South Central Ambulance Service
NHS Foundation Trust

FORMULARY AND NEW MEDICINES POLICY

South Central Ambulance Service NHS Foundation Trust
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DOCUMENT INFORMATION

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Ratifying committee/group: Medicines Optimisation and Governance Group

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1. Introduction

1.1. The controlled and rational introduction of new medicines is a requirement specified by the Care Quality Commission (CQC).

1.2. A formulary is a list of medicines approved for use within a Trust.

1.3. The Medicines Optimisation and Governance (MOGG) Committee is responsible for the approving and updating all medicine related policies and guidelines, such that they promote the rationale, safe and cost-effective use of medicines within the Trust.

1.4. This includes the review of requests for the introduction of new medicine entities, different presentations of existing medicines and unlicensed/off label use of existing medicines

1.5. A formulary of medicines approved for use in the Trust should be in place that is consistent with medicines recommended by NICE and other relevant national guidance.

1.6. The formulary provides many benefits in providing improved patient care at decreased cost through improved selection and rational medicine use

2. Scope

2.1 This policy applies to This policy applies to the formulary of all medicines for use in the Trust, whether prescribing, supply or administration.

2.2 The formulary is applicable to all patients

2.3 This policy applies to all staff involved in the administration of medicines, including those that work under a contract for services, voluntary staff, and those supplied to do work by a third party, including agency staff.

3. Equality statement

3.1 The Trust is committed to promoting positive measures that eliminate all forms of unlawful or unfair discrimination on the grounds of age, marriage and civil partnership, disability, race, gender, religion/belief, sexual orientation, gender reassignment and pregnancy/maternity or any other basis not justified by law or relevant to the requirements of the post. The Trust will therefore take every possible step to ensure that this procedure is applied fairly to all employees regardless of the afore mentioned protected characteristics, whether full or part time or employed under a permanent or a fixed term contract or any other irrelevant factor.

3.2 By committing to a policy encouraging equality of opportunity and diversity, the Trust values differences between members of the community and within its existing workforce, and actively seeks to benefit from their differing skills, knowledge, and experiences in order to provide an exemplary healthcare service. The Trust is committed to promoting equality and diversity best practice both within the workforce and in any other area where it has influence.

3.3 Where there are barriers to understanding; for example, an employee has difficulty in reading or writing, or where English is not their first language, additional support

will be put in place wherever necessary to ensure that the process to be followed is understood and that the employee is not disadvantaged at any stage in the procedure. Further information on the support available can be sought from the HR Department.

4. Aim

4.1 The aim of this policy is This policy aims to support evidence-based use of medicines.

4.2 This policy aims to support the cost-effective use of medicines

4.3 To manage risks associated with the use of medicines

4.4 To improve access to medicines with minimal delay

5. Roles and responsibilities

5.1 The Trust Board will receive the annual report from the Medicines Optimisation and Governance Group to enable the monitoring of compliance with this policy. Has responsibility and accountability for ensuring the provision of appropriate resources required to implement this policy.

5.2 Medicines Optimisation and Governance Group (MOGG): responsible for conducting timely reviews of requests for medicines inclusion to the Trust formulary. The Committee will make decisions based on consideration of the evidence of clinical efficacy, clinical risk, and cost implications. The MOGG will have final approval authorization for formulary management.

5.3 Clinical Review Group (CRG): the CRG will review the clinical guidelines, policies and supporting documents to support the use of the medicine within the Trust.

5.4 999 Lead Pharmacist: the lead pharmacist is responsible for maintaining an up-to-date accessible formulary on behalf of the Trust. Decisions made at MOGG will be implemented by the Lead Pharmacist to ensure purchasing, storage and implementation of a new medicine is done safely and securely

5.5 Pharmacy Team: the pharmacy team are responsible for ensuring the procurement of medicines is only carried out in line with the formulary and as per the Trust Purchasing for Safety Policy

5.6 All staff: all staff involved in the prescribing, supply or administration of medicines are responsible for adhering to the Trust formulary and policy.

6. Formulary Management Principles

6.1. The formulary is a periodically revised list of medicines that reflects the current judgement of the MOGG.

6.2. The formulary system utilized the medical, pharmacy and paramedic expertise to evaluate, appraise and select those medicines that are most efficacious, safest, of adequate quality and available at a reasonable price.

6.3. Formularies should conform to the following principles

6.3.1. Medicines should be selected based on the needs to the community
6.3.2. The formulary should only contain those medicines necessary to provide for the needs of the service; duplication of agents that have therapeutic equivalence should not occur.
6.3.3. Combination products should only be used in specific proven conditions
6.3.4. Medicines should be selected based on explicit criteria that include proven efficacy, safety, quality and cost
6.3.5. The formulary must be consistent with any national or regional formulary approved standard treatment
6.3.6. Medicines should be restricted to appropriate practitioners.

7. Additions to the Formulary

7.1. A request for addition of medicine to the formulary can be made by completing a "New Medicines Request Form" (Appendix 1). The formulary system utilises the medical, pharmacy and paramedic expertise to evaluate, appraise and select those medicines that are most efficacious, safest, of adequate quality and available at a reasonable price.

7.2. Information required includes explanation of why the medicine is superior to any current formulary notifications, literature to support its use and safety data to support its use.

7.3. Medicine's information provided with the application should include (where applicable) primary literature and standard treatment guidelines. All sources of information must be credible and unbiased

7.4. Expert opinions and recommendations can be sought from fellow healthcare professionals; however, they should only complement and not replace the literature.

7.5. Any declarations of interest must be made on the application.

8. MOGG Analysis and Evaluation

8.1. The MOGG should formulate recommendations concerning the medicines on evidence-based information.

8.2. MOGG will present their decision to Clinical Review Group for information

8.3. The following criteria will be considered when evaluating all new requests for addition to the formulary:

8.3.1. Disease patterns: formulary medicines should only be approved after confirmation of actual need to treat the known disease(s) and/or medical condition(s) of the community.
8.3.2. Efficacy: a comprehensive review of unbiased information and careful evaluation of all sources must be done to ensure that evidence of efficacy is supported by literature and is accurate.
8.3.3. Safety: determining safety of medicine requires close attention to established information and a careful risk-benefit assessment considering the use of a medicine in a specific setting by specific personnel. The cost of treating adverse drug reactions is high, both in monetary terms and lowered patient quality of care

8.3.4. Quality: the quality of medicine that is required ensures avoidance of risk of lack of therapeutic effect, toxic and adverse reactions, and waste of financial resources

8.3.5. Storage: the medicine will require safe and secure storage in an agile environment and will require careful evaluation of current medicines management systems to ensure it can be used safely within this.

8.3.6. Administration/supply: the medicine needs to be administered under an appropriate legal framework but authorized and appropriately trained staff.

8.3.7. Financial resources: there must be sufficient financial resource to purchase and maintain the supply of medicine for an indefinite amount of time. A thorough cost analysis is therefore required. Intermittent stocking of a medicine leads to poor continuity in care.

8.4. The Trust will operate a “closed” formulary system whereby all non-formulary medicines are excluded from being available in any form.

8.5. In the event of a supply interruption of a formulary medicine a non-formulary medicine maybe be added to the formulary temporarily to fulfil clinical need. The decision to use a non-formulary product must be authorised by MOGG.

8.6. Some medicines may be “restricted” on the formulary in that they are only for use by certain professional groups

8.7. In the event of a medicine being rejected the applicant will be invited to MOGG to further discuss the application.

9. Training

9.1. Training on formulary management will be given on request by the Head of Pharmacy to those requiring this as part of their job role. This includes guidance on where to access training for critical review of the literature.

10. Equality and Diversity

10.1. An initial screen equality and diversity impact assessment has been carried out on this policy and, as per appendix 4, is available on request.

11. Monitoring

11.1. The effectiveness of this policy will be monitored through Bi-monthly review of the formulary by the Medicines Optimisation and Governance Group

12. Consultation and review

12.1. A consultation exercise on the policy will be carried out with the stakeholders every 3 years, or less if there are any relevant changes to legislation or best practice.

13. Implementation (including raising awareness)

13.1. The policy will be implemented and communicated to managers and staff within the Trust via the weekly newsletter, Staff Matters. Emails will also be sent to senior managers and area managers asking them to bring the existence of the policy to their staff.

14. References

- WHO Developing and Maintaining a Formulary accessed online: https://www.who.int/medicines/technical_briefing/tbs/02-PG_Formulary-Management_final-08.pdf?ua=1

15. Associated documentation

15.1 There are also the following documents associated with this policy:

- Controlled Drug Policy
- Medicines Management Policy
- Prescription Management and Security Policy
- Patient Group Direction Policy
- Purchasing for Safety Policy
- Safe and Secure Handling of Medicines Policy

16. Appendix 1: New Medicines Application Form

New Medicines Application Form

Addition of a New Drug or Drug Use to the South Central Ambulance Service Formulary

Notes for completion:

a. Complete sections A-H. Incomplete forms will be returned.
b. Send electronically to the Head of Pharmacy at least 1 week prior to the next MOGG meeting
c. The request will be reviewed at the next available MOGG meeting.
d. See the Formulary and New Medicines Policy for additional information.

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PART A. Clinician Details		
1.	Clinician requesting new Drug or Drug Use.	
2.	Confirmation of consultation with all relevant consultant colleagues	
3.	Name of clinician presenting to MOGG	

PART B. Drug Information & Intended Use:		
4.	Drug Name, Strength and Formulation	
5.	Indication for Drug	
6.	Intended dose and route	
7.	Is it anticipated that this will replace an existing Drug? (if so state which)	
8.	Average likely dose	
9.	Anticipated length of treatment per patient.	
10.	Average cost **per patient per month** (use ABW of 75kg if applicable) (VAT inc.). *Contact pharmacy for drug cost if needed.*	
11.	Number of patients anticipated to be treated per year	
12.	Total anticipated cost per year	
13.	What is the proposed formulary status? (please tick all that apply)	☐ 1st line ☐ 2nd line ☐ 3rd line
15.	Are there any local or national guidelines available to support the use of this drug as intended? (If so please specify and include a copy with the application where possible)	

16.	Position of drug in treatment pathway (provide details of treatment algorithm)
17.	Statement of support providing rational for proposal (provide details)

PART C. Legal framework and administration/supply:		
18.	What is the legal classification of the medicine?	☐ General sales list (GSL) ☐ Pharmacy medicine (P) ☐ Prescription only medicine (POM) ☐ Controlled Drug (CD)
19.	Which group(s) of staff will be administering, prescribing, or supplying this medication?	☐ ACA ☐ ECA ☐ AAP/Technician ☐ Paramedic ☐ Nurse ☐ Specialist Practitioner ☐ HART ☐ ACCT ☐ Basics Doctors ☐ Enhanced Care (Basics) Practitioners
20.	What is the legal mechanism for supply of this medicine?	☐ Schedule 17 ☐ Schedule 19 ☐ PGD ☐ Protocol (Trust) ☐ Protocol (JRCalc) ☐ Prescription Only
21.	Will training be required to introduce this medicine in the Trust? If yes how will this be delivered? *e.g. PGD training material*	

PART D. Licensing Information:			
22.	Is the product a licensed medicine in the UK?	Yes	No
23.	Is the product being used for a licensed indication?	Yes	No
24.	Is the route of administration licensed for this product?	Yes	No
24b.	If “no” to any of the above questions in section D explain the rationale for inclusion on the		

	formulary over licensed alternatives

PART E. Storage information			
25.	Is the item stored at room temperature?	Yes	No
26.	Does the item require refrigeration?	Yes	No
27.	Does the drug require Controlled Drug storage?	Yes	No
28.	Can the drug be stored in the current medicine's modules?	Yes	No
29.	If "no" to question 25, what is the proposed mechanism for storage on current service vehicles?		

PART F. Clinical Efficacy Evidence Information:	
30a.	Clinical Trial reference paper /authors(1)
	Key findings of trial (1)
30b.	Clinical Trial reference paper/authors (2)
	Key findings of trial (2)

PART G: Safety evidence information

31.	What are the most common adverse effects and how will these be managed?
32.	What are the contraindications?
33.	What are the clinically important Interactions?
34.	Can this drug be used in pregnancy and breastfeeding?
35.	Will this drug be used in the paediatric population?
36.	Is there a risk of miss-selection with existing formulary products? *e.g., similar packaging, same or similar sounding names etc.*

PART H. Declaration of interests and applicant signature:

DECLARATION OF INTERESTS

37.	Do you have any **direct** interests with the manufacturer of this product?	YES / NO
	A **direct** interest would include: • Being a shareholder or a director of a company • Acting as a lecturer or as a consultant to a company or any such relationship where you have personally received money or payment in kind amounting to the equivalent of £200 or more over the last 12 months. This does not apply to money paid to cover fares and other reasonable travel expenses in order to give lecturers or attend scientific meetings. A direct interest is one which has resulted in a payment to you personally and so which could be paid into a private account.	
38.	Do you have any **indirect** interests with the manufacturer of this product?	YES / NO
	An **indirect interest** would include: • You or your co-workers receiving money, equipment or salaries etc to the value of £200 or more over the last twelve months and which has been used to contribute to the running of research or clinical activities. This does not apply to money paid to cover fares and other reasonable travel expenses in order to give lecturers or attend scientific meetings.	
39.	If yes to 22 or 23 above please provide details here	

APPLICANT SIGNATURE		
40.	Name and Signature of applicant	
41.	Contact email or telephone number	

MOGG USE ONLY

MOGG VERDICT	
Date of meeting proposal heard	
Approved:	**Yes / No**
Formulary status: (if approved) *Tick all that apply*	☐ 1st line ☐ 2nd line ☐ 3rd line
Any special requirements if use agreed? *Include staff group(s) & framework for administration*	
Reasons for non-approval	
Date requesting clinician informed	

17. Appendix 2: Review Table

17.1 This policy is regularly reviewed and updated with information in line with relevant national guidance and legislation. A full 'Review Table of Contents' is available on request.

18. Appendix 3: Responsibility

18.1 The responsibility for this policy is shared between various Policy Groups, Lead Director/Officers, Working Groups and Committee members.

18.2 A full list of all responsible parties can be made available upon request.

19. Appendix 4: Equality impact assessment - Screening

19.1 An initial screening equality impact assessment has been carried out and has identified that the policy does not have an adverse or detrimental impact on any of the proscribed equality groups as the policy is designed to protect all staff who carry out work for or on behalf of the Trust.

19.2 The screening element of the initial 'Equality Impact Assessment' is available on request.

20. Appendix 5: Equality impact assessment form – Section Two – Full assessment

20.1 Due to the outcome of the initial screening equality impact assessment, it has not been necessary to carry out a full equality impact assessment.

21. Appendix 6: Ratification

Policy Title: Formulary and New Medicines Policy

Author's Name and Job Title: Victoria Bray, Consultant Pharmacist

Review Deadline: 28/04/22

Consultation From – To (dates): 07/09/22 – 28/09/22

Comments Received? (Y/N): Y

All Comments Incorporated? (Y/N): Y

If No, please list comments not included along with reasons:

Equality Impact Assessment completed (date): 27/07/22
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Name of Accountable Group: Medicines Optimisation and Governance Group

Date of Submission for Ratification: 13/08/22

Template Policy Used (Y/N): Y

All Sections Completed (Y/N): Y

Monitoring Section Completed (Y/N): Y

Date of Ratification: 25/08/22

Date Policy is Active:

Date Next Review Due: June 2024

Signature of Accountable Group Chair (or Deputy):

Name of Accountable Group Chair (or Deputy): Louise Maunick