



Ontario Health
Cancer Care Ontario

Specialized Services Oversight (SSO) Data Dictionary

Manual Data Collection – CAR T-cell Therapy Post Treatment 2021/22

Effective
7/29/2021

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Version Control

Date	Description	Owner
June 19, 2020	First draft developed	SSO
August 14, 2020	Data dictionary finalized	SSO
November 20, 2020	Data dictionary updated	SSO
June 29, 2021	Data dictionary updated	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(12) Alpha-numeric	If HCN is issued by Ontario: Valid 10-digit numeric Ontario health card number. Please note: version code should not be included in entry.	All	Patient identifier. To link data with other OH-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 etc., must contain numbers and/or characters only).	All	Uniquely identifies a patient within the healthcare facility. Necessary to determine a case for hospital tracking.	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 collection/apheresis	All	Patient identifier. For analyses involving patient age.	Yes	
4	CAR T-cell Therapy	Disease Indication Classification	Disease_indication	The primary disease that is being treated	CHAR(62)	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	CAR_T-cell_infusion_centre	Facility number of CAR T-cell infusion centre	CHAR(3)	Valid MOHLTC facility numbers (facilities providing CAR T-cell infusion) listed in the	All	For funding and program planning	Yes	Yes

#	Entity	Data Element	COLUMN_NAME	Definition (Description)	Format	Valid values (Notes)	Applies to	Purpose and Use	Mandatory	Business key (Uniqueness)
		infusion centre				Facility number of CAR T-cell infusion centre table (Appendix-2)				
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) Use "Not determined" when CAR T-cell therapy is cancelled and a product had not been determined	All	For planning, reporting and funding	Yes	Yes
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 Enter 99990101 if 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	Notification date of manufactured product	Notification_date_of_manufactured_product	Date of notification from manufacturer that CAR T-cell product has been manufactured and is ready to ship	CHAR(8) YYYYMMDD	Valid date entered Enter 99990101 if therapy cancelled prior to notification date of manufactured product	All	For wait time reporting and funding	Yes	
9	CAR T-cell Therapy	Date of infusion	Infusion_date	Date that infusion of CAR T-cells was performed	CHAR(8) YYYYMMDD	Valid date only.	when Cancellation_date is null	For reimbursement: to uniquely identify procedure for a patient.	Yes, when Cancellation_date is null	Yes

#	Entity	Data Element	COLUMN_NAME	Definition (Description)	Format	Valid values (Notes)	Applies to	Purpose and Use	Mandatory	Business key (Uniqueness)
								For wait time reporting.		
10	CAR T-cell Therapy	Product meets regulatory specifications	Meets_regulatory_specifications	If administered product meets the regulatory specification	CHAR(3)	Character (dropdown) options: Yes No	when infusion_date is entered	For funding and program planning	Yes, when infusion_date is entered	
11	CAR T-cell Therapy	Infusion type (for commercial product only)	Infusion_type	Initial infusion: for patients who have had no prior episode of CAR 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.	CHAR(19)	Character (dropdown) options: Initial Infusion Subsequent Infusion	when infusion_date is entered	For funding and program planning	Yes, when infusion_date is entered	
12	CAR T-cell Therapy	Date of initial infusion	Initial_infusion_date	Date that initial infusion of CAR T-cells was performed	CHAR(8) YYYYMMDD	Valid date only.	when Infusion_type is "Subsequent Infusion"	For program planning	Yes, when Infusion_type is "Subsequent Infusion"	

#	Entity	Data Element	COLUMN_NAME	Definition (Description)	Format	Valid values (Notes)	Applies to	Purpose and Use	Mandatory	Business key (Uniqueness)
13	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 not able to receive CAR T-cell infusion	CHAR(8) YYYYMMDD	Valid date only	when infusion_date is null	For funding and program planning	Yes, when Infusion_date is null	Yes
14	CAR T-cell Therapy	Reason for cancellation	Cancellation_reason	Identifies reason for patients who are not able to receive CAR T-cell infusion.	CHAR(37)	Valid reason for cancellation listed in the Reason for cancellation table (Appendix-4)	when Cancellation_Date is entered	For program planning	Yes, when Cancellation_Date is entered	
15	CAR T-cell Therapy	Cancellation reason (Other)	Cancellation_reason_other	Identifies reason for cancellation if "Other" selected	CHAR(255)	Free text	when Cancellation_reason is "Other"	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:** Entire file is rejected except Err#106

200's - **Field 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 records warnings:** Entire records are rejected.

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_ffff_ffffMx.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 facility (e.g. 837)ffff_ffff: the two calendar years that make up the fiscal year separated by an underscore character (e.g. 2021_2022)M: a fixed character for Monthx: the month within the calendar year, which is always an integer number between 1 and 12 (e.g. 4 represents April) – no leading 0 required.xlsx: for an excel spreadsheet. <p>Example: CAR_T-cell_837_2021_2022M12.xlsx</p>	File Error - File is incorrectly named.	Yes

#	Type	Condition	Error Message	Reject
		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".		
104	Empty	File is empty 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.	File Error - File is empty	Yes
105	File name	Facility number in the file name does not match with the facility number associated with MFT folder permissions.	File Error - Facility number in the data does not match with the facility number associated with MFT folder permissions	Yes
106	No Data	File includes only one line, and that line is a valid header line. Note: This is a valid submission if there were no procedures in the reported period (Month), so we issue a warning just to make sure.	Warning - No data submitted. If there are data records, please resubmit.	No

Validations: Field Format Errors (Level 200)

Number	Entity	Data Element	Condition	Error Message	Reject
201	All	All Fields Except HCN and Cancellation_reason_other	Data field is not the correct length (either too long or too short)	Invalid field length (For not mandatory fields, ignore if null)	Yes
202	All	All Date Fields	Date is not in YYYYMMDD format	Invalid - Date must be in YYYYMMDD format (For not mandatory date fields, ignore if null)	Yes

Validations: Content Errors, Record Rejected (Level 300)

Num ber	Elem ent #	Data Element	Column Name	Condition	Error Message	Reject
301	1	Health Card Number	Health_card_number	Is Null	Invalid - Null Value	Yes
302	2	Patient chart Number	Patient_chart_number	Is Null	Invalid - Null Value	Yes
303	2	Patient chart Number	Patient_chart_number	Contains non-alphanumeric characters, (i.e. no punctuation etc., must contain numbers and/or characters only).	Invalid Patient Chart Number - Contains non alpha numeric characters	Yes
304	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
305	3	Date of Birth	Patient_birth_date	Is Null	Invalid - Null Value	Yes
306	3	Date of Birth	Patient_birth_date	Is before 1900-01-01	Invalid - Date is before 1900-01-01	Yes
307	3	Date of Birth	Patient_birth_date	Is after date of first cell collection/apheresis (when it is not 99990101)	Invalid – Birth Date cannot be after date of first cell collection/apheresis (when it is not 99990101)	Yes
308	4	Disease Indication Classification	Disease_indication	Is Null	Invalid – Null Value	Yes
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

Num ber	Elem ent #	Data Element	Column Name	Condition	Error Message	Reject
312	5	Facility number of CAR T-cell infusion centre	CAR_T_cell_infusion_centre	Facility number in record does not match the facility number associated with MFT folder permissions	Invalid - Facility number in the data must match with the facility number associated with MFT folder permissions	Yes
313	6	CAR T-cell product (type)	CAR_T_cell_product_type	Is Null	Invalid - Null Value	Yes
314	6	CAR T-cell product (type)	CAR_T_cell_product_type	Does not match predefined list provided in the Appendix-3	Invalid answer	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 99990101	Invalid date	Yes
317	7	Date of first cell collection/apheresis	First_cell_collection_or_apheresis_date	Is 99990101 when date of infusion is entered	Invalid - 99990101 cannot be reported when date of infusion is entered	Yes
318	7	Date of first cell collection/apheresis	First_cell_collection_or_apheresis_date	Date of first cell collection/apheresis (not 99990101) is on or after date of infusion when date of infusion is entered	Invalid - Date of first cell collection/apheresis (not 99990101) cannot be on or after date of infusion when date of infusion is entered	Yes
319	8	Notification date of manufactured product	Notification_date_of_manufactured_product	Is Null	Invalid - Null Value	Yes
320	8	Notification date of manufactured product	Notification_date_of_manufactured_product	Is not a valid date or 99990101	Invalid date	Yes
321	8	Notification date of manufactured product	Notification_date_of_manufactured_product	Is 99990101 when date of infusion is entered	Invalid - 99990101 cannot be reported when date of infusion is entered	Yes

Num ber	Elem ent #	Data Element	Column Name	Condition	Error Message	Reject
322	8	Notification date of manufactured product	Notification_date_of_manufactured_product	Is not 99990101 when date of first cell collection/apheresis is 99990101	Invalid - Notification date of manufactured product can only be set as 99990101 when date of first cell collection/apheresis is 99990101	Yes
323	8	Notification date of manufactured product	Notification_date_of_manufactured_product	Is on or after date of infusion when date of infusion is entered	Invalid - Notification date of manufactured product cannot be on or after date of infusion when date of infusion is entered	Yes
324	8	Notification date of manufactured product	Notification_date_of_manufactured_product	Is before or on date of first cell collection/apheresis when date of first cell collection/apheresis is entered (not 99990101)	Invalid - Notification date of manufactured product (not 99990101) cannot be before or on date of first cell collection/apheresis when date of first cell collection/apheresis is entered (not 99990101)	Yes
325	9	Date of infusion	Infusion_date	Infusion_Date and Cancellation_Date are both Null	Invalid - Date of infusion and Date of documentation of cancellation cannot be both Null	Yes
326	9	Date of infusion	Infusion_date	Infusion_Date and Cancellation_Date are both not Null	Invalid - Date of infusion and Date of documentation of cancellation cannot both be not Null	Yes
327	9	Date of infusion	Infusion_date	is not in current reporting period (month) when it is entered	Invalid - Date of infusion must be in current reporting period (month) when it is entered	Yes
328	9	Date of infusion	Infusion_date	is not Null when CAR_T-cell_product_type is "Not determined"	Invalid - Date of infusion cannot be entered when CAR T-cell product (type) is "Not determined"	Yes
329	10	Product meets regulatory specifications	Meets_regulatory_specifications	is Null when Infusion_date is entered	Invalid - Product meets regulatory specifications must be reported when Date of infusion is entered	Yes
330	10	Product meets regulatory specifications	Meets_regulatory_specifications	is not Null when Infusion_date is null	Invalid - Product meets regulatory specifications should not be reported when Date of infusion is not entered	Yes

Num ber	Elem ent #	Data Element	Column Name	Condition	Error Message	Reject
331	10	Product meets regulatory specifications	Meets_regulatory_specifications	is not "Yes" or "No" when Infusion_date is entered	Invalid answer - Does not match predefined drop down menu - "Yes" or "No" - when infusion date is entered	Yes
332	10	Product meets regulatory specifications	Meets_regulatory_specifications	is not Null when CAR T-cell product (type) is "Not determined"	Invalid - Product meets regulatory specifications should not be reported when CAR T-cell product (type) is "Not determined"	Yes
333	11	Infusion type (for commercial product only)	Infusion_type	is Null when Infusion_date is entered	Invalid - Infusion type (for commercial product only) must be reported when Date of infusion is entered	Yes
334	11	Infusion type (for commercial product only)	Infusion_type	is not Null when Infusion_date is null	Invalid - Infusion type (for commercial product only) must not be reported when Date of infusion is not entered	Yes
335	11	Infusion type (for commercial product only)	Infusion_type	Is not "Initial Infusion" or "Subsequent Infusion" when infusion date is entered	Invalid answer	Yes
336	12	Date of initial infusion	Initial_infusion_date	is Null when Infusion_type is "Subsequent Infusion"	Invalid - Date of initial infusion must be reported when Infusion type is "Subsequent Infusion"	Yes
337	12	Date of initial infusion	Initial_infusion_date	is not Null when Infusion_type is Null	Invalid - Date of initial infusion should not be reported when Infusion type is not entered	Yes
338	12	Date of initial infusion	Initial_infusion_date	is not Null when Infusion_type is "Initial Infusion"	Invalid - Date of initial infusion should not be reported when Infusion type is "Initial Infusion"	Yes
339	12	Date of initial infusion	Initial_infusion_date	is on or after infusion_date when Infusion_type is "Subsequent Infusion"	Invalid - Date of initial infusion must be before Date of Infusion when Infusion type is "Subsequent Infusion"	Yes
340	13	Date of documentation of cancellation	Cancellation_date	Infusion_Date and Cancellation_Date are both Null	Invalid - Date of infusion and Date of documentation of cancellation cannot be both Null	Yes
341	13	Date of documentation of cancellation	Cancellation_date	Infusion_Date and Cancellation_Date are both not Null	Invalid - Date of infusion and Date of documentation of cancellation cannot both be not Null	Yes

Num ber	Elem ent #	Data Element	Column Name	Condition	Error Message	Reject
342	13	Date of documentation of cancellation	Cancellation_date	is not in current reporting period (month) when it is entered	Invalid - Date of documentation of cancellation must be in current reporting period (month) when it is entered	Yes
343	13	Date of documentation of cancellation	Cancellation_date	is Null when CAR_T-cell_product_type is "Not determined"	Invalid - Date of documentation of cancellation should not be Null when CAR T-cell product (type) is "Not determined"	Yes
344	14	Reason for cancellation	Cancellation_reason	is Null when Cancellation_date is entered	Invalid - Reason for cancellation must be reported when Date of documentation of cancellation is entered	Yes
345	14	Reason for cancellation	Cancellation_reason	is not Null when Cancellation_date is null	Invalid - Reason for cancellation should not be reported when Date of documentation of cancellation is not entered	Yes
346	14	Reason for cancellation	Cancellation_reason	Does not match predefined list provided in Appendix-4 when cancellation date is entered	Invalid answer	Yes
347	15	Cancellation reason (Other)	Cancellation_reason_other	Is Null when Cancellation_reason is "Other"	Invalid - Cancellation reason (Other) must be reported when Reason for cancellation is "Other"	Yes
348	15	Cancellation reason (Other)	Cancellation_reason_other	is not Null when Cancellation_reason is not "Other"	Invalid - Cancellation reason (Other) should not be reported when Reason for cancellation is not "Other"	Yes

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

Number	Element #	Data Element	Column Name	Condition	Error Message	Reject
401	1	Health Card Number	Health_card_number	Is not a valid Ontario ten-digit HCN	Warning – check if the HCN is issued by Ontario, if yes, then this is an invalid Ontario Health Card Number	No

Validations: Duplicate or Apparent Duplicate Records (Level 500)

No.	Type	Data Element	Condition	Error Message	Reject
501	Uniqueness of record	Health_card_number CAR_T-cell_infusion_centre CAR_T-cell_product_type Infusion_date Cancellation_date	The following data elements (Health card number, CAR T-cell infusion centre, CAR_T-cell_product_type, Infusion_date, and Cancellation_date) are the same for two or more records in the same file.	Error: Apparent duplicate records	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 3 digit identifying code.

(For details, please refer to Ontario Health Cancer Care Ontario's Data Book - 2021-2022, Appendix A: MOHLTC Master Numbering System, at link: <https://ext.cancercare.on.ca/ext/databook/db2122/databook.htm>).