

**Advice on accessing non-formulary and unlicensed medicines in GGC Mental Health Services**

**Non-formulary**

The following medicines are currently non-formulary within NHS GGC Mental Health Services (MHS) and are subject to mental health non-formulary (MHS-NF) requests;

- agomelatine
- paliperidone (oral)
- quetiapine MR
- vortioxetine

**PACS2**

Peer Approved Clinical System tier 2 (PACS2) is the process that has replaced Individualised Patient Treatment Requests (IPTRs) in most situations. Within MHS, the only medicine that is currently subject to the PACS2 process (on cost grounds and non-SMC status) is;

- olanzapine long-acting injection (Zypadera ®)

**Unlicensed medicines**


Medicines that do not have a marketing authorisation (or product licence) in the UK are subject to unlicensed medicine (ULM) requests and require completion of a ULM form.

A number of blanket unlicensed protocols exist within MHS to allow use of some ULMs in certain clinical situations without submitting a full ULM form. These are;

- pirenzepine for clozapine-related hypersalivation [Protocol for unlicensed pirenzepine](#)
- benztropine for clozapine-related hypersalivation [Protocol for unlicensed benztropine](#)
- short-acting IM olanzapine [Protocol for unlicensed IM olanzapine](#)
- thioridazine for legacy patients [Protocol for unlicensed thioridazine](#)

Off-label use of medicines occurs when medication is used outside the terms of its marketing authorisation. Where the off-label use is supported by evidence-based texts, the use is generally considered low risk and a ULM form will not be required. Where the off-label use is higher risk, a ULM form may be required. Please contact the Mental Health Prescribing Management Group (PMG-MH) for further advice.

Prior to prescribing any medicine subject to restrictions within GGC MHS, the appropriate form must be completed and sent to the PMG-MH for consideration. Feedback regarding approval or otherwise from the PMG-MH will be provided to the requesting clinician within an agreed timescale.

<b>Medicines subject to NF, PACS2 or ULM processes within MHS and forms to complete</b>		
<b>NF</b>	<b>PACS2</b>	<b>ULM *not exhaustive</b>
 MHS NF request form	<a href="#">PACS2 form</a>	<a href="#">ULM form</a>
agomelatine	olanzapine LAI	sertindole
paliperidone (oral)		ziprasidone
quetiapine MR		clozapine IM
vortioxetine		

**Feedback requests**

Following approval of medicines subject to NF, PACS2 or ULM processes, PMG-MH will retain a copy of the form for audit purposes and may request feedback after a period of time in order to evaluate local clinical experience.

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