Service/Hospitals/Dept. etc.
Ward/Team: .....

NHS Lanarkshire

Appendix 2 - **Blanket** Unlicensed & High Risk Off Label Medicine Application

Date: .... Time: .... (24 hour)

Application Form
This form is to be used in conjunction with the NHS Lanarkshire Policy for Unlicensed Medicines. Before completion, you must have read this policy which identifies your responsibilities. It is the responsibility of the original requestor to communicate the outcome to all signatories

Requester details		
Prescriber name:		Hospital site: Ward/Outpatient dept:
Speciality:		
Contact details:		Date requested: Date required:

Patient details
Anticipated usage (please tick) - Estimated patient numbers:
☐ For your patients only ☐ For patients within your speciality on all sites ☐ For patients within your speciality on a single site ☐ Any patient within the Health Board

Unlicensed Medicine Details
Product name: (International Non Proprietary Name)
Proprietary Name (if known):
Strength and Pharmaceutical Form:
Manufacturer (if known):
Indication:
Dose/frequency/route:
Duration of Treatment:
Category of request: 1. The intended use of the medicine is outside of the marketing authorisation for a licensed medicine (off-label prescribing) and is considered 'high risk' in Appendix 4 ☐ 2. The medicine is an unlicensed medicine as described in the above policy ☐
If the medicine is unlicensed – please complete the following Why is an unlicensed medicine being considered? (Tick as appropriate): 1. There is no UK licensed product available to treat or diagnose medical condition. ☐ 2. The UK licensed product used to treat or diagnose the medical condition is temporarily unavailable ☐ 3. The UK licensed product used to treat or diagnose the medical condition is unsuitable ☐ 4. No therapeutically equivalent UK licensed product available or suitable (provide details): ☐ 5. Patient Safety: ☐ 6. Other (provide details):

Was a product licence in the UK withdrawn? ☐ Yes ☐ No ☐ Not known
If yes, contact manufacturer to find out reasons for withdrawal.

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Clinical Evidence			
Is there any evidence to support its use for the proposed indication?	☐ Yes	☐ No	
Is there evidence to support its proposed administration schedule? (dose, duration, concentration for parenteral products and route)	☐ Yes	☐ No	
Is the active drug currently in a licensed product for use via the same route of administration e.g. tablet, suspension?	☐ Yes	☐ No	
Is the product licensed for the specified indication in another country?	☐ Yes	☐ No	☐ Not known
UK product licence applied for? If yes, record date of application for licence:	☐ Yes	☐ No	☐ Not known
Are other Boards using this medicine? If so, name:	☐ Yes	☐ No	☐ Not known
Summarise below the supporting evidence, list references and attach copies of references where available.			
What are the risks to the patient of not using this drug?			
What side effects **and** significant interactions have been reported? Is any monitoring required? Describe:			
Give details of contraindications and any other risks to the patient. Include precautions in use.			
Will there be any primary care implications? (e.g. need for a shared care protocol) If so, describe:			
Estimated Annual Cost per patient:			

Prescriber ☐ **Consultant** ☐ **Specialist Registrar (SpR)** ☐ **GP or** ☐ **other prescriber (Tick one)**	
Print name:	Speciality/Directorate:
Signature:	Date:
If SpR, state name of patient's consultant:	

Authorisation of Application (pharmacy – acute senior pharmacist or locality prescribing adviser)		
Name	Designation	Signature & Date

Medicines Cost	
a. Medicines costing less than £5,000 per patient/year can go straight to Final Process Approval at ADTC.	
b. For medicines costing more than £5,000 but less than £25,000 per patient/year? ☐ Yes ☐ No Approved by acute site Chief of Medicine, or Associate Director (Primary Care)	Signature
c. For medicines costing more than £25,000 per patient/year? ☐ Yes ☐ No Approved by acute site Chief of Medicine AND Medical Director, or Associate Director (Primary Care)	Signature Signature

Final process approval Area Drug and Therapeutics Committee
Approval for use ☐ Yes ☐ No Date: ....
If no, give reasons
State restrictions on prescribing/use and any further information

Completed by: (PRINT NAME)	**Designation of approver:**
Signature:	**Date:** .... **Time:** ....