Hywel Dda University Health Board Medicines Management Group

Request for Addition to Formulary

Please complete all sections fully, as incomplete information may delay the decision of the Medicines Management Group (HDHB MMG)

Name of preparation and form	
Strength of preparation	
Route of administration	
Indication	

Requestor's Name		**Requestor's Signature**	
Date		**Telephone Number**	
Fax Number		**E-mail address**	
Base Organisation		**Directorate**	
Clinical Lead who supports this application:			
Name(s)		**Directorate**	
General Manager(s) who supports/are aware of this application			
Name(s)		**Signature**	

Medicine Characteristics

1	**What is the proposed use of the medicine?** What are the licensed indications?
2	**Is it a novel medicine or an 'addition to class' medicine?**
3	**Are there licence restrictions on who should initiate the medicine?**
4	**Please identify which groups of patients would require this medicine?**
5	**Where would patients be treated?** (e.g. primary or secondary care, inpatient or outpatient)

Evidence of Clinical Effectiveness

6	**Evidence of effectiveness** **(e.g. NICE or AWMSG guidance, NSF, clinical trial reports, peer-reviewed evidence)**
7	**List of references to be considered as evidence/information in support of application:** (please attach electronic copies or provide links to journal web-sites where possible or paper copies of papers)

8	**Are there national guidelines for this condition?** (if yes, please specify) **Are they being followed?**
9	**Are there any local protocols available?** (If yes, please attach)

How safe is the medicine?

9	**Are there any contra-indications to this medicine?** (e.g.Patients who should not receive it?) (If yes, please specify)
10	**Are there any special warnings or precautions for use?** (If yes, please specify)
11	**Are there any clinically important drug interactions?** (If yes, please specify)
12	**Adverse effects profile** (Are there any published comparative safety trials?)
13	**Has it been widely used in other countries?** (If yes, please specify)

14	**Are there any monitoring requirements?** (If yes, please specify)

Place in Therapy

15	**What are the advantages of this medicine over current treatments available?**
16	**Number needed to treat =**
17	**Proposed treatment outcomes (when will treatment be reviewed?)**
18	**What are the implications/risks of not approving/funding this medicine?**
19	**Would this medicine replace any existing preparation in the formulary? (if yes, please specify)**
20	**Do a specific group of patients benefit from this medicine?** (if yes, please specify)
21	**What are the considerations from the patient's perspective?**
22	**Is this medicine suitable for a 'Shared Care Policy'?**
	('Shared Care' is where the patient care while taking the medicine is shared between the GP and the Consultant)

Cost Implications

22	**Duration of treatment**
23	**Predicted number of patients per year**
24	**Cost per patient (including VAT)**
	per month/course/year **(Delete as appropriate)**
25	**Estimated total annual cost/savings to the whole of the local health community?** (Hywel Dda Health Board population is approximately 356,000)
26	**Estimated total annual cost/savings for primary care?**
27	**Estimated total annual cost/savings for secondary care?**
28	**Additional Service implications/costs?** (e.g. Monitoring, staffing, resources)
29	**Are there any potential savings that can be identified?**

Declaration of interests

4a. Please complete the table on the basis of commitments, which have happened, or funding/gifts, which have been received within the last 12 months. Also include any which are planned in the next 6 months.
This should include any personal or *departmental* interest in, or financial associations with, the company producing this drug.

	Outline description/comments
Paid consultancy work (either direct or via an agency)	

Occasional payments for lecturing	
Sponsorship of posts in clinical team	
Sponsorship for conferences or other educational events	
Other sponsorship (e.g. travel)	
Free or compassionate supply of the drug	
Have you or your colleagues been involved in a clinical trial of this medicine?	
Any other associated connections with you or any supporting applicants	
Have the Company been involved in the Preparation of this application?	

I confirm that the above information is correct to the best of my knowledge

…….. (signature)

or

I have nothing to declare …….. (signature)

Please complete and return an electronic copy to: Sue Beach Lead Clinical Development Pharmacist)
Email: sue.beach@.wales.nhs.uk

You will be sent an acknowledgement when your completed form is received. Your request will be taken to the next Hywel Dda UHB Medicines Management Group. You will be asked to comment on the evaluation prepared and encouraged to attend the meeting to present the application.

For Office use only:

- Date received
- Application acknowledged
- Evaluation allocated to: Date:
- Further information requested
- Further information received
- Date of meeting
- Applicant informed of result

- Pharmacy informed

For Committee use

Generic name

Date of meeting

Declared interests

Outcome:
1. Approved
2. Approved for hospital use only
3. Six/twelve month trial period
4. Approval for limited indication (state)
5. Prescribing protocol required
6. Further information required from applicant (state)
7. Opinion from independent specialist/sub-group required
8. To delay the application pending publication of further evidence
9. Application rejected (state reason)

Remarks

Comments/notes