
New licensed/unlicensed ATMP Governance Checklist

Organisation: Manchester University Foundation Trust

Document version number: 1

Date written: 09/08/2020

End user rights:

This document is shared with permission for re-use to distribute, remix, adapt, and build upon the material in any medium or format for non-commercial purposes only, so long as the attributions listed below are given.

Attributions: Name of Organisation; [others as required by Organisation to be listed here]

This document is made available under a Creative Commons Attribution-NonCommercial 4.0 International License as described here:

<https://creativecommons.org/licenses/by-nc/4.0/>

The information, materials and any opinions contained in this document are provided for general information and educational purposes only, are not intended to constitute legal, medical or other professional advice and should not be relied on or treated as a substitute for specific advice relevant to particular circumstances. Although we make all reasonable efforts to ensure the information is up to date, we make no representations, warranties or guarantees in that regard. In no event shall the creator(s) be liable for any direct, indirect, special, consequential or other claims, losses or damages that are related to the use or reliance whatsoever in the content of the document or any part thereof, except to the extent that such liability cannot be excluded by law. We do not seek to exclude or limit in any way our liability to the user for personal injury or death caused as a result of our negligence or seek to exclude or limit our liability for fraud or fraudulent misrepresentation by us.

Funded by

Coordinated by

We reserve the right to make changes and improvements to any information contained within this document, at any time and without notice. Where this document contains hyperlinks to other websites operated by parties not connected to us, such hyperlinks are provided for your reference only. We do not control such websites and are not responsible for their contents. The inclusion of hyperlinks from this document or the website to such websites does not imply any endorsement of the material on such websites or any association with their operators. We accept no responsibility of any nature whatsoever for linked web sites or any information contained in them.

Funded by

Coordinated by

**NEW LICENSED/UNLICENSED ATMP PRODUCT
PHARMACY GOVERNANCE CHECKLIST**

Product Name			
Supplier			
Manufacturer (if different to above)			
Regulatory status	Licensed/Unlicensed*		
	*For Unlicensed products in addition please complete Appendix 1		
Checking step	Yes/No	Checker Initials	Date
Treatment centre selected by NHSE to deliver ATMP therapy			
Type of Therapy			
Treatment centre accredited by JACIE to deliver CAR-T cell therapy			
Treatment centre qualified by manufacturer to deliver product			
Governance approvals in place for use of product as applicable: - Medicines Management/Formulary - ATMP Oversight Group/ (or similar)			
ATMP safety risk assessment completed / Virologist involved in the decision for gene therapy			
SMPC available			
Prescription added to electronic SACT prescribing system			
Product added to Pharmacy Ordering system			
Intravenous risk assessment completed			
Trust funding process approved			
Ordering process in place			

Ensure product being tracked by Medicines Finance team and Contracts for Trust reimbursement			
Pharmacy product specific folder in place			
Pharmacy SOP in place for cancellation of order			
Pharmacy SOP in place for credit claims			
Pharmacy SOP in place for deviations			
Pharmacist Final Check (Print name, sign, date)			
Comments			

Appendix 1. Additional Checklist for Unlicensed Products

Is the product licensed in another country outside UK, if so, please add the name of country	
Is the product being delivered as part of a trial? If so, indicate name of the trial, sponsor and in which countries the trial is delivered	
Will the protocol be followed, please attach it. Indicate any modifications to the clinical protocol	
Will the Investigational Brochure be followed as a safety reference document and to report any adverse event? Indicate any exceptions	

Checking step	Yes\No	Checker Initials	Date
Approval of Local Ethics Committee			
Patient Information Leaflet and written consent designed and approved by the local Ethics committee			
External Peer review by an expert for suitability of treatment and patient (including HTA when applicable)			
Hospital Medical Director Approval			
MFT quality and Safety Approval			
Vendor assessment and Technical/quality agreement in place for the manufacturing and supply of the product. - This will include verification that the correct manufacturing, importing/exporting licenses are in place			