Bwrdd Iechyd Prifysgol Caerdydd a'r Fro
Cardiff and Vale University Health Board

SUPPORTING MANAGED INTRODUCTION OF MEDICINES

(INCLUDING AWMSG/NICE TECHNOLOGY APPRAISAL RECOMMENDATIONS and Local applications)

New Drug Application Process: Part 3

IMPLEMENTATION PLANNING DOCUMENT

Application ID Number (office use)	
Drug name: (Generic, Brand, Form & Strengths):	

Indication(s)/ Summary of recommendation:	

Type of Guidance	NICE Technology Appraisal	
	NICE Clinical Guideline	
	AWMSG Recommendation	
	NICE/AWMSG Evidence Summary	
	Local application	
NICE or AWMSG Reference No. & Date		
Proposed Formulary prescribing category (see tabulation appended for further information)	Initiation (e.g. SI, HO)	
	Place in therapy /pathway (e.g. 2nd line)	
	Special arrangement (e.g. SCP)	

Implementation Lead (Clinician):	
Lead Clinical Board	

Service/commissioning support:	

Summary costs

Please estimate the average annual cost per patient of THIS treatment option (i.e. assuming implementation of this appraisal)		1

Please estimate the average annual cost per patient of **CURRENT** treatment option (i.e. before implementation of this appraisal)		2

Please estimate the total number of NEW patients eligible for treatment with this drug annually (i.e. what is the incidence of this condition)		3

Potential total annual cost impact of this IPD	

Further details of 1-3 will be required below

To which Clinical Boards and/or Directorates does this treatment relate? Please include all areas where patient pathway is relevant i.e. prescribing and/or monitoring.

Is the treatment intended as short- or limited-term, or for longer-term/ongoing maintenance? Please specify details of anticipated duration of treatment.

How is it envisaged that this treatment will be provided? e.g. Consider will it be provided in primary or secondary care? If in secondary care can it be provided in the outpatient setting or as a day case? ***NOTE*** *Where treatment will be provided in multiple settings please indicate all with the most frequent setting first*

Please estimate the average annual cost per patient of THIS treatment option (i.e. assuming implementation of this appraisal)		1

Is there an incremental approach that may be adopted to implement this new treatment option? (Please provide full details, including eligibility criteria and estimated patient numbers for each stage of implementation and outlining risks and benefits of this approach).

Prior to introduction of this treatment how are patients currently managed? (please provide details of usual treatment regimens) Outline current treatment options ***NOTE*** *Please describe the nature of existing treatment (e.g. the names of any medications or procedures used currently)*

How is current treatment provided? *See NOTE 2A*

Please estimate the average annual cost per patient of **CURRENT** treatment option (i.e. before implementation of this appraisal)		2

Is this cost covered by existing LTA, WHSSC or other service agreement?	Yes / No

If yes, please provide details of how costs are recovered and agreements	

Please summarise the clinical benefits of implementing this treatment over existing treatment options

Please summarise the clinical risks of implementing this treatment over existing treatment options

Please quantify the potential impact of this development on the following areas:		Named service lead
Outpatient Attendances		

Daycase Attendances		
Inpatient Activity		
General Practice Workload		
Supporting Investigations (e.g. biochemistry/radiological examinations)		
Pharmacy (e.g. aseptic preparation)		
Other		

For areas identified above, how will increased demand be met, or how will freed resource be released? *(Information to support this section should come from named service leads)*

List specific criteria that will be used to select patients to a) receive this treatment? b) continue or stop treatment? *(Link to audit standards)*

How will measures be introduced that will assure the UHB that patients on treatment meet these criteria?

How will data be collected to demonstrate that patients have met the necessary criteria, and by whom?

Please estimate the total number of NEW patients eligible for treatment with this drug annually (i.e. what is the incidence of this condition)		3

Please list any assumptions made in arriving at this figure:

Please estimate the maximum number of patients currently eligible for treatment with this drug (i.e. what is the prevalence of this condition).	
Of this number, what are the predicted numbers of patients requiring this treatment in	
Year One	

Year Two	
Year Three	

Please list the assumptions made in arriving at the above figures:

Will this treatment be given to patients referred from or resident in Health Boards other than Cardiff and Vale?	
What proportion of patients treated will reside within Cardiff and Vale?	

What will be the strategy for managing the initial demand presented by the prevalent population?

Where treatment is limited to defined course duration, will additional courses of treatment be indicated after completion of the first or subsequent course(s) (e.g. after a period of remission)?	Yes / No / N/A

Please estimate the number of patients likely to receive additional courses of treatment in each year, and the number of such treatments per patient per year:	No. pts:
	No. tx:

Please list any assumptions made in arriving at this figure:

If this treatment is discontinued how will patients be managed?

Estimated total annual drug treatment costs	C&V UHB patients	Other HB patients
Year One		
Year Two		
Year Three		

Estimated total costs avoided as a result of implementing this technology	C&V UHB patients	Other HB patients
Year One		

Year Two		
Year Three		

What is the appropriate audit timescale following introduction of this treatment?
3 months ☐ 6 months ☐ 12 months ☐ Other (specify) ……

Named audit lead(s):

Please provide any additional information in support of effective implementation: *(e.g. relating to associated costs/benefits not otherwise identified; any impact on training needs of prescribers including GPs)*

For all signatories listed below: Please declare any connection you have with the manufacturers of this drug, including personal or financial interests, attendance at conferences or funding of research posts

This implementation planning document must be ratified by the relevant leads and by EACH relevant Clinical Board Director below:

Function	Name	Job title	Date
Clinical lead:			
Pharmacy lead:			
Finance lead:			
Clinical Board Director 1:			
Clinical Board Director 2:			
Clinical Board Director 3:			

(Each box must be completed before IPD is submitted to Medicines Management Group)

INFORM Formulary Prescribing Categories Explained
Please refer to extra notes and pathways for further detail on place in therapy.

Symbol	Category	Definition
G	General Use – all prescribers	Initiation, stabilisation and ongoing monitoring may be undertaken by any prescriber including those in Primary Care.
R	Specialist Recommended	The recommendation to use a specific medicine is made by a specialist but there is no need for the specialist to initiate the medication.
S	Specialist Initiated	Initiation and stabilisation should be undertaken by a specialist. Follow-up prescriptions may be issued by any prescriber.
S (with SCP tag)	Specialist initiated with a Shared Care Protocol	Initiation, stabilisation and on-going monitoring should be undertaken by a specialist, but follow-up prescriptions may be issued by any prescriber following agreement to share care, in accordance with the Shared Care Protocol.
S (with NPT tag)	Specialist initiated with a Shared Care Protocol and Near Patient Testing	Initiation, initial monitoring and stabilisation should be undertaken by a specialist. On-going monitoring and follow-up prescriptions may be issued by any prescriber, following agreement to share care and undertake Near Patient Testing, in accordance with the protocol. Note: Near Patient Testing is subject to a Local Enhanced Service agreement.
H	Hospital Only	Prescribing and monitoring responsibility remains with a specialist. Prescriptions are normally issued from Secondary Care or use only applies in a Secondary Care setting. Any exception to this should be supported by an approved protocol.
NIP	Not In Pathway	Clinical Board Director approval is required
NF	Non-formulary	Medicines that are not included on INFORM medicines formulary. Cardiff and Vale UHB recognises that some patients may require treatment with a non-formulary medicine. See the Health Board's Medicines Code section 4.3.1 "Formulary and non-formulary medicines" for further information.

Diana Fletcher, Formulary Pharmacist. 17/3/16 updated May 2020