

# User Manual for ATMP Cost Model

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## 1 Introduction:

Advanced therapy medicinal products (ATMPs) are an exciting new therapeutic approach based on genes, cells or tissues. They offer ground-breaking new opportunities for the treatment of disease and injury, with the potential to provide marked and durable responses for a diverse array of serious diseases and disorders.

There is clinical data in the literature for the approved Advanced Therapy Medicinal Products (ATMPs) and service specifications published by NHSE which set out the level of commissioned care. However historically there has been a paucity of financial constructs to inform the financial building blocks for ATMPs.

There is a need for a simple costing tool to support NHS institutions to map the baseline financial and resource impact from the routine introduction of ATMPs into their clinical practice.

NHS institutions are currently reimbursed through a range of financial vehicles. ATMPs are listed as a general exclusion to national tariffs although individual drugs are not listed in the list of exclusions. Additional service funding is set out under regional specialised commissioning arrangements and, in exceptional cases such as CAR-T therapy, a bespoke service tariff.

Further approaches to reimbursement for service delivery are in development, however detailed costing information will be required to be collected and submitted to commissioners to improve the approach to reimbursement for service costs. The challenges are discussed in the previous report by the Health Economics and Market Access function at Cell and Gene Therapy Catapult<sup>1</sup>

The modelling assumes all centres offering ATMP services have complied with the training, competencies, policies and procedures as defined in the current FACT-JACIE standards.

## 2 The Model.

The modelling supports NHS institutions and commercial companies to map activity against a defined data set of unitary costs to inform the impact from the routine introduction of an ATMP in clinical practice.

The modelling assumptions are informed by the NHS interim CAR-T tariff which currently recognises services are commissioned from 30 days prior to infusion to 100 days post

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<sup>1</sup> White Paper: Healthcare system readiness for the adoption of advanced therapies: learnings from the introduction of CAR T cell therapies in the UK Written by the Health Economics and Market Access function at Cell and Gene Therapy Catapult

infusion, however the model allows the user to extend the adverse event tab to capture the impact beyond the 130 days.

Enrolment is triggered by an appropriate approval that the patient is suitable for treatment with an ATMP, for example for CAR-Ts by the National CAR-T panels. Patients will need to be consented and the pre-requisite Blueteq form associated with the product submitted to initiate the process.

Arrangements prior to enrolment including any medical investigation or assessments are **not eligible** under the CAR-T tariff and these costs will need to be recorded separately.

As new ATMP therapies are approved the modelling will need to evolve to embrace new funding models.

To set up the model the user is required to select an organisation the treatment to be modelled and the proposed target population from the drop-down boxes in the introduction tab. (**Figure 1**)

**Figure 1** Model inputs introduction tab

**ATMP Cost model**

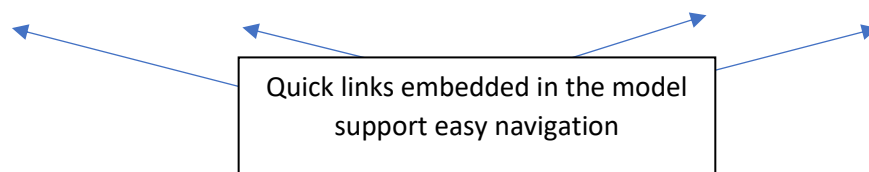
Advanced therapy medicinal products (ATMPs) is a rapidly growing area of medicine which presents several challenges to clinical delivery. ATMPs are considerably different from existing treatments and require new ways of working by hospital staff, including a need to develop close links with the developing ATMP industry. ATMPs are broadly classed into either: gene therapy medicinal products, somatic cell therapy medicinal products, tissue engineered products, and combined ATMPs. This modelling is designed to support the system to build a greater understanding of the costs and impact on services associated with the delivery of new and emerging therapies. It has been developed using the current CAR-T approvals and the user will need to understand the differences in the clinical pathways for emerging ATMP therapies to adapt the model.

Please select lead organisation	Leeds Teaching Hospitals NHS Trust
Please select the drug you would like to run the model with	Tisagenlecleucel (Kymriah) patients up to 25 years old with B cell acute lymphoblastic leukaemia
Please indicate target population	1
Please indicate % population of eligible for Hotel accommodation	0%
Please indicate population unfit for infusion after consent	10%

[Click to view ATMP \(CAR-T\) pathway inputs](#)
[Click to view Standard Pathway inputs](#)

[Click to view financial summary ATMP inputs](#)
[Click to view utility summary ATMP inputs](#)
[Click to view overall utility summary](#)
[Click to view overall financial summary](#)

Disclaimer The assumptions in the model were validated and correct at the time the model was produced - The author accepts no liability for any changes going forward



The model allows the user to select from the current range of approved ATMP therapies supported by NHSE – the list is subject to change as new treatments are approved.

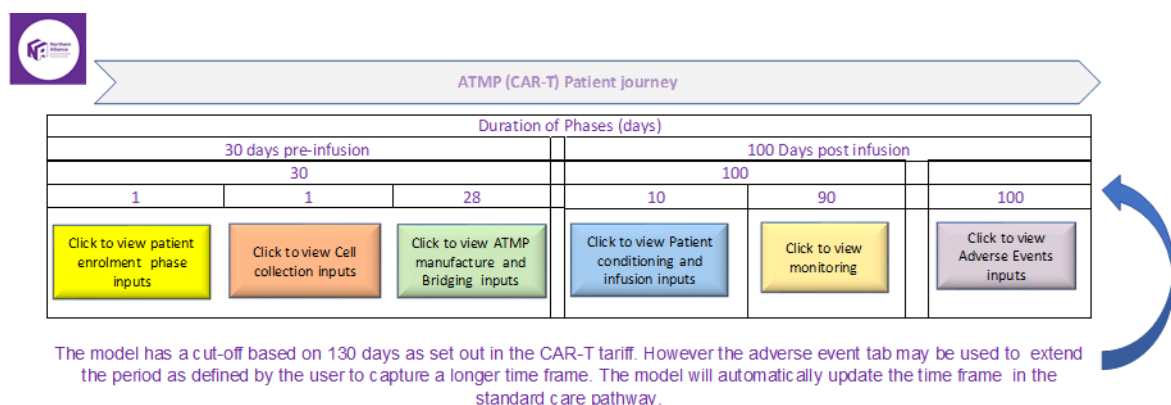
The user is able to populate the number of patients in the model and provides the flexibility to exclude patients who following an initial approval are too unwell to proceed for conditioning and infusion.

An additional field allows the user to identify patients eligible for hotel Costs. Product specific guidance requires discharged patients should remain within 1 hours drive time of the administering unit for up to 4 weeks post infusion and should be offered hotel accommodation which is eligible for funding under the CAR-T tariff.

## 2.1 ATMP Phasing across the Model

The modelling recognises 5 phases in the model as described in the CAR-T literature. The modelling applies a universal template to each phase to simplify the inputs for the user.

**Figure 2:** ATMP pathway



The modelling recognises the timelines set out by NHSE against the interim CAR-T tariff to frame the resource use and should guide the user when populating the model.

An adverse event tab has the flexibility to extend the follow-up period to capture an extended time frame..

The user is presented with the option to populate the ATMP pathway and the standard care pathway to generate a control arm in the model.

### 2.1.1 Enrolment Phase

The enrolment tab commences on a patient-by-patient approval by the appropriate Multi-Disciplinary Team. Post approval patients will need to be consented and the pre-requisite Bluteq form submitted to initiate the process.

Contracting between the treating hospital and the manufacturer should be enabled through the SACT/Bluteq prescribing system and included in the pharmacy ordering system.

Please note, clinical investigation prior to the patient being confirmed as suitable for treatment with an ATMP fall outside any treatment specific tariff.

### 2.1.2 Cell Collection Phase (Leukapheresis)

The user will need to refer to product-specific leukapheresis protocols to populate the model. Leukapheresis usually takes 3.5–4.5 hours, however patients may be unstable and/or recovering from chemotherapy during cell harvest and require additional in-patient support.

Once the patient's cells have been obtained, appropriate labelling and linkage to the manufacturer's logistics/tracking system is required.

With no bench mark costs for cryopreservation and storage of cell material the modelling allows the user to report their own costs associated with compliance with specific temperature requirements -150 degrees Celsius prior to handover to the courier for shipping to the manufacturing site.

### 2.1.3 ATMP Manufacture and Bridging Therapies

3<sup>rd</sup> party costs are commercially confidential and fall outside the scope of the model. The model applies the published list price however pricing is subject to confidential managed access agreements.

The interim CAR-T tariff supports the patient to manage their disease in the 3-4 week period during ATMP off-site manufacture, however the user will need to note the model will assign any costs incurred for interim chemotherapy or radiation as per local specialised commissioning arrangements.

The optimal bridging therapy for any individual will depend on disease and patient-specific factors and will be described in the service specification and the literature.

As discussed earlier patients failing to progress for further treatment will cease to accrue any further costs after the bridging phase.

#### 2.1.4 Lymphodepletion and Infusion

CAR-T patients require conditioning therapy – lymphodepletion - prior to infusion conditioning is usually spread over 4 days prior to infusion however the user should refer to local guidelines and the national service specifications. It should be completed 2-14 days before infusion to ensure no delays occur. Lymphodepletion is currently captured in the modelling as Chemotherapy and the cost assigned as per local specialised commissioning arrangements.

At least 4 doses of tocilizumab per patient should be available prior to infusion of the ATMP. The modelling requires the user to select the drug from the embedded drop down lists however the user will need to refer to local formulary guidelines and specific patient dosing schedules to populate the pricing. All the drug costs in the modelling require the user to input the cost (cells are flagged in red).

Following infusion, patients may be required to remain as an inpatient for ≈10 days. The modelling allows the user to capture the length of stay (LOS) as bed days which are costed using the national excess bed day tariffs. Other inpatient episodes of care are captured separately.

Daily monitoring is required by providers during the inpatient stay for signs of Cytokine Release Syndrome (CRS) and for neurologic toxicities.

All adverse events are captured separately in the adverse event tabs where the incidence can be defined by the user as Grade 1-2 and Grade 3-4.

The user should refer to the product-specific protocols for further information.

#### 2.1.5 Routine Monitoring

The modelling allows the user to capture routine monitoring required post infusion (≈4 weeks) for signs and symptoms of CRS and up to the cap of 100 days post infusion under the CAR-T tariff.

Additional hotel costs may also be captured.

#### 2.1.6 Adverse Event management

The modelling recognises adverse events may occur any time post infusion and are captured independently in the adverse event tabs.

The modelling recognises the grading system applied by NHSE. Users should refer to the service specification for the grading used for Cytokine Release Syndrome (CRS) & Immune effector Cell-Associated Neurotoxicity Score (ICANS):

- Grade 1-2 adverse events
- Grade 3-4 adverse events.

The grading is weighted to allow the user to capture the impact of A/E's. The weighting can be lifted from the service specification and the literature or adapted by the user (**Figure 3**)

**Figure 3: Table for entering Weightings**

	Please enter Weighting to be applied
<a href="#">A/E grade 1-2</a>	92%
<a href="#">A/E grade 3-4</a>	4%

Resource captured in the modelling include:

- Age-appropriate critical care which meets the NHS England service specification
- Electroencephalogram (EEG). For grade 1 CRES, and upwards - management will involve daily 30min EEG until toxicity symptoms resolve
- Continuous ECG monitoring and pulse oximetry monitoring are required if patients develop CRS symptoms of grade 2 or above.
- Provision of immunoglobulin may be required for the management of complications until symptoms resolve.
- Blood transfusion services

## 2.2 Standard Care Pathway

The standard care pathway mirrors the ATMP inputs over the duration described in the ATMP pathway.

## 3 Modelling Inputs:

The Model is designed to provide a point of references for service providers and commissioners to inform existing service commitments and future developments. However, as new treatments and interventions are identified the functionality in the model will need to evolve to accommodate new therapy areas and ATMP treatments.

Phases can be excluded in the financial and utility summaries for emerging new clinical pathways where cell collection or bridging treatment may not be required in the future.

Each phase of the ATMP pathways as described above offers the user a range of activities to populate. For simplicity the tabs are duplicated across the phases with minor changes to capture specific activities related to the phase.

An example includes the Lymphodepletion phase which has a bespoke entry for the chemotherapy regimen. (Figure 4)

**Figure 4: Indicative input tab**

Activity refer to the relevant published NICE guidance which sets out the commissioned position for NHSE - Investigations and interventions not specified by NICE will not be supported or funded under the ATMP tariff.		Modellers must	Unit cost	Please enter number of investigations interventions	Eligible treatment costs including BNF drugs	Commissioned services Local NHSE Block Contract	HCD Drugs Pass through funding
Please select Investigations and frequency	Positron Emission Tomography with		£1,062.21	1	£1,062.21		
	No MRI		£0.00	1	£0.00		
	Direct Access Plain Film		£30.59	0	£0.00		
	Haemostasis Testing		£29.42	1	£29.42		
	ECG		£37.00	1	£37.00		
	Complex Long-Term EEG Monitoring		£228.47	0	£0.00		
	No echocardiogram		£0.00	1	£0.00		
	No spinal puncture		£0.00	1	£0.00		
	No diagnostic biopsy		£0.00	1	£0.00		
	Lung Volume Studies		£152.00	0	£0.00		
Please select on-going treatment	Viral serology test		£7.40	1	£7.40		
	Insertion of Central Venous Catheter	Insertion of Non-Tunnelled Central	£1,115.56	0	£0.00		
	(The cost of the delivery HRGs includes the cost of supportive drugs listed on the NHS England and Improvement chemotherapy supportive drugs list. NTPS high cost drug list (see Annex A, tab 13c) and those funded via the Cancer Drug Fund are excluded <a href="http://www.england.nhs.uk/wp-content/uploads/2019/03/nhs-england-chemotherapy-supportive-drugs-list-v2.pdf">www.england.nhs.uk/wp-content/uploads/2019/03/nhs-england-chemotherapy-supportive-drugs-list-v2.pdf</a> )	No Chemotherapy	£0.00	0		£0.00	
		No Chemotherapy	£0.00	0		£0.00	
		No Radiation treatment	£0.00	0		£0.00	
		No Radiation treatment	£0.00	0		£0.00	
	Red Blood Cell infusion	No Red Blood Cell infusion	£0.00	0		£0.00	
	Platelet infusion	No platelet infusion	£0.00	0		£0.00	
	Paediatric Clinical Haematology	Consultant Led	£283.71	1	£283.71		
		No activity	£0.00	0	£0.00		
Outpatient activity Please select departments (Outpatient attendances for Children would fall under NHSE local contract)	Upper Gastrointestinal Surgery	No activity	£0.00	0	£0.00		
		No activity	£0.00	0	£0.00		
		No activity	£0.00	0	£0.00		
		No activity	£0.00	0	£0.00		
	N/A	No activity	£0.00	0	£0.00		
	ATMP provider specialist Multi-Disciplinary Teams (MDT)	Other Cancer MDT Meetings	£109.64	0	£0.00		
	National ATMP Multi-Disciplinary Teams (NCMDT), weekly	Other Cancer MDT Meetings	£109.64	0	£0.00		
	Emergency medicine A & E attendance	No emergency attendance	£0.00	0	£0.00		
	Day case drop down reference costs driven by drug therapy selected in modelling tab	Malignant Lymphoma, including Hodgkin's and Non-Hodgkin's, with CC Score 0-1	£444.26	0	£0.00		
	Elective Admitted care drop down indicative excess Bed day costs a determined by drug therapy selected in introduction tab	No admission recorded	£0.00	0	£0.00		
Inpatient care When selecting the CC scores please ensure the drop down boxes has been refreshed to ensure it is referencing the correct ATMP.	Non-elective Admitted care drop down NHS reference costs determined by drug therapy selected in the introduction tab	No admission recorded			Please note only the excess bed days costs and utility are captured		
	ICU days (Split by speciality and number of organs supported)	No ICU /HDU	£0.00	0		£0.00	
	Storage costs	liquid nitrogen tanks or freezing facilities suitable for the CAR-T therapies (e.g. capable of meeting the -150 degrees Celsius specification local costs to be applied)	£2,000.00	1	£2,000.00		
	Medication (Excludes Chemo supportive drugs) Please note due to formulary considerations and patient specific dosing regimens drug costs should be populated by the user	BNF Medication funded through NHS Drugs Tariff					
		Fligrastrim 60 mega unit per 1 ml (hospital use only)	£0.00	0	£0.00		
		Bendamustine hydrochloride 25 mg (Lymphodepletion dosing regimen 90	£0.00	0	£0.00		
		High Cost Drugs funded NHSE Local Block contract	£0.00	0		£0.00	
		Not selected	£0.00	0		£0.00	
		Not selected	£0.00	0			£0.00
		High Cost Drugs Pass through Payment (CDF fund)	£0.00	0			£0.00
Other	Hotel Costs if patients with low disease burden, patients may be discharged earlier on an individual basis. Following discharge patients should then remain within c.1 hour drive time of the administering unit for c4 weeks post infusion	No hotel costs applied	£0.00	0	£0.00		
Total Health Care resource cost Cell Collection					£3,419.75	£0.00	£0.00

Once the investigation or intervention has been selected from the drop-down options embedded in the model, the costs will auto populate from the NHS reference cost tables embedded in the model.

The user is required to specify the frequency of the activity to generate the overall cost for the investigation of intervention.

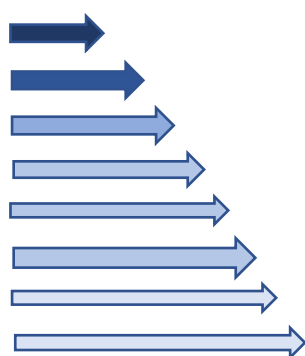


A broad range of potential investigations and interventions to deliver a CAR-T therapy have been identified and the costs assigned to the responsible agency, however the list is subject to on-going review as new therapies and treatment pathways emerge.

Prospective modellers should refer to specific published NICE guidance which sets out the commissioned position from NHS England.

### 3.1 Health Care Resource

The core activities in the modelling are split into:

- 
- Investigations
  - On-going therapies
  - Out-Patient Activities
  - MDT
  - Emergency Care
  - In-Patient care
  - Medications
  - Other (includes hotel costs)

#### 3.1.1 Investigations

The user is required to select from a range of potential investigations. The investigations are drawn from the service specifications, the literature and expert advice. **(Figure 5)**

**Figure 5:** Table of investigations

Please select Investigations and frequency	Positron Emission Tomography with	£1,062.21	1
	No MRI	£0.00	1
	Direct Access Plain Film	£30.59	0
	Haemostasis Testing	£29.42	1
	ECG	£37.00	1
	Complex Long-Term EEG Monitoring	£228.47	0
	No echocardiogram	£0.00	1
	No spinal puncture	£0.00	1
	No diagnostic biopsy	£0.00	1
	Lung Volume Studies	£152.00	0
	Viral serology test	£7.40	1

The list is not exhaustive however each entry has a range of sub-options which can be explored through the embedded dropdown boxes behind each investigation to arrive at “the best fit”. **(Figure 6)**

**Figure 6:** Illustration of drop-down flexibility

Currency	Currency Description
	<b>No MRI</b>
RD01A	Magnetic Resonance Imaging Scan of One Area, without Contrast, 19 years and over
RD01B	Magnetic Resonance Imaging Scan of One Area, without Contrast, between 6 and 18 years
RD01C	Magnetic Resonance Imaging Scan of One Area, without Contrast, 5 years and under
RD02A	Magnetic Resonance Imaging Scan of One Area, with Post-Contrast Only, 19 years and over
RD02B	Magnetic Resonance Imaging Scan of One Area, with Post-Contrast Only, between 6 and 18 years
RD02C	Magnetic Resonance Imaging Scan of One Area, with Post-Contrast Only, 5 years and under
RD03Z	Magnetic Resonance Imaging Scan of One Area, with Pre- and Post-Contrast
RD04Z	Magnetic Resonance Imaging Scan of Two or Three Areas, without Contrast
RD05Z	Magnetic Resonance Imaging Scan of Two or Three Areas, with Contrast
RD06Z	Magnetic Resonance Imaging Scan of more than Three Areas
RD07Z	Magnetic Resonance Imaging Scan Requiring Extensive Patient Repositioning

### 3.1.2 Clinical Intervention

The modelling is based on the current licensed CAR-T ATMPs which are focussed on oncology.

The model allows the user to capture the one-off cost of the insertion of a central venous catheter.

The modelling provides the user with a range of additional bridging therapies based on the need to support the patient whilst awaiting infusion or if the patient deteriorates post infusion. **(Figure 7).**

**Figure 7:** Table Clinical Therapies

Please select on-going treatment	Insertion of Central Venous Catheter	Insertion of Non-Tunnelled Central Venous Catheter,	£1,115.56
	(The cost of the delivery HRGs includes the cost of supportive drugs listed on the NHS England and Improvement chemotherapy supportive drugs list. NTPS high cost drug list (see Annex A, tab 13c) and those funded via the Cancer Drug Fund are excluded <a href="http://www.england.nhs.uk/wp-">www.england.nhs.uk/wp-</a>	Deliver more Complex Parenteral Chemotherapy at First Attendance	£475.67
		Deliver more Complex Parenteral Chemotherapy at First Attendance	£475.67
		No Radiation treatment	£0.00
		No Radiation treatment	£0.00
	Red Blood Cell infusion	No Red Blood Cell infusion	£0.00
	Platelet infusion	No platelet infusion	£0.00

Chemotherapy and Radiation are routinely funded through the regional specialised commissioning team and will fall outside the ATMP tariff. In addition, blood transfusion falls under specialised services.<sup>2</sup>

### 3.1.3 Outpatients

The model recognises patients may access multiple clinical specialities during their care and affords the user 3 open clinical speciality options for all the phases based on clinical need. Once the speciality has been selected the user can define the type of out-patient resource i.e. consultant and non-consultant led. (**Figure 8**)

**Figure 8:** Out-Patient selection fields

Outpatient activity Please select departments (Outpatient attendances for Children would fall under NHSE local contract)	Breast Surgery	Consultant Led
		Consultant Led
	Upper Gastrointestinal Surgery	No activity
		Consultant Led
	Clinical Immunology	No activity
		Consultant Led

### 3.1.4 Multi-Disciplinary Team (MDT) Meetings

MDT's play a critical role in patients' approvals and on-going monitoring and allows the user to capture the activity.

The modelling allows the user to describe the split and frequency across provider led specialist Multi-Disciplinary Teams (MDT) and the National CAR-T Multi-Disciplinary Teams (NCMDT).

Costs are applied from National MDT reference costs.

### 3.1.5 Emergency Attendances

The model allows the user to select the emergency care setting with the intervention and the frequency. Costs are assigned from NHS reference costs.

<sup>2</sup> [https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/22825/price\\_list\\_bc\\_nhs\\_full-cost-per-item\\_2021-22.pdf](https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/22825/price_list_bc_nhs_full-cost-per-item_2021-22.pdf)

### 3.1.6 Elective and Non-elective Inpatient Costs (Admissions)

The modelling recognises the lack of existing activity codes to capture a large proportion of the elective activities including leukapheresis and the conditioning and infusion phases. The modelling utilises the excess bed day costs to generate a surrogate daily cost to generate the overall length of stay costs.

The modelling maps the diagnostic ICD10 code for the underlying condition described in the published CAR-T service specifications to identify the associated Health Resource Group (HRG) as described in the literature

The model maps the HRG across the National Reference cost workbooks to build the excess bed days costs and the elective and non-elective cost assumptions for all other admissions (Figure 9)

**Figure 9: In-Patient costs**

Activity Modellers must refer to the relevant published NICE guidance which sets out the commissioned position for NHSE - Investigations and interventions not specified by NICE will not be supported or funded under the ATMP tariff.			Unit cost	Please enter number of investigations interventions
Inpatient care When selecting the CC scores please ensure the drop down boxes has been refreshed to ensure it is referencing the correct ATMP.	Emergency medicine A & E attendance	Type 01 admitted Emergency Medicine, Any Investigation with Category 5 Treatment	£624.16	0
	Day case drop down reference costs driven by drug therapy selected in modelling tab	No admission recorded	£0.00	0
	Elective Admitted care drop down indicative excess Bed day costs a determined by drug therapy selected in introduction tab	No admission recorded	£0.00	0
	Non-elective Admitted care drop down NHS reference costs determined by drug therapy selected in the introduction tab	No admission recorded	Please note <b>only</b> the excess bed days costs and utility are captured	
	ICU days (Split by speciality and number of organs supported)	No ICU /HDU	£0.00	0

HRG4+ applies a methodology to indicate the interactive nature of these CCs. The HRG4+ design allocates a score to each recorded CC, and these scores are then totalled to derive HRGs based on stratified values of summed CC – imply the higher the CC score the higher the HRG.

Embedded dropdown boxes enable the user to describe the level of complexity and morbidity utilising the HRG 4+ CC scores to establish the costs. The greater the CC score selected the higher the cost.

Excess bed day costs are applied to the enrolment, leukapheresis, conditioning and infusion phases. Other inpatient activity is reported through the elective tariffs.

**No non-elective costs** should be assigned to the routine monitoring tabs as they are reported separately in the adverse event tab.

The CC drop down boxes need to be updated each time a new ATMP is selected. **Red text reminds the user to refresh the drop-down boxes each time.**

### 3.1.7 ICU Activity

A critically ill adult patient is defined as someone who immediately requires any form of organ support (intubation, ventilation, inotropes), or is likely to suffer acute cardiac, respiratory, or neurological deterioration requiring such support.

The user is asked to capture ICU activity in days. The embedded drop-down boxes allow the user to select the clinical admitting speciality and the complexity based on the reference costs methodology, the number of organs supported.

All ICU activity in the model is reported against the regional specialised commissioning funding arrangements.

### 3.1.8 Drugs

The modelling recognises the overall split in the funding for drugs across Medication funded through the NHS Drugs which are embedded in tariff, High-Cost Drugs funded through NHSE local specialised commissioning contractual arrangements and High-Cost Drugs funded through pass through payment. **(Figure 11)**

Each category offers the user a range of potential drugs with which fall into each category. The user is required to select the medication and manually enter the pricing due to patient specific drug regimens the user should refer to the local formulary for dosing guidelines.

The lists are subject to change as new treatments are added to the model and bespoke drug regimens evolve.

**Figure 11:** Medication table

Medication (Excludes Chemo supportive drugs) <i>Please note due to formulary considerations and patient specific dosing regimens drug costs should be populated by the user</i>	BNF Medication funded through NHS Drugs Tariff	Not selected	£0.00
		Not selected	£0.00
	<a href="#">High Cost Drugs funded NHSE Local Block contract</a>	Not selected	£0.00
		Not selected	£0.00
	High Cost Drugs Pass through Payment (CDF fund ...)	Not selected	£0.00
		Not selected	£0.00

### 3.1.9 Other (includes Hotel Costs)

There are a range of hotel cost models. The user should enter the local costs manually in Cell D463 on the “In-patient reference cost tab”

### 3.2 Health Care Staff Resource use

The primary focus on the model is on the health care resource associated with ATMPs supported by the NHSE ATMP tariff, however a simple staffing tool has been aligned with the phases to help the user to understand the impact of ATMPs on staffing levels from exclusive activities for ATMPs.

Staff time is expressed in minutes and cost applied from Agenda for Change 2021/22 Pay Scales based on the pay grade selected from the embedded drop-down boxes. WTE's are expressed for the aggregate times.

Staff resource is split into: **(Figure12)**

- Clinician
- Nurse
- Administration / Procurement / Commissioning
- Advanced Pharmacist
- ATMP Handling Team

**Figure 12:** Staff table with Agenda for change pay grades applied.

Activity			Pay Grade (Years service)	Unit cost	Please enter time (mins)
Staff Resource	General resource	Clinician	Band 9 (0-5)	£0.80	270
		Nurse	Band 7 (2-5)	£0.36	270
		Administration / Procurement / Commissioning	Band 4 (3+)	£0.21	0
		Advanced Pharmacist	Band 8a (0-5)	£0.40	0
		ATMP Handling Team	Band 1 (0+)	£0.16	0
	MDT	Clinician	Band 1 (0+)	£0.16	30
		Nurse	Band 1 (0+)	£0.16	30
		Administration / Procurement / Commissioning	Band 1 (0+)	£0.16	30
		Advanced Pharmacist	Band 1 (0+)	£0.16	0
		ATMP Handling Team	Band 1 (0+)	£0.16	0

A general resource category and MDT activity been created for each phase. Additional activities have been identified however the list is not exhaustive.

**Please note staffing cost are not included in the overall NHS costs as these costs risk duplication in the modelling as staff costs are captured in the reference cost reporting systems.**

## 4 ATMP Financial and Utility summaries

The modelling captures the inputs from the phases into the ATMP utility and financial summary.

## 4.1 ATMP Financial Summary

The modelling calculates the total costs within a phase and assigns to the cost to the accountable organisation (**figure 13**)

**Figure 13:** Accountable agencies

Eligible treatment costs including BNF drugs	Commissioned services Local NHSE Block Contract	HCD Drugs Pass through funding
----------------------------------------------	-------------------------------------------------	--------------------------------

Eligible treatment cost qualifies under the interim CAR-T tariff which in 2021/22 attracts a tariff of £93,754 + MFF for adult patients and are captured separately and reported in the financial summary

In addition, Local specialised commissioned services including the Cancer therapies, High-cost drugs and the ICU impact and the pass through NHSE drugs are captured. (**Figure 14**)

The model presents the user with a summary of all the costs attributed to each cost centre for each of the phases. Individual tabs can be excluded through the drop-down functionality behind each entry to allow the user to explore the impact of new service delivery models.

**Figure 14:** Financial outputs

Phases can be unselected	Axicabtagene-ciloleucel, (Yescart), adult patients whose large cell lymphoma				
	NHS Total costs			Total 3rd Partie Costs	Staff Costs
	Standard treatment costs including BNF drugs	Commissioned services Local NHSE Block Contract	HCD Drugs Pass through funding		
Enrolment costs	£980.80	£0.00	£0.00	£0.00	£96.00
Cell Collection costs	£2,925.94	£0.00	£0.00	£0.00	£682.83
ATMP and bridging costs	£4,289.48	£0.00	£0.00	£300,000.00	£327.74
Lymphodepletion and Infusion costs	£7,972.10	£4,807.32	£0.00	£0.00	£284.99
Routine Monitoring	£31,525.60	£0.00	£3,652.48	£0.00	£334.56
Management of adverse event costs	£16,220.80	£1,706.63	£7,304.96	£0.00	£325.02
<b>Total Modelling costs</b>	<b>£63,914.71</b>	<b>£6,513.95</b>	<b>£10,957.44</b>	<b>£300,000.00</b>	<b>£2,051.13</b>
ATMP NHS reimbursement +MFF	£97,587.32			£300,000.00	
Net Trust position	£33,672.61			£0.00	

The modelling provides the user with a summary of the financial impact against the CAR-T tariff, however the user will need to refer to local specialised commissioning arrangements to understand the impact on other budgets.

The Market Force Factor (MFF) to be applied against the tariff is automatically generated from the organisation selected in the introduction tab.

Please note staff costs are presented however they are excluded from the total NHS costs.

## 4.2 ATMP Utility Summary

The model presents the user with a snapshot of the potential impact on service delivery and the potential resource implication from the routine introduction of new ATMPs in the future. (Figure 15)

**Figure 15: ATMP Utility summary**

	Utilities	Health Care Resource						Total
		Enrolment phase outputs	Cell Collection phase outputs	ATMP & Bridging treatments	Infusion phase outputs	Monitoring phase outputs	Weighted Adverse Events outputs	
Investigations	Single Photon Emission Computed Tomography with Computed Tomography (SPECT CT)	0	1	2	0	20	4	27
	Magnetic Resonance Imaging S	0	1	2	0	20	4	27
	X ray	0	0	1	0	20	4	25
	Biological exams Haemostasis	0	1	4	1	20	4	30
	Electrocardiogram (ECG(a)	0	1	4	1	20	4	30
	electroencephalogram (EEG)	0	0	0	10	10	4	24
	Complex Echocardiogram	0	1	1	1	1	1	5
	Lumbar puncture	0	1	1	1	1	1	5
	Biopsy	0	1	1	1	1	0	4
Interventions	Viral serology test	0	1	1	0	1	0	3
	Chemotherapy	0	0	5	2	3	0	10
	Radiotherapy	0	0	0	0	0	0	0
	Red Blood Cell infusion	0	0	0	0	0	0	0
Outpatient app's	Platelet infusion	0	0	0	0	0	0	0
	Please refer to individual phases for user defined out-patient specialities	3	1	11	0	20	2	37
MDT	MDT	3	0	0	0	0	0	3
In-Patient care	Emergency care A & E	0	0	0	0	0	0	0
	Day Case	0	0	0	0	0	2	2
	Ward days	0	0	0	10	5	5	20
	ICU days	0	0	0	0	0	1	1

## 5 Overall Summary

The model presents the user of an overall summary of the impact on services from the routine introduction of an ATMP.

The model has a cut-off based on 130 days specified in the existing interim CAR-T tariff however the adverse event tab may be used for an extended period as defined by the user to capture a longer time frame and need to be mirrored in the standard care pathway.



## 5.1 Overall Financial Summary

The user is presented with a summary of all the costs for the ATMP phases and the standard care against the responsible commissioner.. Hyperlinks allow the user to revisit the phases and revise any assumptions. All the phases as per the ATMP summaries tabs have embedded drop-down boxes to allow the user to exclude a phase. **(Figure 16)**

**Figure 16** Overall financial summary table

Axicabtagene-ciloleucel, (Yescart), adult patients whose large cell lymphoma					
NHS Total costs for model population selected					
The CAR-T phases can be unselected to reflect different clinical pathways for other ATMP therapies	Standard treatment costs including BNF drugs	Commissioned services Local NHSE Block Contract	HCD Drugs Pass through funding	Total 3rd Partie Costs	Staff Costs
No Enrolment costs	£0.00	£0.00	£0.00	£0.00	£0.00
No Cell Collection costs	£0.00	£0.00	£0.00	£0.00	£0.00
ATMP Manufacture and bridging costs	£4,289.48	£1,379.77	£0.00	£300,000.00	£327.74
Lymphodepletion and Infusion costs	£7,125.02	£0.00	£0.00	£0.00	£284.99
Routine Monitoring	£28,655.21	£0.00	£0.00	£0.00	£334.56
Management of adverse event costs	£21,871.08	£1,706.63	£0.00	£0.00	£0.00
<b>Total</b>	<b>£61,940.78</b>	<b>£3,086.40</b>	<b>£0.00</b>	<b>£300,000.00</b>	<b>£947.29</b>
Standard clinical pathway costs	£17,103.56	£17,103.56	£0.00	0	£94.01
Variance	-£44,837.22	£14,017.16	£0.00	Subject to Managed access agreement	-£853.27

## 5.2 Overall Utility Summary

In addition to summarising the financial impact the modelling presents the user with an overall summary of the impact on investigations and interventions. **(Figure 17)**

**Figure 17: Overall Financial summary table**

	Utilities	Total Resource across ATMP service delivery (130 days)	Total resource across current standard of care (equivalent period)	Variance
<b>Investigations</b>	Single Photon Emission Computed Tomography with Computed Tomography (SPECT-CT)	27	10	17
	Magnetic Resonance Imaging S	27	20	7
	X ray	25	30	-5
	Biological exams Haemostasis	30	30	0
	Electrocardiogram (ECG(a)	30	30	0
	electroencephalogram (EEG)	24	0	24
	Complex Echocardiogram	5	1	4
	Lumbar puncture	5	1	4
	Biopsy	4	4	0
	Viral serology test	3	0	3
<b>On-going treatment</b>	Chemotherapy	10	8	2
	Radiotherapy	0	0	0
<b>Outpatient app's</b>	Please refer to individual phases for user defined out-patient specialities	37	30	7
<b>MDT</b>	MDT	3	0	3
<b>In-Patient care</b>	Emergency care A & E	0	0	0
	Day Case	2	2	0
	Ward days	20	20	0
	ICU days	1	0	1

The staffing elements are also captured, and the user presented with a WTE overall summary analysis of the impact from the task described in the phases and the standard care pathway. (Figure 18)

**Figure 18 Staffing tables**

		Total Resource across ATMP service delivery (130 days)		Total resource across current standard of care (equivalent period)		Variance	
Staff Resource		Total Time	WTE	Total Time	WTE	Variance Time	Variance WTE
Staff resource (Consultant 40Hrs week other staff 37.5Hrs))	Clinician	1802	0.01	61	0.00	1741	0.01
	Nurse Band 7	1892	0.02	90	0.00	1802	0.02
	Administration / Procurement / Commissioning	183	0.00	60	0.00	123	0.00
	Pharmacist	540	0.00	0	0.00	540	0.00
	ATMP Handling Team	15	0.00	0	0.00	15	0.00