Managed Entry Process for SBU Health Board Joint Drug Formulary

November 2021

Policy Owner:

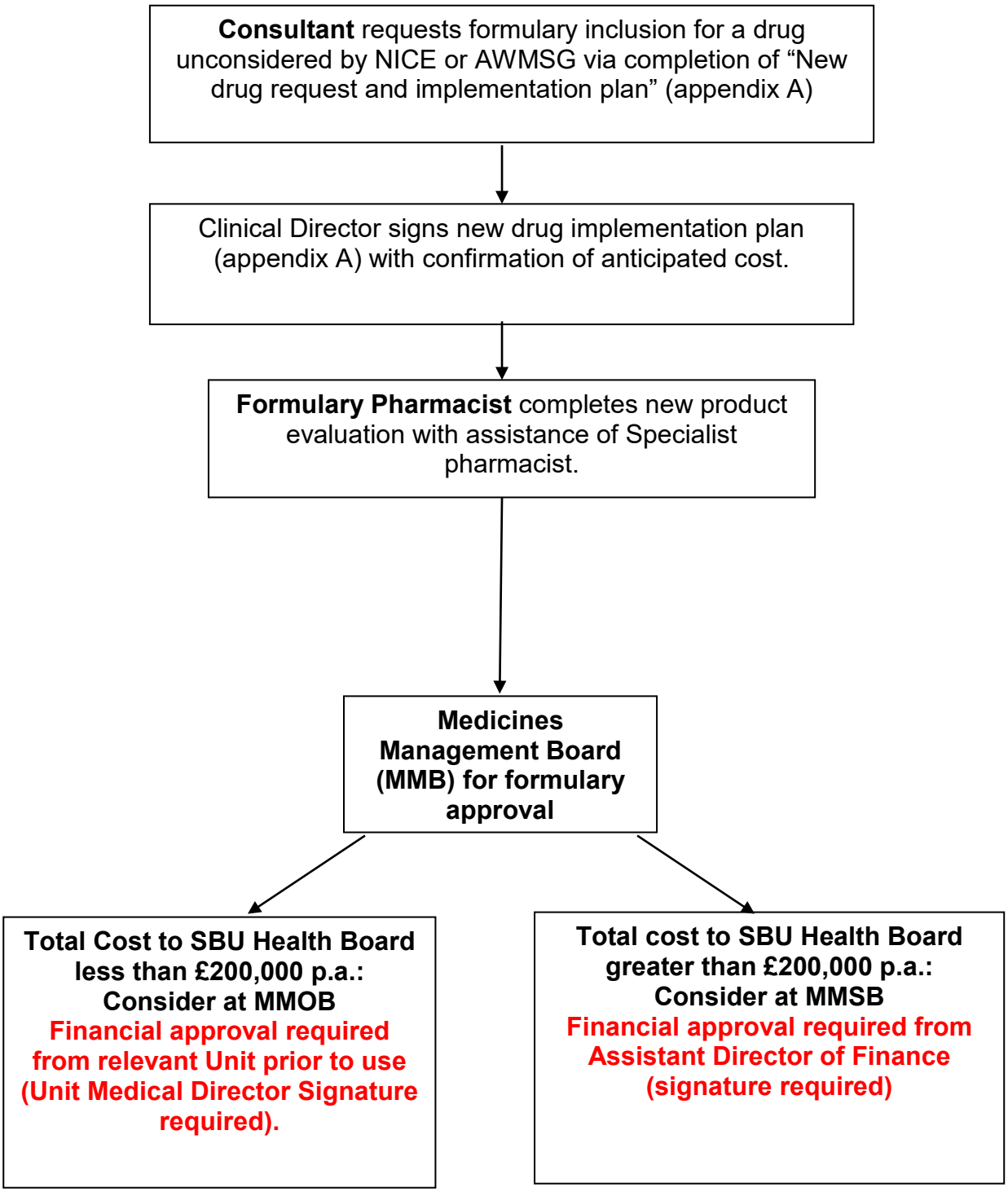
Approved by: Medicines Management Board

Issue Date: November 2021

Review Date: November 2023

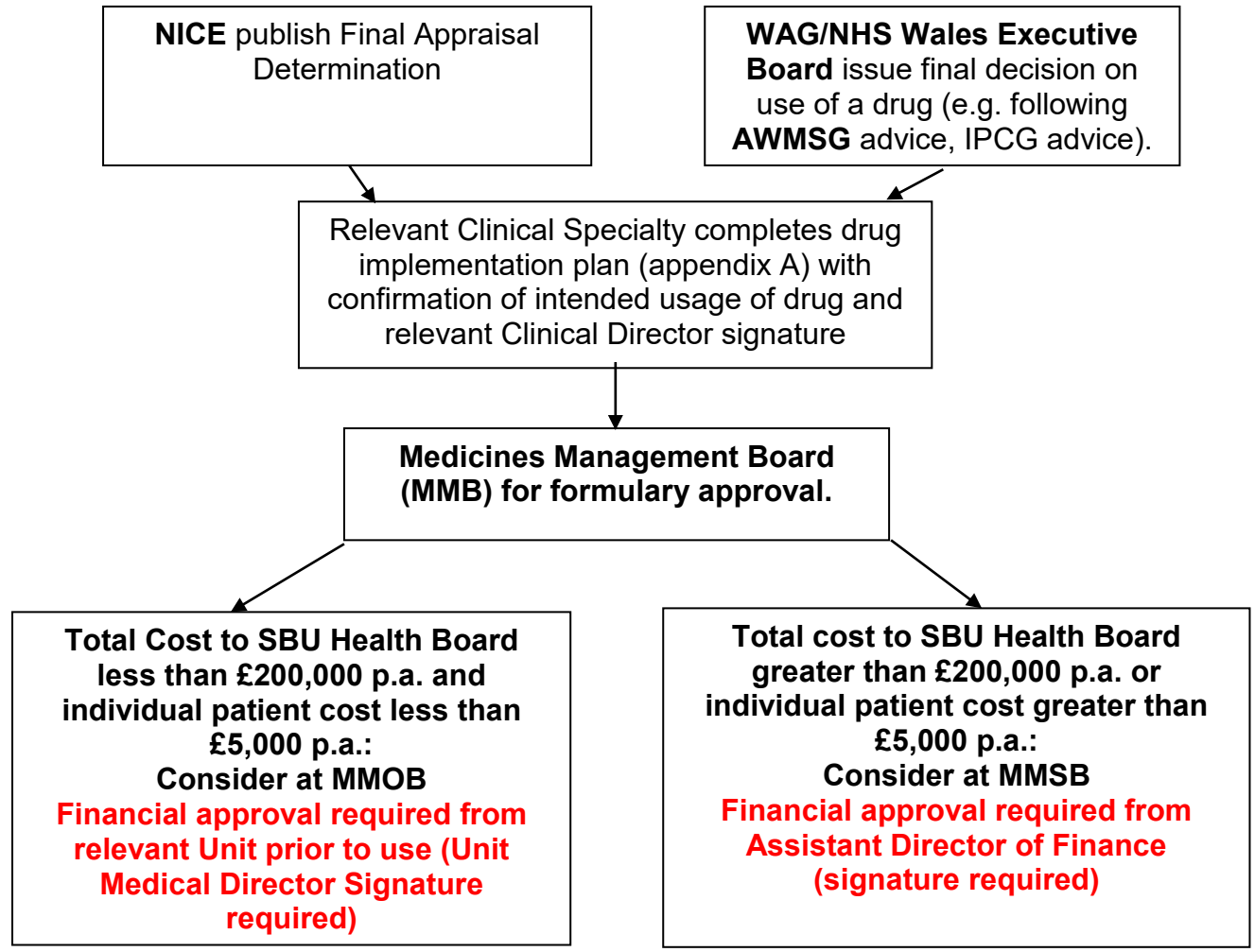
Policy ID: CID440

Managed Entry Process for SBUHB Drug Formulary: Non-NICE or Non-AWMSG drugs.



MMOB: Medicines Management Operational Board.
MMSB: Medicines Management Strategic Board.

Managed Entry Process for SBUHB Formulary: NICE and AWMSG recommended drugs.



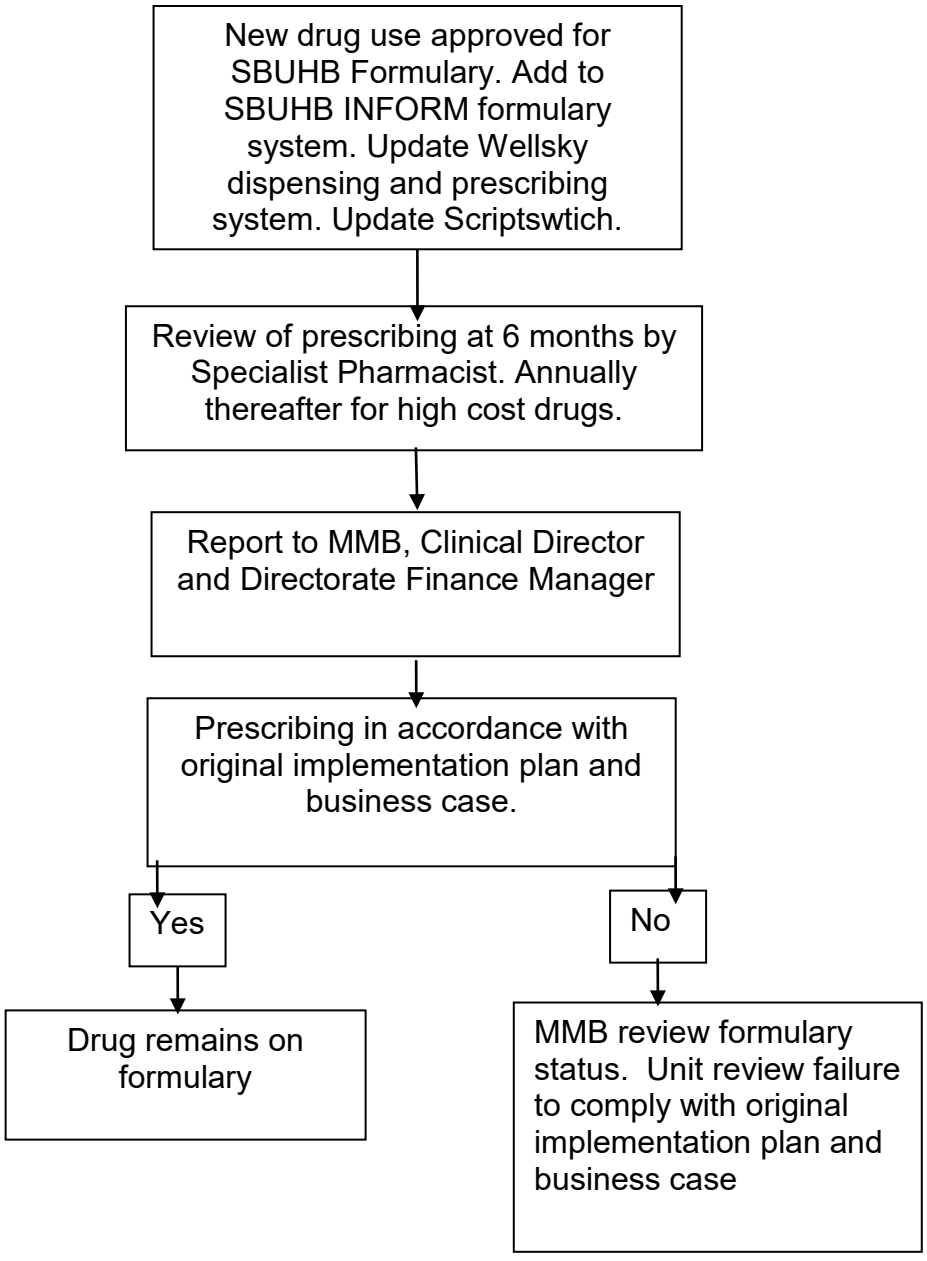
Formulary Compliance Note: **Due to Welsh New Treatment Fund time requirements, drugs will be automatically added to formulary that are subject to NICE FAD or AWMSG approval, however, until completion of an implementation plan by the relevant Delivery Unit the drug cannot be cross-charged to the NICE/AWMSG high cost drug budget.** The process should be completed within 2 months of NICE FAD or AWMSG.

Responsibility for completion of implementation plan lies with the requesting Clinical lead/Clinical Director within relevant Delivery units. To ensure that SBU Health Board is able to make a timely decision on new drug technologies, Managed Units are encouraged to complete an implementation plan at the earliest opportunity (this may be well in advance of final publication by NICE or AWMSG or in some cases full marketing authorisation of the product within the UK).

Where it is agreed between Unit and Medicines Management Board early formulary adoption as an interim formulary position in advance of final NICE/AWMSG publication will be considered if it improves patient outcomes by optimising the use of medicines and improving quality through access to cost-effective medicines in the best interests of the Health Board and its local population. This will further they high value medicine strategic aim of Health Board. This will also apply for specific indications/patient cohorts/treatment regimens that are beyond the central scope of existing/anticipated national guidance.

The IPFR process is available for consideration of individual patient cases for non-formulary drugs, however, it is intended that early submission of “New drug request and implementation plan” will minimise the need for repeated IPFR applications for the same drug technology.

Review Process for Formulary Changes



Review Process for Therapeutic areas of the Formulary

Each of the 12 main sections of the formulary (Gastro-intestinal, Cardiovascular, Respiratory, Central Nervous System, Endocrine system, Obstetrics/Gynaecology/Urinary Tract, Malignant disease and Immuno-suppression, Nutrition and Blood, Musculoskeletal and Joint disease, Eye, ENT, Skin) will be reviewed every 2 years or when significant changes to relevant clinical guidelines occur. Wellsky, INFORM and Scriptswtich to be updated.

Roles & Responsibilities of Individuals and Groups within the Managed Entry Process.

Medicines Management Board will make final formulary decision on all new formulary requests, however, financial approval will be required from budget holder prior to use unless subject to Welsh New Treatment Fund (NTF). Drugs subject to NTF will be charged to the SBUHB NICE/AWMSG high cost drug ledger once the relevant Unit have committed to submitting an implementation plan to MMB.

Clinical Considerations

1. "New Drug Implementation plan" forms (appendix A) are available from Formulary/Interface Pharmacists (also available on SBUHB intranet under Medicines Management pages). These forms need to be completed for all new proposed drug usage, including recommendations made by NICE or AWMSG. Forms will only be processed if completely and correctly filled out by Medical Consultant level staff and returned to Clinical effectiveness/Formulary pharmacist.

2. A "new product evaluation" will be completed by formulary pharmacist for drugs not on the work plan of NICE or AWMSG.
   This evaluation will be based upon the "STEPS" methodology i.e. Safety, Tolerability, Effectiveness, Price, and Simplicity. In addition a summary page will be included, where necessary with a background section, to assist non-clinicians in reaching a formulary decision.

3. It is recognised that implementation of a NICE Technology Appraisal (TA) or AWMSG approval (with subsequent endorsement from the Welsh Assembly Government Minister for Health and Social Services) is a statutory obligation in Wales. Increasingly, NICE and AWMSG state that a new drug may be considered as an option in treatment and it is therefore essential that an implementation plan is completed for each new drug by the relevant Clinical Specialty(s) and approved by SBU Health Board prior to prescribing. Further, it is imperative that implementation is as efficient as possible to meet the demands of the Welsh New Treatment Fund, to this end the Health Board must introduce new medicines recommended by NICE within two months of the first publication of the Final Appraisal Determination (not the formal publication of Technology appraisal) and new cancer drugs recommended for an interim period by NICE within two months (provided manufacturer offers NHS Wales the same or similar package, including price as NHS England).

4. Drugs recommended as potential treatment options in a NICE Clinical Guideline will be reviewed via the managed entry process system for

consideration of addition to the formulary pending submission of an implementation plan from the relevant Clinical Specialty(s). This may necessitate a review of relevant section of the formulary.

5. It is recognised that some drugs recommended by NICE/AWMSG may not be considered for use by Acute Care as the place of prescribing/initiation is recognised as being primary care. In this situation an implementation plan may be completed by Primary care Head of Medicines Management.

6. If drugs are already on the AWMSG or NICE TA work programme (within 12 month forward work programme), local formulary adoption shall usually (see point 7 for exceptions) be deferred until formal publication/Ministerial endorsement is received, however, early submission of new drug request and implementation plan is encouraged to ensure a timely final SBU Health Board decision on use of that drug, particularly for high value medicines.

7. SBUHB will make interim formulary decisions on new drug technologies in advance of anticipated National guidance (e.g. NICE, AWMSG) if it is agreed between relevant Unit(s) and MMB that it may improve patient outcomes by optimising the use of medicines and improving quality through access to cost-effective medicines at a stage which is in the best interests of the Health Board and its local population. This will also apply for specific indications/patient cohorts/treatment regimens that are beyond the scope of existing/anticipated related national guidelines.

8. It is recognised that National processes (e.g. NICE, AWMSG, “One Wales” Interim Commissioning Process) are increasingly becoming streamlined with many drugs fast tracked, as a result National recommendations on certain drugs may be published without advanced notification. In this situation the drugs will be automatically incorporated onto the formulary and these changes reported through Medicines Management Board. This allows SBUHB to comply with Welsh Government target times for NICE and AWMSG implementation. An implementation plan will still need to be produced and approved through MMB, however, this will not delay the approval to formulary and availability of the treatment.

9. In the case of wound care products, MMB will take advice and receive completed implementation plans from the SBUHB Wound Care Group prior to making final formulary decisions.

10. In the case of antimicrobial agents, MMB will take advice and receive completed implementation plans from the SBUHB Antimicrobial Group prior to making final formulary decisions.

11. In the case of dietetic products, MMB will take advice and receive completed implementation plans from the SBUHB Dietetic Formulary Group prior to making final formulary decisions.

12. Horizon Scanning- Wherever possible, potential cost impacts of new drugs will be identified as part of the 3 year cycle “horizon scanning” process completed by the clinical effectiveness pharmacists and the Welsh Medicines Horizon scanning and forecasting group. Annual forecasting for new drugs, with regular updates through SBUHB NICE high cost drugs group.

13. The Health Board permits formulary requests for off-label prescribing of drugs where it has been are assessed and approved by the Medicines Management Board as in the best interests of the Health Board and as having sufficient evidence base and/or experience of using the medicine to show its safety and efficacy. In such situations it recognises the usage is outside of license and indemnifies the healthcare professionals involved. Where possible such requests should be referred to the OMAG (One Wales) process which can consider unlicensed drugs usage for Wales.

14. A three month timescale for the introduction of new medicines recommended by NICE or AWMSG is being retained as a long-stop date for use in genuinely exceptional circumstances where the scale of service planning to introduce the medicine will require longer than two months. Use of the three month long-stop date must be agreed in advance with Welsh Government.

15. Free of charge supply: Health technology assessment by AWMSG or NICE is the preferred approach for advising on the clinical effectiveness and cost effectiveness of newly licensed medicines. However, in the absence of, or whilst awaiting publication of health technology assessment advice, some pharmaceutical companies offer NHS Wales a free of charge medicine supply agreement for treatments with marketing authorisations, to enable patients and clinicians access to a particular medicine at no cost. Such offers are subject to the All Wales free of charge medicines policy, agreement for the Health Board to participate in specific schemes requires the approval of the Clinical Director for pharmacy and Medicines Management with retrospective reporting through MMB. In line with Welsh policy, the following criteria will be considered as part of the approval process: • The medicine has been submitted for health technology assessment by AWMSG or NICE, but a significant delay (e.g. over 6 months) is anticipated before health technology assessment guidance is expected .•The medicine is not associated with significant additional administration costs (e.g. testing, administration or significant monitoring requirements).•The medicine is fully free of charge and the offer is not a partial price discount .•The marketing authorisation holder makes a written commitment to supply the medicine for the specified indication free of

charge until: 60 days following publication of positive HTA guidance by AWMSG, or, 60 days following publication of a positive final appraisal determination (FAD) or final evaluation determination (FED) and, where appropriate, with an agreed commercial access agreement or patient access scheme in place- as long as the patient(s) continue to require it on clinical grounds if the HTA guidance is negative. Medicines expected to help patients with life-threatening, long lasting or seriously debilitating illnesses, where no suitable licensed medicine is available, will be prioritised.

16. Compassionate use schemes are outside of the formal managed entry system. Compassionate use schemes refer to schemes involving unlicensed medicines. The European Medicines Agency defines compassionate use as "a treatment option that allows the use of an unauthorised medicine. Under strict conditions, products in development can be made available to groups of patients who have a disease with no satisfactory authorised therapies and who cannot enter clinical trials." Please refer to Health Board Protocol for making decisions on Compassionate Use / Expanded Access / Named Patient supply programmes.
17. Formal Early Access to Medicines Schemes (EAMS): The aim of the Early Access to Medicines Scheme is to provide earlier availability of promising new unlicensed medicines to UK patients that have a high unmet clinical need. A positive scientific opinion is only issued by MHRA if the criteria for the EAMS are fulfilled, which includes demonstrating a positive benefit risk balance (quality, safety and efficacy assessment) and the ability of the Company to supply a medicine according to a consistent quality standard. Health Board participation within a specific EAMS requires the authorisation of Clinical Director for Pharmacy and Medicines Management, decisions are subsequently reported through MMB.
18. Non-formulary drug treatments which are specifically recommended by specialist centres for use as antidotes or as management of adverse effects from treatments administered by the Health Board, can be approved by Clinical Director for Medicines Management (or deputy) and retrospectively reported through MMB.

Dissemination

1. All new drugs decisions in relation to the Joint formulary will be marked as formulary on the hospital pharmacy Wellsky system and the INFORM Formulary system.

2. Relevant NICE guidance (TA or NG) and AWMSG final positional statements will be linked to relevant drug monographs on the INFORM formulary system for information.

3. All new formulary decisions will be disseminated to Unit Medical Directors and Primary care Head of medicines management. A medicines update newsletter will be completed to provide concise

information on formulary changes and other relevant MMB prescribing decisions following each MMB meeting to facilitate the dissemination process.

Additional Details

1. The formulary applies to specific indications for specific drugs i.e. a drug may be restricted in its formulary availability to specific circumstances. It is important for prescribers to understand that a drug may be available for use in one condition and be prohibited from use by formulary in another condition. These restrictions may extend to limiting use to specific prescribers and grades of staff.

2. The Joint formulary applies to prescribing and recommendations to prescribe. For this reason it is requested that routine recommendations for non-formulary drugs arising from secondary care should be referred to the formulary pharmacist to discuss potential formulary request with relevant Consultant ("one off cases" will not give rise to a formulary request unless it can be reasonably expected that another such instance will arise. Formulary pharmacist will not intervene in specific patient cases.)

3. In cases of non-urgent clinical need for an individual patient for a non-formulary drug costing >£5000 pa (or defined treatment course), the case should be referred to the SBU Health Board Individual Patient Funding Request Panel.

4. Where an urgent decision is required for a non-formulary drug costing >£5000 pa (or defined treatment course), agreement of the Chair of the Individual Patient Funding Request (IPFR) panel is required. This process is facilitated through the planning department.

5. For non-formulary drugs costing below £5000 pa (or defined treatment course) the drug may be agreed by the relevant Clinical Director (or deputy) and hospital pharmacy site manager for one individual patient following notification of the formulary pharmacist. For drugs between £2,000 and £5,000 the signature of relevant Clinical Director (or deputy) must be obtained before purchasing the drug. Requesting consultants will be invited to submit a formulary request at this point. Such usage will be reported back through MMB.

6. Drugs on the formulary will be categorised according to the following definitions to clarify how and where a drug should be prescribed:
   - Hospital only - All prescriptions are issued from hospitals or use only applies to hospitals;

- Specialist initiated- Follow up prescriptions may be issued by GPs but initialisation/stabilisation should be performed by a specialist. This group includes drugs for which shared-care protocols exist;
- 1st line- A suitable first choice for GPs and non-specialists and;
- 2nd line- Also suitable for the above, but possibly reserved until after a first line agent has been tried or rejected on grounds of side effects or allergy. In many cases these will be the more expensive agents.

7. Products that are licensed as medical devices will only be considered through the drug formulary managed entry process in cases where the product is to all intents and purposes being used as a drug. In such cases a presentation by the requesting Consultant directly to the Medicines Management Board may be required (this presentation must cover potential associated costs**).**

8. Ongoing funding of drug therapies following completion of clinical trials involving SBUHB patients will not be automatically granted. In such cases, the usual managed entry process will apply which will require a full formal formulary submission. For this reason, it is imperative arrangements are agreed for ongoing prescribing of drug therapies post study completion prior to initial clinical trial involvement.

Appeals Process

An appeal may be lodged in writing, by the original applicant with the Chair of the Medicines Management Board within 15 working days of being informed of a formulary rejection.
Where new relevant supporting data is submitted after formulary decision has been taken the request will be dealt with as a resubmission.

An appeal will be considered where:

- There has been a failure to act fairly and in accordance with the Joint formulary managed entry process.

The appeals panel will consist of 3 members nominated by the Chair of Medicines Management Board, which will include a pharmacist, GP and Hospital Consultant that have not been involved with the original formulary consideration for that drug. The applicant will be informed within 28 days of a legitimate appeal being lodged.

Appendix A.

NEW DRUG REQUEST AND IMPLEMENTATION PLAN

See Managed Entry Process for SBU Health Board Joint Formulary.

This form is to be completed for all new drugs or new indications proposed for addition to the SBUHB Formulary. This includes those subject to recommendation by NICE (in a Technology Appraisal or Clinical Guideline) or AWMSG.
Please note, no drug will be admitted to the local SBUHB Formulary through the Managed entry process without a fully completed implementation plan, irrespective of National guidance on a drug therapy.

Forms completed by Pharmaceutical Industry will not be accepted.

1. DRUG NAME(S):
2. NICE TA/CG or AWMSG reference (where relevant):
3. Indications for use (If covered by NICE or AWMSG; Is this exactly in accordance with their recommendations?)**:**
4. Estimated number of new patients each month:

5. Will this replace an existing Formulary drug(s)?
6. Evidence of Efficacy: For drugs outside of NICE and AWMSG appraisal process or when proposing to use drug in a manner not in accordance with NICE/AWMSG please provide a reference list of key papers:
7. Place in therapy: (e.g. First line, second line etc) **What are the advantages over existing Formulary drug options and therapies?** **Are there some patient groups who may particularly benefit? (if 'yes' please specify)** **Are there some patient groups that this drug is not suitable for? (if 'yes' please specify)** **Is the proposed usage compatible with current practice in SBUHB? If 'NO' how will practice change to meet these recommendations:**

8. Safety **Is the drug licensed within UK for the requested indication?** **If unlicensed/off-label, what are the alternative treatment options and why can't they be used?** **Are there any restrictions on who should initiate and where this drug should be prescribed?** **Are there any published comparative safety data?** **Are there any clinically important drug interactions?** **Are there any monitoring requirements?**
9. Value for money? **Is there any good quality evidence that it is more cost-effective than other available interventions?**

Are the benefits from this drug worth the costs involved?

What impact would this drug have on the prescribing budget?

10. Infrastructure
What (if any) changes in infrastructure are required to implement use of this drug? (describe any cost impacts of such issues)

Can implementation be achieved via service/role re-design?

Will there be any staff training issues associated with use of this drug?

Will this drug be offered in the same manner in all parts of SBUHB? (if 'no' please specify)

11. Evaluation:

How will you locally monitor implementation of use of this drug? **How will you audit local practice once usage established?**
Requesting Consultant Signature
Date
Relevant Unit Medical Director Signature(s)
Assistant Directorate Finance manager Signature(s) (for NICE/AWMSG/One Wales approvals only):
Date

PLEASE RETURN THE COMPLETED FORM TO FORMULARY PHARMACIST
C/O PHARMACY DEPARTMENT MORRISTON HOSPITAL
ALAN CLATWORTHY
e-mail: Alan.Clatworthy@wales.nhs.uk

COIN clinical online information network

Swansea Bay University Health Board

Authorisation Form for Publication onto COIN

PLEASE ENSURE THAT ALL QUESTIONS ARE ANSWERED – IF NOT APPLICABLE PLEASE PUT N/A

COIN ID.	CID440
Title.	Managed Entry Process for SBU Health Board Joint Drug Formulary
Name and Signature of Author/Chair of Group or Committee.	Alan Clatworthy, Clinical Effectiveness & Formulary Pharmacist
Name and Signature of Lead Pharmacist.	Alan Clatworthy, Clinical Effectiveness & Formulary Pharmacist
Please specify whether the document is New, Revised or a Review of a previous version.	Revised
Please specify the section on COIN where you wish the document to be published.	Pharmacy Formulary & Interface
Please sign to confirm that the document has been authorised by an approved governance process in a specialty or delivery unit.	Medicines Management Board – November 2021
Has NICE guidance been considered/referenced when producing this guidance? If yes, please state the title or reference number.	No
Is the document relevant to the GP Portal?	Yes
Equality Statement (Mandatory for Policies). (1)	N/A
Please specify keywords to assist with searching. (2)	Formulary, New Drug Request, Managed Entry.
Published.	March 2012
Last Review.	November 2021
Next Review/Expiry Date.	November 2023

(1) All policies need to comply with the Policy for the production, consultation, approval, publication and dissemination of strategies, policies, protocols, procedures and guidelines

(2) Relevant keywords will assist COIN users with searching for documents.