Non-formulary medicines request process

Non-formulary medicine request

Request for licensed medicine for a licensed indication?

YES

SMC approved (pre-formulary approval – follow early access to medicines process)

NO

SMC submission not recommended or
SMC evaluation ongoing or
SMC approval for restricted use and requested use outside of restrictions

Unlicensed/off-label request – follow unlicensed/off-label medicines request policy

Request for SMC designated ultra-orphan medicine?

YES

PACS Tier One process and request form (Annex B)

Submit form to appropriate Principal/Lead Pharmacist

PACS Tier One Panel

Further information or amendments to outcome reporting plan made

Outcome Review process Tier One (PACS Tier One Annex B)

Tier One Approval

Review required new PACS Tier Two Panel

Tier Two Approval

National Review Process (if applicable) (PACS Tier Two Annex C, Appendix 1)

Review required new PACS Tier Two Panel

Tier Two Approval

Not approved

Further review not required - decision upheld

For full details see the NHS Grampian, NHS Orkney and NHS Shetland staff policy for requesting non-formulary licensed medicines for licensed indications (including Peer Approved Clinical System (PACS) Tier One and Tier Two), click here.

For the ‘Patient information letter for PACS Tier Two process’, click here.