



Ymddiriedolaeth Prifysgol GIG  
Abertawe Bro Morgannwg  
University NHS Trust

**Drug Managed Entry Process for Joint  
Formulary**

**(Abertawe Bro Morgannwg University Trust,  
Bridgend LHB, Neath Port Talbot LHB, Swansea  
LHB)**

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***Policy Owner: Medical Director***

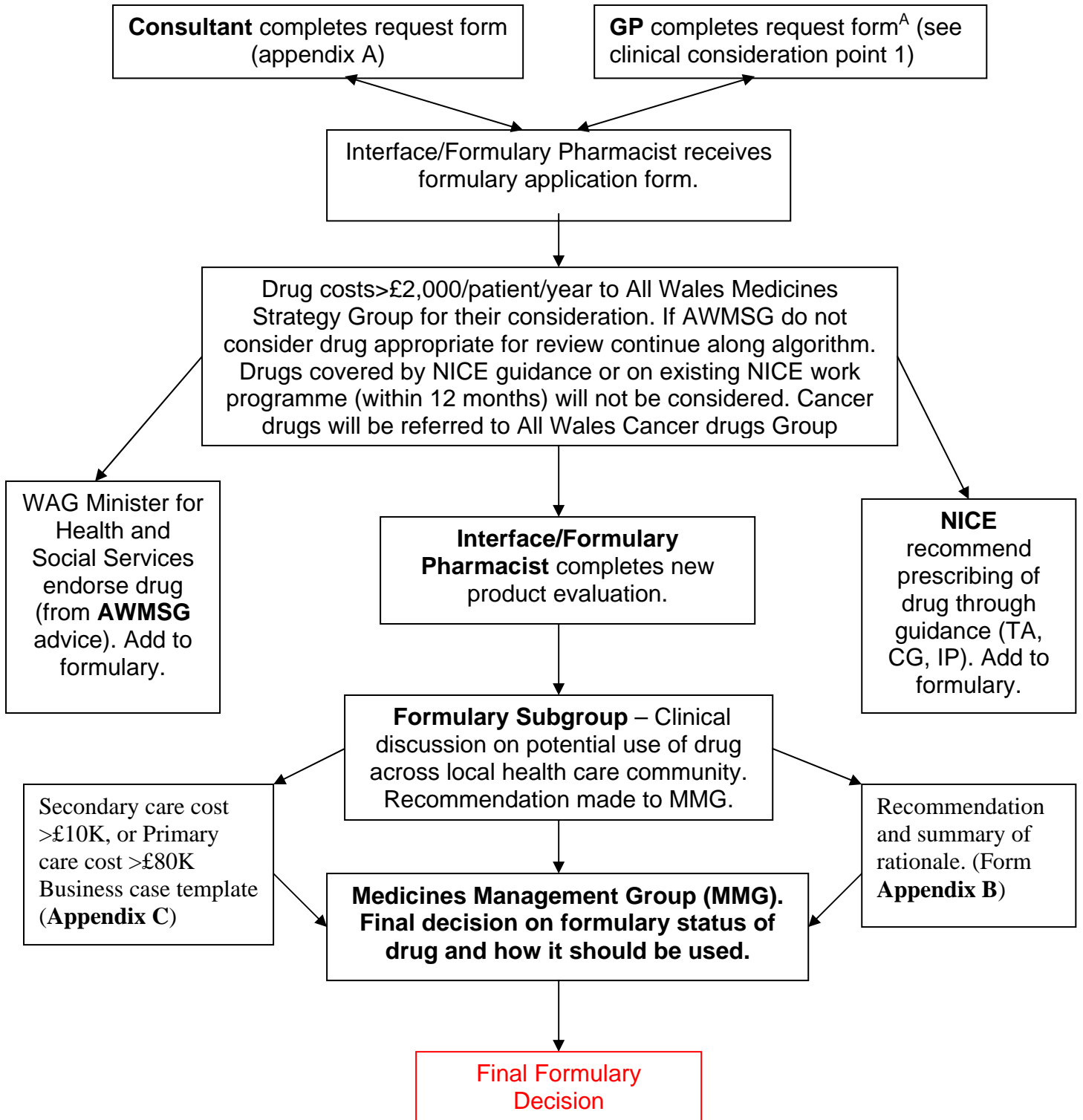
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# Drug Managed Entry Process for Joint Formulary



# **ROLES & RESPONSIBILITIES of INDIVIDUALS and GROUPS within the MANAGED ENTRY PROCESS**

**The Medicines Management Group (MMG) will make final formulary decision on all new formulary requests.**

## **Clinical Considerations**

1. The Joint formulary allows for requests for drug inclusion to the formulary via Consultants in Secondary Care or General Practitioners in Primary Care (in the latter case it is acknowledged that GPs are independent practitioners and as such not bound to the terms of the Joint formulary, however, it is anticipated GPs will recognise the value of the Joint formulary and Medicines Management group as a source of independent prescribing advice and on this basis utilise the managed entry process). Specific “Request to assess a product for formulary inclusion” forms (appendix A) are available from Formulary/Interface Pharmacists (also available on Joint Formulary eBNF site) for this purpose. Forms will only be processed if completely and correctly filled out and returned to Formulary/Interface pharmacists.

The Formulary/Interface pharmacist will contact requestor where specific additional details and rationale for request are required.

2. A “new product evaluation” will be completed by formulary/Interface pharmacist where it is agreed with requestor to process application. 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. If current guidance from NICE (Technology Appraisal (TA), Clinical guideline (CG), Interventional procedure (IP), with specific guidance on use of a drug) or AWMSG approval (with subsequent endorsement from the Welsh Assembly Government Minister for Health and Social Services) already exists, the drugs will automatically be added to the formulary without production of “new product evaluation”. If drugs are already on the AWMSG or NICE work programme (within 12 month forward work programme), local formulary process shall be deferred.

4. The current remit of the All Wales Medicines Strategy Group (AWMSG) requires that all new drugs with a cost in excess of £2,000/patient/year will be considered by that group to make a recommendation on its use in Wales. For this reason, the local managed entry process will only be applied to drugs AWMSG does not consider appropriate (or workload does not allow) for them to review.

**5. Formulary requests for cancer drug treatments will be referred to All Wales Cancer Drugs Group for prioritisation planning.**

**6. A formulary recommendation is made to Medicines Management Group (MMG) from Formulary Sub-group including rationale for this recommendation. MMG members will where relevant receive the full new product evaluations.**

**In addition MMG members will receive a summary of the Formulary Sub-group meeting debate for the requested drug (see appendix B). This will include the pros and cons put forward in consideration of the evidence and whether the group reached unanimous or split decision in terms of the final recommendation made. The group will also specify how the drug should be prescribed (in terms of whether it should be confined to specific areas within the hospital or whether it may also be prescribed in primary care, or subject to shared care- see additional information point 6) and rationale behind this decision.**

### **Financial Considerations**

**1. Secondary Care- Requests with a net cost impact of above £10,000 pa to the Trust will require the drug business case template (appendix C) to be completed and submitted to MMG.**

**2. Primary Care- Requests with a net cost impact of above £80,000 pa to Primary Care across the locality will require the business case template (appendix C) to be completed and submitted to MMG.**

**3. Horizon Scanning- Wherever possible, potential cost impacts of new drugs will be identified by an annual “horizon scanning” process carried out by the Interface/Formulary pharmacists.**

**Note: Directors of Finance for Abertawe Bro Morgannwg University NHS Trust and Local Health Board will receive a completed drug business case template (appendix C) for drugs that meet the above criteria within 48 hours of a positive Formulary Sub-group recommendation being made. Logistically the Formulary Sub-group will meet at alternate months to the Medicines Management Group (both will meet every two months), allowing a minimum of 3 weeks notice to Directors of Finance prior to discussion of that drug at MMG. A final formulary decision (including acceptance or rejection of business case) will be made at that Medicines Management Group meeting. MMG will not approve items where Directors of Finance have rejected the business case.**

## **Dissemination**

- 1. All new drugs added to the Joint formulary will be marked as formulary on the hospital pharmacy system and the eBNF Joint Formulary system.**
- 2. New product evaluations will be linked to the specific drug on the eBNF for information.**
- 3. A list of recent formulary decisions (over last 2 years) will be kept on the Trust Intranet Pharmacy clinical site (accessible via HOWIS).**
- 4. All new formulary decisions will be disseminated via an e-mail to finance manager and clinical director and relevant pharmacist for each Directorate/Division in Secondary Care.**
- 5. Heads of Medicines Management for LHBs will be assisted by Formulary/Interface pharmacist in disseminating information on new formulary approvals in Primary Care.**

## **Audit/Review**

- 1. All new drugs added to Joint formulary will be audited every 6 months after formulary inclusion for a period of 2 years in Primary and Secondary care to ensure cost predictions are not exceeded.**

**For all requests with a cost impact of above £10,000 pa to Trust or LHB a business case will need to be completed by directorate before processing request further.**

- 2. 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; - infection will be reviewed through the antimicrobial sub-group) will be reviewed in turn by MMG at each of its meetings. This will ensure a thorough review of all drugs every 2 years across the locality.**

## **ADDITIONAL DETAILS**

- 1. A list of pending formulary requests will be kept on the Trust Intranet Pharmacy clinical site (accessible via HOWIS) until final formulary decision is reached- it should be noted that the requesting Consultant in Secondary Care may prescribe or recommend the requested product which is pending final formulary decision up to a maximum cost impact of £2,500pa.**

**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/interface 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/Interface pharmacist will not intervene in specific patient cases.)**

**3. Where an immediate decision is required for a non-formulary drug costing >£500 i.e. fast track process for urgent clinical need, agreement of the Medical Director/Deputy Medical Director of the Trust (or LHB if prescribing is in Primary care) is required. This process may be facilitated through the Formulary/Interface pharmacists).**

**4. For non-formulary drugs costing below £500 the drug may be dispensed for one individual patient, for one specific Consultant- Such usage will be audited every 6 months. Requesting consultants will be invited to submit a formulary request at this point and informed that prescriptions for further patients for this drug will need to be discussed with the formulary/interface pharmacist.**

**5. In cases of non-urgent clinical need for an individual patient for a non-formulary drug costing >£2000, the case should be referred to the relevant LHB Individual patient commissioning panel.**

**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.**

**1<sup>st</sup> line- A suitable first choice for GPs and non-specialists.**

**2<sup>nd</sup> 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 Group will be required (this presentation must cover potential associated costs).**

## **APPEALS PROCESS**

**An appeal may be lodged in writing, by the original applicant with the Chairman of the Medicines Management Group 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 Group, 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.**