

Unlicensed Medicines Policy FAQs June 2025

Question 1	What has changed?
Answer	The current policy; 'NHS Lanarkshire Policy for the Availability of Unlicensed Medicines' has been refreshed and updated. The new version is called ' NHS Lanarkshire Unlicensed Medicines Policy ' and includes new appendices and is accompanied by two helpful flowcharts to guide prescribers.
Question 2	Where can I find the policy and/or appendices?
Answer	The new policy sits with all other NHS Lanarkshire Policies (All Corporate Policies NHS Lanarkshire). The appendices are included as part of this policy but can also be found individually along with the flowcharts in the Medicines Approval Process section within Medicines Guidance tile on the Right Decisions platform (otherwise known as the guidelines site).
Question 3	What is High risk Off Label Use?
Answer	This is described within the new policy (Unlicensed-Medicines-Policy NHS Lanarkshire). Off Label Use is use of a licensed medicine out with the terms of its marketing authorisation. This would be considered High Risk if any of the following apply <ul style="list-style-type: none"> • If the medicine is teratogenic, carcinogenic, cytotoxic or a biological agent • If administration is intrathecal, epidural, to be instilled into cavity or bone or intravenous use that is not considered established intravenous practice • If the medicine is being used as part of a clinical trial
Question 4	When would I use the Blanket Unlicensed & High Risk Off Label Medicine Application Form (Appendix 2)?
Answer	Blanket approval is required when treatment is required for more than one patient, across either one or more sites.
Question 5	What is meant by established practice?
Answer	This is described within the new policy (Unlicensed-Medicines-Policy NHS Lanarkshire). Established practice refers to treatments described as an evidence based treatment option in national or specialist guidance. This includes BNF, BNFC, SIGN, NICE, The Maudsley Prescribing Guidelines in Psychiatry, Scottish Palliative Care Guidelines, British Association of Dermatologists.
Question 6	Who should complete the forms?
Answer	The initiating clinician should complete all relevant forms and follow necessary approval processes, including obtaining patient consent prior to writing the prescription/request to prescribe.
Question 7	Can I make a request on behalf of someone else?
Answer	No, you should only complete unlicensed medicine application forms for patients under your care.
Question 8	I am a consultant who has inherited a retired colleague's patients. Do I need to complete new forms for each patient?

Answer	Yes, as each patient will be undergoing treatment review anyway, this is a good opportunity to review the ongoing need for an ULM. If the forms have been recently completed however, contact the dispensary manager for further advice.
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Question 9	Do I need to complete a form if the medicine is considered Established Practice and costs less than £5,000 per year?
Answer	No, please see the medicines approval flow chart (Which Form Do I Need?). See Appendix 4 for the Criteria for Clinical Risk assessment for more information on what is considered Established Practice.

Question 10	What if the unlicensed medicine costs <£5000 at the time of initiation, but future dose adjustments/escalation or cost increases may have the cost exceed the £5000 cut off?
Answer	If a treatment plan is expected to exceed the threshold, a form should be completed prior to initiation. If costs increase, the pharmacy team may ask a clinician to complete a form for authorisation of continued treatment.

Question 11	Do I need to complete Appendix 3 if it is a medicine with established practice evidence and costs <£5,000; and primary care are being asked to prescribe it?
Answer	Appendix 3 is an optional form that can be used when the clinical circumstances or clinicians require. Whilst it is not mandated that the form in Appendix 3 is completed in this situation; there may be occasions where it is helpful for a primary care prescriber. Please note, Appendices 1 or 2 are the authorising forms. Completion of Appendix 3 solely does not provide board approval.

Question 12	Do I need to complete a form for an unlicensed medicine if it is either established practice OR <£5,000 per year?
Answer	If only one of the criteria are met, an unlicensed medicine application form is required.

Question 13	Is a consent form (Patient Consent to Unlicensed Medicine use - Appendix 6) required every time?
Answer	Guidance recommends that all medicines are prescribed following informed consent by the patient where possible. If prescribing of an unlicensed/high risk medicine is considered "established practice", further consent is not required. Clinicians should seek consent when treatment is out with established practice.

Question 14	Where do I send completed patient consent forms?
Answer	These should be filed in patient case notes by the requesting clinician; copied to the patients GP for filing in primary care notes if the item is to be continued in primary care.

Question 15	When is it helpful to complete Appendix 3?
Answer	This form has been utilised successfully for some years and has now had only minor changes to its content. It is usually completed when additional information will facilitate prescribing in primary care. This may be if the GP practice requests assurance of the need for ULM or where a specific brand or formulation is required. For example, if the patient has an allergy to an excipient, supply without the allergen is needed. This is commonly seen in paediatrics, where formulations without alcohol are preferred.

Question 16	What if I need an unlicensed medicine urgently?
Answer	Contact dispensary manager/on call pharmacist who will make decision on timescale for supply of item and support the process.

Question 17	When will this policy be reviewed?
Answer	The usual period for a policy to be reviewed is after 3 years; however because there are a number of changes to process with this particular policy, the medicines guidance team will carry out an interim review after 12 months.

Question 18	What is the process if the clinician requesting the prescribing of an unlicensed medicine in NHS Lanarkshire is from a different health board? (For example, request from another health board to NHS Lanarkshire GP practice to prescribe the unlicensed medicine)
Answer	It is expected that any clinician requesting an unlicensed medicine to be prescribed in NHS Lanarkshire would follow the NHS Lanarkshire process, including the completion of any relevant paperwork in line with the ULM policy. However, completion of forms specified in the policy does not automatically equate to the NHS Lanarkshire clinician being obligated to issue the prescription. The prescriber of the unlicensed medicine has clinical responsibility for the use of the medicine and the patient's welfare in line with this and their own professional judgement should be utilised.

Question 19	What if the use of the medicine for the particular indication is classed as established practice, but the dose/route/formulation etc. is not typical?
Answer	If the use of the medicine does not fall under what is considered 'Established Practice' as outlined in the ULM policy in any way, then the use of the medicine is <i>not</i> considered Established Practice. As a result, unlicensed medicine forms may be required in line with the policy.

Question 20	What if the up-front cost of the off-label medication costs >£5000 but the medicine 'lasts' for more than one year? (i.e. an implant)
Answer	The upfront cost should be considered when using the flowchart to confirm if a ULM form is needed for the off-label medicine. I.e. if the off-label medicine has an upfront cost of > £5000 then this would still require a form, despite the medicine 'lasting' longer than 1 year.

Term	Definition
IPTR	Individual Patient Treatment Request
PACS2	Peer Approved Clinical System Tier 2
ULM Form	Unlicensed Medicine Request Form
Blanket ULM Form	Blanket Unlicensed Medicine Request Form
ULM	Unlicensed Medicine
ULM Primary Care Request Form	Unlicensed Medicine Primary Care Request Form

Note, the policy cannot cover every possible situation. Please contact medsguidance@lanarkshire.scot.nhs.uk for support and advice.