



Ontario Health
Cancer Care Ontario

Specialized Services Oversight (SSO) Data Dictionary

Manual Data Collection – CAR T-cell Therapy Post Treatment
2020/21

Effective
8/14/2020

Table of Contents

Version Control.....	3
CAR T-cell Therapy Post Treatment Data Elements.....	4
Quality Assurance Checks.....	8
Validations: File Level Validations (Level 100)	9
Validations: File Format Errors (Level 200)	10
Validations: Content Errors, Record Rejected (Level 300).....	10
Validations: Content Errors, Record Not Rejected (Level 400).....	14
Validations: Duplicate or Apparent Duplicate Records (Level 500).....	14
Data Submission, Validation and Error Reporting Schedule	15
Appendix 1: CAR T-cell Disease Classification	15
Appendix 2: Facility number of CAR T-cell infusion centre	15
Appendix 3: CAR T-cell Product	16
Appendix 4: Reason for cancellation.....	16
Appendix 5: MOHLTC Master Numbering System.....	16

Version Control

Date	Description	Owner
June 19, 2020	First draft developed	SSO
August 14, 2020	Data dictionary finalized	SSO

CAR T-cell Therapy Post Treatment Data Elements

#	Entity	Data Element	COLUMN_NAME	Definition (Description)	Format	Valid values (Notes)	Applies to	Purpose and Use	Mandatory	Business key (Uniqueness)
1	CAR T-cell Therapy	Health Card Number	Health_card_number	Patient's most recent health insurance number assigned by their province of residence	CHAR(10) Alpha-numeric	Valid 10-digit provincial health card number Please note: version code should not be included in entry.	All	To identify OHIP vs. non-OHIP patients. To link data with other CCO data holding areas.	Yes	Yes
2	CAR T-cell Therapy	Patient chart Number	Patient_chart_number	Patient identifier that is unique within the healthcare facility	CHAR (12) Alpha-numeric	Must be alpha-numeric (i.e. no punctuation, must have numbers and characters).	All	Uniquely identifies a patient. Necessary to determine a case for hospital tracking. Foundational to most measures and indicators.	Yes	Yes
3	CAR T-cell Therapy	Date of Birth	Patient_birth_date	Patient birth date	CHAR(8) YYYYMMDD	Valid date only Patient birth date is between Jan 01 1900 and date of first cell	All	Uniquely identifies a patient. For analyses involving patient age.	Yes	Yes

#	Entity	Data Element	COLUMN_NAME	Definition (Description)	Format	Valid values (Notes)	Applies to	Purpose and Use	Mandatory	Business key (Uniqueness)
						collection/apheresis		To link data with other CCO data holding areas.		
4	CAR T-cell Therapy	Disease Indication Classification	Disease_indication	The primary disease that is being treated	CHAR(50)	Valid values listed in the CAR T-cell Disease Classification Table (Appendix-1)	All	For planning and reporting	Yes	
5	CAR T-cell Therapy	Facility number of CAR T-cell infusion centre	CAR_T-cell_infusion_centre	Facility number of CAR T-cell infusion centre	CHAR(4)	Valid MOHLTC facility numbers (facilities providing CAR T-cell infusion) listed in the Facility number of CAR T-cell infusion centre table (Appendix-2) An additional leading zero is acceptable.	All	For funding and program planning	Yes	Yes
6	CAR T-cell Therapy	CAR T-cell product (type)	CAR_T-cell_product_type	Name of CAR T-cell Product	CHAR(14)	Valid CAR T-cell products listed in the CAR T-cell product table (Appendix-3)	All	For planning, reporting and funding	Yes	

#	Entity	Data Element	COLUMN_NAME	Definition (Description)	Format	Valid values (Notes)	Applies to	Purpose and Use	Mandatory	Business key (Uniqueness)
7	CAR T-cell Therapy	Date of first cell collection/apheresis	First_cell_collection_or_apheresis_date	Date that first cell collection/apheresis was performed	CHAR(8) YYYYMMDD	Valid date entered 0-Therapy cancelled prior to first cell collection or apheresis (after patient enrolled)	All	For wait time reporting and funding	Yes	
8	CAR T-cell Therapy	Date of infusion	Infusion_date	Date that infusion of CAR T-cells was performed	CHAR(8) YYYYMMDD	Valid date only.	All	For reimbursement: to uniquely identify procedure for a patient. For wait time reporting.	Yes, when Cancellation_date is null	
9	CAR T-cell Therapy	Product meets regulatory specifications	Meets_regulatory_specifications	If administered products meets the regulatory specification	CHAR(3)	Character (dropdown) options: Yes No	All	For funding and program planning	Yes, when infusion_date is entered	
10	CAR T-cell Therapy	Infusion type (for commercial product only)	Infusion_type	Initial infusion: for patients who have had no prior episode of CAR	CHAR (19)	Character (dropdown) options: Initial Infusion	All	For funding and program planning	Yes, when infusion_date is entered	

#	Entity	Data Element	COLUMN_NAME	Definition (Description)	Format	Valid values (Notes)	Applies to	Purpose and Use	Mandatory	Business key (Uniqueness)
				T-cell therapy infusion. Subsequent infusion: for patients who have had a prior episode of CAR T-cell therapy infusion, this involves re-infusion of cell products remaining from initial manufacturing production.		Subsequent Infusion				
11	CAR T-cell Therapy	Date of initial infusion	Initial_infusion_date	Date that initial infusion of CAR T-cells was performed	CHAR(8) YYYYMMD D	Valid date only.	All	For program planning	Yes, when Infusion_type is Subsequent Infusion	
12	CAR T-cell Therapy	Date of documentation of cancellation	Cancellation_date	Identifies patients as no longer a candidate for CAR T-cell therapy. This would apply only to patients who have been enrolled for CAR T-cell therapy in Ontario but are	CHAR(8) YYYYMMD D	Valid date only	All	For funding and program planning	Yes, when Infusion_date is null	

#	Entity	Data Element	COLUMN_NAME	Definition (Description)	Format	Valid values (Notes)	Applies to	Purpose and Use	Mandatory	Business key (Uniqueness)
				not able to receive CAR T-cell infusion						
13	CAR T-cell Therapy	Reason for cancellation	Cancellation_reason	Identifies reason for patients who are not able to receive CAR T-cell infusion.	CHAR(50)	Valid reason for cancellation listed in the Reason for cancellation table (Appendix-4)	All	For program planning	Yes, when Cancellation_Date is entered	
14	CAR T-cell Therapy	Cancellation reason (Other)	Cancellation_reason_other	Identifies reason for cancellation if "Other" selected	CHAR(50)	Free text	All	For program planning	Yes, when Cancellation_reason is "Other"	

Quality Assurance Checks

The QA checks are grouped by number as follows:

100's - **File level checks**

200's - **File format errors:** Entire record is rejected.

300's - **Rejected content errors:** Entire record is rejected.

400's - **Non-rejected content errors:** Entire record is retained, including erroneous field.

500's - **Apparent duplicate record warnings:** These are not necessarily errors, but could be.

Built-in Data Assurance Checks within the Manual Submission Template

Cells in the submission template will light up **red** for data elements that are mandatory based on the treatment data being submitted on each row of the template. Cells in the submission template will light up **yellow** when the format of the data elements, which are dates, are incorrect. For all other data elements, an error message will appear if the format is incorrect.

Validations: File Level Validations (Level 100)

The following rules will be applied and checked against every file submitted for the SSO Program.

#	Type	Condition	Error Message	Reject
101	Invalid Header	Header list in excel file is incorrect	File Error- Header list is incorrect.	Yes
102	Incorrect number of Columns	Record in file has incorrect number of data elements	File Error- Record has incorrect number of data elements.	Yes
103	Monthly File name mask	<p>File name does not follow the convention for file name mask: CAR_T-cell_nnn_fff_fffMx.xlsx</p> <p>Where:</p> <ul style="list-style-type: none"> CAR_T-cell: a fixed string indicating the program data needed (CAR T-cell Therapy) nnn: the three-digit code of the submitting site (e.g. 837) fff_fff: the two calendar years that make up the fiscal year separated by an underscore character (e.g. 2020_2021) M: a fixed character for Month x: the month within the calendar year, which is always an integer number between 1 and 12 (e.g. 4 represents April) .xlsx: a fixed string indicating that the file includes comma-separated values. <p>Example: CAR_T-cell_837_2020_2021M12.xlsx</p> <p>Note: This validation should be non-case-sensitive so that, for example, the string "CAR_T-cell" can also be sent as "car_t-cell".</p>	File Error - File is incorrectly named.	Yes
104	Empty	<p>File is empty</p> <p>Note: files with only one row (i.e. the header row is present and not patient level data) are considered valid. This error applies only when there is no such header.</p>	File Error - invalid number of data columns in "file_name" file.	Yes
105	No Data	<p>File includes only one line, and that line is a valid header line.</p> <p>Note: This is a valid submission if there were no procedures in the reported quarter, so we issue a warning just to make sure.</p>	Warning - No data submitted. If there are data records, please resubmit.	No

Validations: File Format Errors (Level 200)

Number	Entity	Data Element	Condition	Error Message	Reject
201	All	All Fields	Data field is too long	Invalid field length	Yes
202	All	All Date Fields	Date is not in YYYYMMDD format	Invalid - Must be in YYYYMMDD format	Yes

Validations: Content Errors, Record Rejected (Level 300)

Number	Element #	Data Element	Column	Condition	Error Message	Reject
301	1	Health Card Number	Health_card_number	Is Null	Invalid - Null Value	Yes
302	1	Health Card Number	Health_card_number	Is not a valid ten-digit HCN-	Invalid Health Card Number	Yes
303	2	Patient chart Number	Patient_chart_number	Is Null	Invalid - Null Value	Yes
304	2	Patient chart Number	Patient_chart_number	Contains blanks or special characters (e.g. *,/,}) or is more than 12 characters	Invalid Patient Chart Number - Contains non alpha numeric characters or is more than 12 characters	Yes
305	2	Patient chart Number	Patient_chart_number	Contains a cell format that is not the 'Text' Category in Excel. Text format cells are treated as text even when a number is in the cell. The cell is displayed exactly as entered.	Invalid cell format	Yes
306	3	Date of Birth	Patient_birth_date	Is Null	Invalid - Null Value	Yes
307	3	Date of Birth	Patient_birth_date	Is before 1900-01-01	Date is before 1900-01-01	Yes
308	4	Disease Indication Classification	Disease_indication	Is Null	Invalid – Null Value	Yes

Number	Element #	Data Element	Column	Condition	Error Message	Reject
309	4	Disease Indication Classification	Disease_indication	Does not match predefined list provided in the Appendix-1	Invalid answer	Yes
310	5	Facility number of CAR T-cell infusion centre	CAR_T-cell_infusion_centre	Is Null	Invalid - Null Value	Yes
311	5	Facility number of CAR T-cell infusion centre	CAR_T-cell_infusion_centre	Does not match the valid facility number from the MOHLTC classification listed in Appendix-2	Invalid Facility Number - consult lookup table in template.	Yes
312	6	CAR T-cell product (type)	CAR_T-cell_product_type	Is Null	Invalid - Null Value	Yes
313	6	CAR T-cell product (type)	CAR_T-cell_product_type	Does not match predefined list provided in the Appendix-3	Invalid answer	Yes
314	6	CAR T-cell product (type)	CAR_T-cell_product_type	"Not determined" CAR T-cell product (type) reported when date of infusion is entered	"Not determined" CAR T-cell product (type) cannot be reported when date of infusion is entered	Yes
315	7	Date of first cell collection/apheresis	First_cell_collection_or_apheresis_date	Is Null	Invalid - Null Value	Yes
316	7	Date of first cell collection/apheresis	First_cell_collection_or_apheresis_date	Is not a valid date or 0	Invalid answer	Yes
317	7	Date of first cell collection/apheresis	First_cell_collection_or_apheresis_date	0 reported when date of infusion is entered	0 cannot be reported when date of infusion is entered	Yes

Number	Element #	Data Element	Column	Condition	Error Message	Reject
318	7	Date of first cell collection/apheresis	First_cell_collection_or_apheresis_date	Date of first cell collection/apheresis is on or after date of infusion	Date of first cell collection/apheresis cannot be on or after date of infusion	Yes
319	8	Date of infusion	Infusion_date	Is not in current reporting quarter or reporting month	Date of infusion is not in the current reporting quarter or month	Yes
320	8	Date of infusion	Infusion_date	Date of infusion reported when CAR T-cell product (type) is null or "Not determined"	Date of infusion cannot be reported when CAR T-cell product (type) is null or "Not determined"	Yes
321	9	Product meets regulatory specifications	Meets_regulatory_specifications	Does not match predefined drop down menu	Invalid answer	Yes
322	9	Product meets regulatory specifications	Meets_regulatory_specifications	Product meets regulatory specifications reported when CAR T-cell product (type) is null or "Not determined"	Product meets regulatory specifications cannot be reported when CAR T-cell product (type) is null or "Not determined"	Yes
323	9	Product meets regulatory specifications	Meets_regulatory_specifications	Product meets regulatory specifications reported when infusion_date is null	Product meets regulatory specifications cannot be reported when infusion_date is null	Yes
324	10	Infusion type (for commercial product only)	Infusion_type	Infusion Type reported when Infusion Date is null	Infusion type cannot be reported when Infusion Date is null	Yes

Number	Element #	Data Element	Column	Condition	Error Message	Reject
325	11	Date of initial infusion	Initial_infusion_date	Date of initial infusion not reported when Infusion type is "Subsequent infusion"	Date of initial infusion should be reported when Infusion type is "Subsequent infusion"	Yes
326	11	Date of initial infusion	Initial_infusion_date	Date of initial infusion is after infusion date	Date of initial infusion cannot be after infusion date	Yes
327	12	Date of documentation of cancellation	Cancellation_date	Is not in current reporting period	Date of documentation of cancellation is not in the current reporting period	Yes
328	12	Date of documentation of cancellation	Cancellation_date	Date of documentation of cancellation reported when Date of infusion is not null	Date of documentation of cancellation cannot be reported when date of infusion is not null	Yes
329	12	Date of documentation of cancellation	Cancellation_date	Date of documentation of cancellation not reported when CAR_T-cell_product_type is "Not determined"	Date of documentation of cancellation should be reported when CAR T-cell product (type) is "Not determined"	Yes
330	13	Reason for cancellation	Cancellation_reason	Does not match predefined list provided in the Appendix-4	Invalid answer	Yes

Number	Element #	Data Element	Column	Condition	Error Message	Reject
331	13	Reason for cancellation	Cancellation_reason	Reason for cancellation reported when date of documentation of cancellation is null	Reason for cancellation cannot be reported when date of documentation of cancellation is null	Yes
332	14	Cancellation reason (Other)	Cancellation_reason_other	Cancellation reason (other) reported when reason for cancellation is not "Other"	Cancellation reason (other) cannot be reported when reason for cancellation is not "Other"	Yes
333	14	Cancellation reason (Other)	Cancellation_reason_other	Cancellation reason (other) not reported when reason for cancellation is "Other"	Cancellation reason (other) must be reported when reason for cancellation is "Other"	Yes

Validations: Content Errors, Record Not Rejected (Level 400)

Number	Element #	Data Element	Column	Condition	Error Message	Reject

Validations: Duplicate or Apparent Duplicate Records (Level 500)

No.	Entity	Data Element	Condition	Error Message	Reject
501	Uniqueness of record	Health_card_number Patient_chart_number Patient_birth_date CAR_T-cell_infusion_centre	The four data elements (Health card number, Patient chart number, Patient birth date, and CAR T-cell infusion centre) are the same for two records in the same file.	Error: Apparent duplicate records	Yes
502	Facility number	CAR_T-cell_infusion_centre	Facility number in the data does not match with the facility number associated with MFT Tumbleweed folder permissions.	Facility number mismatch	Yes

Data Submission, Validation and Error Reporting Schedule

CAR-T Manual Data Collection Submission Timelines					
Quarter or Month	Corresponding Time Frame	Submission Window	Initial Data Validation and Error Report Send Back for all submissions received	Second Data Validation and Error Report Send Back	Data Resubmission Window Open (Optional) with data validation for all submissions received
Month	First to last day of the month Example: Month of May (1 st -31 st)	Last two weeks of the following month Example: June 15 th -30 th	Example: Every Friday from June 15 th -30 th	Example: July 1 st – 15 th	N/A

Appendix 1: CAR T-cell Disease Classification

Description
Diffuse large B-cell lymphoma, not otherwise specified
Diffuse large B-cell lymphoma arising from follicular lymphoma
High grade B-cell lymphoma
Primary mediastinal large B-cell lymphoma
B-cell acute lymphoblastic leukemia

Appendix 2: Facility number of CAR T-cell infusion centre

Facility Number	Facility Name
837	Hospital for Sick Children (The)
942	Hamilton Health Sciences Centre
947	University Health Network – Princess Margaret Cancer Centre
958	Ottawa Hospital (The)

Appendix 3: CAR T-cell Product

Product name
Kymriah
Yescarta
Not determined*

* Use "Not determined" when CAR T-cell therapy is cancelled and a product had not been determined.

Appendix 4: Reason for cancellation

Description
Disease progression
Failure to collect cells from patient
Failure to produce cells
Patient choice
Other

Appendix 5: MOHLTC Master Numbering System

The Master Numbering System has been developed for the purpose of bringing together all Health Facilities and Programs under one system of identification. The list is a composite of health and health related units, facilities, clinics, programs and services. Each such organization has been assigned a unique four digit identifying code.

(For details, please refer to Ontario Health Cancer Care Ontario's Data Book - 2020-2021, Appendix A: MOHLTC Master Numbering System, at link <https://ext.cancercare.on.ca/ext/databook/db2021/databook.htm>).