specify Brand Advice Guidance requirements, but the working group has objective evidence that available presentations of the medicine are not interchangeable.

### Supportive care medicines

Supportive care value sets and supportive care medicines do not form part of the name of a regimen.

## Regimen SNOMED CT concepts

Each regimen is to be modelled as a SNOMED CT concept in the SNOMED CT New Zealand Extension. Such SNOMED CT concepts will be published when the regimen it models receives final approval from Te Aho o Te Kahu.

## Unapproved medicines and unapproved indications

Where an ACT-NOW regimen refers to an unapproved medicine or the indication for one or more of the medicines has not been approved by Medsafe, software displaying the regimen will alert users to the presence of an unapproved medicine or indication. Users will be responsible for securing any additional levels of patient consent needed before the relevant medicines can be administered.

Unapproved indications involve medicines that are used in routine clinical practice in New Zealand which have not been through a formal review process by Medsafe for a particular type of cancer. This use is often described as off–label use. These medicines may be used under section 25 of the Medicines Act 1981 when informed patient consent is obtained before they are used.

Unapproved medicines are medicines that are used in routine clinical practice which have not been through a formal review process by Medsafe. They may be used under section 29 of the Medicines Act 1981 when informed patient consent is obtained before they are used.

## Use of numbers in dosage information documentation

ACT-NOW regimens will follow [HISO 10042 Medication Charting and Medicine Reconciliation Standards](https://www.health.govt.nz/publication/hiso-10042-medication-charting-and-medicine-reconciliation-standards) in the way doses and medicines are recorded and expressed in regimen documentation to minimise the risk of medication error. The key requirements are:

* Avoid leading zeros by expressing the dose as number between 1 and 999 using appropriate units of measure
* Never use a zero after a decimal point unless it is followed by another digit that is not a zero (eg. 10.0mg is not acceptable, but 10.05mg is acceptable)
* Use the full name of a measurement instead of an abbreviation to avoid confusion (eg, microgram instead of mcg or μg, nanogram instead of ng)?
* Do not use abbreviated medicine names when specifying a medicine in the detail of regimen documentation
* Use unit or international unit as appropriate rather than the abbreviations U or IU.

Also see Health Quality and Safety’s [Error-prone abbreviations, symbols and dose designations](https://www.hqsc.govt.nz/assets/Medication-Safety/Alerts-PR/Poster-error-prone-abbreviations-not-to-use.pdf).

## Publication of regimens

Approved national standard regimens will be published in the SACT Regimen Library (SRL). The published regimens can be found on <https://nzf.org.nz/regimens>.

## FHIR API

ACT-NOW regimen definitions are accessible to authorised users via a FHIR API using the PlanDefinition resource.

## Retention of discontinued and superseded regimens

Discontinued and superseded regimens must be retained for clinical and medico–legal reference purposes. Clinical users of the ACT-NOW regimen system will not be able to routinely access discontinued or superseded regimens via their clinical system or through the New Zealand Formulary cancer regimens pages. The system administrator will provide access to nominated discontinued or superseded regimens on application.

## Regimen creation and maintenance process

The process for maintaining regimen concepts, terms and definitions across SNOMED CT and New Zealand Universal List of Medicines (NZULM) is outlined in Figure 1.

Figure : Regimen creation and maintenance process



# IMPLEMENTATION requirements

## Adoption roadmap

Te Aho o Te Kahu will lead national adoption of this standard as an element of the ACT-NOW project under the [Cancer Action Plan](https://www.health.govt.nz/publication/new-zealand-cancer-action-plan-2019-2029) 2019-2029.

The ACT-NOW project will develop a data and information roadmap that will:

* identify and understand the priority cancer data and information needs of key stakeholders
* understand how to support the implementation of digital technology that can help deliver care in more clinically and cost-effective ways to improve equity
* implement and support an integrated standards-based approach to the collection, retrieval and linkage of high-quality, comparable data at all stages of cancer care, including post-cancer care
* ensure timely distribution of relevant and accurate cancer data and information that addresses identified priorities and addresses our obligations under Te Tiriti o Waitangi
* develop a sustainable approach to ensure rapid access for stakeholders to data and information that enables them to develop actionable insights
* develop a policy and pathway that drives coordination, prioritisation and consistency of approach to cancer information systems to support patient-centred and coordinated care.

The planned steps to implement this standard are as follows:

* publication of approved national standard regimens at the completion of each cancer type working group’s consideration of available cancer unit regimens. The regimens will be published on <https://nzf.org.nz/regimens>.
* uptake of published regimens by individual cancer units for new patients via manual inclusion into patient care plans created in cancer management software. This supports the capture of data about patient management across the country required by the [Cancer Action Plan](https://www.health.govt.nz/publication/new-zealand-cancer-action-plan-2019-2029)
* addition of new functionality allowing electronic importation of regimens into cancer management software
* individual cancer units move from manual inclusion of regimens into software care plans to electronic importation of regimens via FHIR API.
1. Tall Man lettering is an error–prevention strategy to reduce the risk of look-alike and sound-alike medicine name confusion and errors. It uses selective capitalisation to make similar looking medicine names easier to differentiate. [↑](#footnote-ref-1)
2. See <https://standards.iso.org/ittf/PubliclyAvailableStandards/index.html> [↑](#footnote-ref-2)