WORCESTERSHIRE AREA PRESCRIBING COMMITTEE

Supporting the Decision-Making Process within Worcestershire: Operating Procedures

October 2013

Version:	**3.0**
Ratified by (name of Committee):	Worcestershire Area Prescribing Committee (APC)
Date ratified:	1st October 2013
Date issued:	1st October 2013
Expiry date: (Document is not valid after this date)	1st October 2016
Name of originator/author:	Mandy Matthews
Target audience:	APC members; Redditch and Bromsgrove Clinical Commissioning Group; South Worcestershire Clinical Commissioning Group; Wyre Forest Clinical Commissioning Group; Worcestershire Acute Hospitals Trust; Worcestershire Health and Care NHS Trust; GPs; Other Service Providers

Distribution list
Worcestershire GP Practices
All Providers

CONTENTS

Section	Content	Page
1	Glossary of terms	3
2	Introduction	5
3	Worcestershire Area Prescribing Committee	6
4.1	Governance and accountability	7
4.2.1	Procedures – Agenda setting	8
4.2.2	Procedures – New medicines application	8
4.3.1	Decision making process and criteria	10
4.3.2	Pharmaceutical Industry Schemes	11
4.4	Documentation	12
4.5	Timeliness	12
4.6	Engagement	13
4.7	Communication	13
4.8	Implementation and process improvement	13
5.0	References	14
Appendix 1	Worcestershire Area Prescribing Committee Terms of Reference	15
Appendix 2	New Medicines Application form	21
Appendix 3	Checklist template for New Medicines Application	25
Appendix 4	Guidance on completing New Medicines Application form	27
Appendix 5	Summary of New Medicines Application	29
Appendix 6	Decision Dissemination	31
Appendix 7	Horizon Scanning Framework	32

1. Glossary of Terms

Term	Definition
Annual Commissioning Plan	The *Annual Commissioning Plan or Commissioning Intentions* is a document prepared by the Commissioner which defines the healthcare interventions that will be commissioned for defined categories of patients in each financial year.
Annual Commissioning Round	*The Annual Commissioning Round* is the process by which major funding decisions are taken, including the allocation of new money coming into the NHS. This involves a complex process of prioritisation which involves a series of decisions. This process occurs during the months of October to March for the following financial year.
Clinical effectiveness	C*linical effectiveness* is a measure of how well a healthcare intervention achieves the pre-defined clinical outcomes of interest in a real life population under real life conditions.
Clinical trial	*A clinical trial* is a research study in human volunteers to answer specific health questions. Clinical trials are conducted according to a plan called a protocol. The protocol describes what types of patients may enter the study, schedules of tests and procedures, medicines, dosages, and length of study, as well as the outcomes that will be measured. Each person participating in the study must agree to the rules set out by the protocol. The ethical framework for conducting trials is set out in the Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended). It includes, but does not refer exclusively to, randomised control trials.
Cost effectiveness	*Cost effectiveness* is an assessment as to whether a healthcare intervention provides value for money.
Efficacious	A treatment is *efficacious* where it has been shown to have an effect in a carefully controlled and optimal environment. However, it is not always possible to have confidence that data from trials which suggest that treatments will be efficacious will translate into clinically meaningful health gain and more specifically the health gain of interest. This is the difference between disease oriented outcomes and patient oriented outcomes. For example a treatment might have demonstrated a change in some physiological factor which is used as a proxy measure for increased life expectancy but this relationship might not be borne out in reality.
Exceptional	*Exceptional* means out of the ordinary, unusual or special.
Exceptional clinical circumstances	*Exceptional clinical circumstances* are clinical circumstances pertaining to a particular patient which can properly be described as exceptional. This will usually involve a comparison with other patients with the same clinical condition and at the same stage of development of that clinical condition and refer to features of the particular patient which make that patient out of the ordinary, unusual or special compared to other patients in that cohort. It can also refer to a clinical condition which is so rare that the clinical condition can, in itself, be considered exceptional. That will only usually be the case if the NHS commissioning body has no policy which provides for the treatment to be provided to patients with that rare medical condition.
Experimental and unproven treatments	*Experimental and unproven treatments* are medical treatments or proposed treatments where there is no established body of evidence to show that the treatments are clinically effective. The reasons may include the following: • The treatment is still undergoing clinical trials for the indication in question. • The evidence is not available for public scrutiny. • The treatment does not have approval from the relevant government body. • The treatment does not conform to an established clinical practice in the view of the majority of medical practitioners in the relevant field. • The treatment is being used in a way other than that previously studied or for which it has been granted approval by the relevant government body. • The treatment is rarely used, novel, or unknown and there is a lack of evidence of safety and efficacy.

	• There is some evidence to support a case for clinical effectiveness but the overall quantity and quality of that evidence is such that the commissioner does not have confidence in the evidence base and/or there is too great a measure of uncertainty over whether the claims made for a treatment can be justified.
Healthcare intervention	A *healthcare intervention* means any form of healthcare treatment which is applied to meet a healthcare need.
In-year service development	An *in-year service development* is any aspect of healthcare, other than one which is the subject of a successful individual funding request, which the commissioner agrees to fund outside of the annual commissioning round. Unplanned investment decisions should only be made in exceptional circumstances because, unless they can be funded through disinvestment, they will have to be funded as a result of either delaying or aborting other planned developments.
NHS commissioned care	*NHS commissioned care* is healthcare which is routinely funded by the patient's responsible commissioner. The Commissioner has policies which define the elements of healthcare it is and is not prepared to commission for defined groups of patients.
Priority setting	*Priority setting* is the task of determining the priority to be assigned to a service, a service development, a policy variation or an individual patient at a given point in time. Prioritisation is needed because the need and demands for healthcare are greater than the resources available.
Rule of rescue	*Rule of rescue* is the observation that human beings, in situations where an individual's life is at risk, have the proclivity to take action to rescue the individual regardless of the cost and the chances of success. Action taken, therefore, is in part about meeting the emotional needs of the decision maker. In the healthcare setting the term has been used in a number of ways. In the West Midlands the term refers to agreeing funding for treatments for patients whose prognosis is grave on the basis that their prognosis is grave and without regard to cost or ability to benefit.
Service Development	A *Service Development* is an application to the commissioner to amend a commissioning policy to provide that a particular healthcare intervention should be routinely funded for a defined group of patients. The term refers to all new developments including new services, new treatments (including medicines), changes to treatment thresholds, and quality improvements. It also encompasses other types of investment that existing services might need, such as pump-priming to establish new models of care, training to meet anticipated manpower shortages and implementing legal reforms. Equitable priority setting dictates that potential service developments should be assessed and prioritised against each other within the annual commissioning round. However, where investment is made outside of the annual commissioning round, such investment is referred to as an *in-year service development*.
Strategic planning	*Strategic planning* is the process by which an organisation determines its vision, mission, and goals and then maps out measurable objectives to accomplish the identified goals. The outcome is a *strategic plan* which sets out what needs to be done and in what time scale. Strategic planning focuses on what should be achieved in the long term (3, 5, 7, or 10 year time span) while operational planning focuses on results to be achieved within one year or less. Strategic plans should be updated through an annual process, with major re-assessments occurring at the end of the planning cycle. Strategic planning directs how resources are allocated.
Treatment	*Treatment* means any form of healthcare intervention which has been proposed by a clinician and is proposed to be administered as part of NHS commissioned and funded healthcare.
Value for money	*Value for money* in general terms is the utility derived from every purchase or every sum spent.

2. Introduction

Commissioners of healthcare services are required to provide a comprehensive health service which is available to the entire community based on clinical need, not the ability to pay. They are also required to operate within finite budgets and so have to prioritise some treatments over others according to the needs of local communities. Such local priority decisions have led to variations between services funded by commissioners, which can give rise to concerns.

The Next Stage Review[1] outlined plans for guaranteed access to the most clinically and cost-effective treatments. These are reinforced by the NHS Constitution[2], which aims to address variations in the availability of medicines and treatments resulting from inconsistency in local decision-making processes.

The constitution provides guidance for the public, including what they can expect about how decisions are made locally. It states '***You have the right*** *to expect local decisions on funding of other drugs and treatments to be made rationally following a proper consideration of the evidence. If the local NHS decides not to fund a drug or treatment you and your doctor feel would be right for you, they will explain that decision to you.'*

NHS Directions and guiding principles came into effect on 1st April 2009, to support local decision making about medicines. The scoping statement and nine guiding principles are shown in Figure 1:

Figure 1

THE GUIDING PRINCIPLES FOR PROCESSES SUPPORTING LOCAL DECISION MAKING ABOUT MEDICINES[3]

SCOPING STATEMENT

The guiding principles have been developed to support local decision making about medicines. This includes decisions on medicines made as part of the development of the annual operating plan as well as consideration of in-year service developments and individual funding requests (IFRs). The principles are designed to cover decision making across primary and secondary care on all medicines not, or not yet, appraised by NICE. While these principles are directed at PCTs*, they should equally apply to any collaborative arrangements PCTs* may choose to adopt.

Local decisions about medicines should be made in the context of, and be consistent with, national policies including local priorities, prioritisation processes and governance frameworks. Decisions should take into consideration clinical and cost effectiveness relative to other interventions commissioned by the PCT* for its population, as well as the available budget.

PCTs* should:

1. Establish decision-making groups, with a clearly designated focus of accountability, which include a locally-defined mix of members with the appropriate range of skills

2. Establish a set of robust decision-making procedures which, where appropriate, allow recommendations to be developed through collaboration across PCTs*

3. Define clearly, and then consistently apply, standard criteria for decision making.
Decisions should be based on the best available evidence, take into account the appropriate ethical frameworks and comply with statutory requirements

4. Document thoroughly the application of decision-making procedures and the rationale for each decision

5. Make decisions in a reasonable and practical timeframe, but without compromising the minimum process requirements, even when requests are urgent

6. Establish an appeals process for decisions made on IFRs, including clearly defined grounds for appeal, independent of the original process and open to patients and their clinicians

7. Take reasonable steps to engage with stakeholders including the wider NHS, patients and the public to help increase understanding of local priority setting about medicines

8. Communicate clearly with stakeholders including the wider NHS, patients and the public. Communication should include the processes, decisions and the rationale for decisions, while maintaining appropriate confidentiality

9. Establish assurance processes to monitor the application and performance of decision-making arrangements, and to enable learning to be incorporated into future process improvements

*From 1st April 2013 this should be read as Clinical Commissioning Groups (CCGs)

3. Worcestershire Area Prescribing Committee

The Worcestershire Area Prescribing Committee (APC) is a strategic decision-making committee of health care provider representatives across Worcestershire operating in a partnership capacity. The overall aim of the committee is to manage medicines usage across the Worcestershire health economy. This requires that the committee is pro-active with its health economy partners, taking a strategic approach by co-ordinating and directing policy across primary and secondary care, between Trusts and between clinical networks where possible.

The central principles of equitable, rational prescribing and medicines use, namely clinical and cost effectiveness, appropriateness (including convenience), safety, equitable provision of medicines and financial management, guide the thinking and outputs of the committee. The Terms of Reference for the Worcestershire APC are shown in Appendix 1.

The Worcestershire APC is one of a number of groups which feed into the overall decision-making process, as shown in figure 2:

Figure 2: Decision-Making Map

National level:	NICE and other national guidance NHS England (NHSE)	
Local Area Team:	Prescribed Specialist Services	Strategic Clinical Networks* Clinical Senate*
Arden & Worcestershire:	Commissioning Support Unit (CSU)	
Local level:	Area Prescribing Committee (APC) Worcestershire Clinical Commissioning Groups	NHSW Clinical Policy Collaboration (CPC)*
Individual patient level:	Individual Funding Request Process	

* Represents advisory groups, which may provide recommendations to the Worcestershire APC for consideration.

In February 2009 the National Prescribing Centre (NPC) produced a handbook of good practice guidance, 'Supporting rational local decision-making about medicines

(and treatments)'[4], which included a DH guiding principles checklist for all decision-making or advisory committee groups to complete to ensure their fitness for purpose. The Worcestershire APC completed the checklist and developed an action plan to ensure that they have a robust, transparent process in place for considering new medicines and treatments, and so improve the consistency of decision-making within NHS Worcestershire. A copy of the action plan is available via the professional secretary of the APC. One of the key actions agreed by the APC members was the need for operating procedures defining the committee's role in supporting NHS Worcestershire to make decisions about new medicines and treatments.

This document does not apply to those medicines which are within the remit of the National NHS Commissioning Board (NCB), via the Prescribed Specialist Services.

4. Supporting Effective Decision-Making within Worcestershire

4.1. Governance and Accountability

The membership and governance arrangements are included in the APC Terms of Reference (see Appendix 1).

The Worcestershire APC will undertake work on behalf of the three Worcestershire Clinical Commissioning Groups (CCGs), Worcestershire Acute Hospitals Trust and Worcestershire Health and Care Trust. This is defined in the Collaborative Arrangement as part of the Terms of Reference Appendix 1.

Clinical decision-making will be based on the consensus[1] view of the members of the APC. Financial decision-making will be via delegated authority. The Head of Medicines Commissioning in South Worcestershire CCG has delegated authority for all three CCGs for decision making associated with operation of the APC in accordance with its Terms of Reference. The Head of Medicines Commissioning will make decisions relating to use of medicines within Worcestershire, on the basis of the consensus[1] view of the members of the APC.

Where clinical agreement is not reached by members of the APC, the application will be reconsidered at a future meeting together with further supporting information. Should members still not reach a consensus view, the decision will be to reject the application. Financial approval is required from each CCG Governing Body where significant, unplanned cost or risk is identified.

All applications for in-year service developments, relating to new medicines and new indications for existing medicines, should be submitted to the Worcestershire APC for consideration in line with local strategic priorities and financial commitments.

In deciding whether to introduce a service 'in year' and/or in considering whether to introduce an interim commissioning policy, the Worcestershire APC

[1] For the purpose of this document, consensus is defined as: 'a group decision making process that seeks the consent of all participants; it may be defined professionally as an acceptable resolution, one that can be supported, even if not the 'favourite' of each individual'. The term 'consensus' describes both the decision and the process of reaching a decision. Consensus decision-making is thus concerned with the process of deliberating and finalising a decision, and the social and political effects of using this process.

will seek to apply the principles of priority setting, albeit that it will need to engage in an element of singular decision making. Considerable evidence of both the clinical effectiveness and cost effectiveness of the proposed service development will be required before a change to local policy in-year, to make the treatment available, is made. When making this decision the following factors will be considered:

- What is the quality and quantity of evidence in support of the treatment? The APC will require a substantial body of impartially verified evidence before agreeing to fund a treatment in-year.
- What are the proven benefits of the treatment versus standard treatment?
- Is this value for money?
- How much does the treatment cost per patient?
- What disinvestment opportunities are there within the programme budget to fund this new service development?
- How many patients are likely to seek the treatment and what will be the overall cost to the health economy if the request is granted and the decision made to fund the treatment in-year?
- What is the current financial position?
- What service development proposals were not funded in the last annual commissioning round or have been refused in-year funding, and does the proposed treatment have a clearly higher priority than those proposals?

For further information on service developments, refer to the Commissioning Policy 'In-Year Service Developments and the PCT approach to treatments not yet assessed and prioritised, WM/8' and Worcestershire CCGs' 'Prioritisation Framework for the Commissioning of Health Services', currently available at: http://www.worcestershire.nhs.uk/policies-and-procedures/commissioningindividual-funding-requests-ifr/

4.2. Procedures

4.2.1. Agenda setting

The professional secretary will set the agenda for each APC meeting, in collaboration with the Chair, using a standard template. A number of standing agenda items are included, such as financial update, new medicine applications and local guidance. Members may submit items for inclusion on the agenda to the Chair or professional secretary. One meeting per year, usually in November, will focus entirely on horizon scanning for the following financial year. Potential financial implications for the following year will be considered by the three CCGs. The Horizon Scanning Framework is outlined in Appendix 7.

4.2.2. New medicine applications

- **The following information applies to those medicines which are within the remit of CCGs and so does not apply to those medicines which are within the remit of the NCB Prescribed Specialist Services.**
- Until a service development has been assessed and a policy decision has been taken as the result of prioritisation, whether in-year or during the annual commissioning round, the default interim position will usually be not to fund a treatment unless otherwise stated.

- An application is required for any new product likely to be used in more than one similar patient, which is not on the Worcestershire Joint Medicines Formulary. This applies to products normally prescribed on FP10 or kept within secondary care. It also applies to new indications for use of existing products on the formulary.
- An application form may be obtained from one of the secretaries of the APC, Worcestershire Acute Hospitals Trust Medicines Safety Committee (MSC) or the Worcestershire Health and Care Trust Medicines Management & Safety Sub-Committee (MMSSC). A copy of the application form is shown in appendix 2.
- The form has been designed to guide the applicant through the thought processes necessary to consider the incorporation of a product into routine practice, using a rational and evidence-based approach. Provision of detailed information will help the Committee make a faster decision. If the application form does not contain sufficient information for full consideration of the request it will be returned to the applicant.
- Applicants should discuss the application and the completed form with colleagues within the appropriate pharmacy team. Suggested contacts are*:*
    - Worcestershire Acute Hospitals Trust: Nick Hubbard, Alan Catterall
    - Worcestershire Health and Care Trust: John Morrison, Andy Down
    - Primary Care: Anne Kingham
    - Clinical Networks: Mandy Matthews

  This is initially to ensure that the application form has been completed satisfactorily. Incomplete forms received by the APC secretary, including those which are not signed by the applicant and countersigned by the relevant clinical director, will be returned to the applicant. The application should also be considered within the requesting organisation to ensure that there is sufficient evidence to progress the application.
- Whilst applicants may seek support from the Pharmaceutical Industry in completing sections of the application, completion of the entire form by the Industry is not acceptable.
- The completed application, together with supporting papers, should be submitted to the APC secretary. The form must be received a minimum of two weeks before the next APC meeting in order to be discussed at that meeting. The APC meets monthly and the applicant will be notified when the application is due to be discussed.
- Clinicians are encouraged to put forward a case in person at the APC and in some cases this is essential. If other commitments prevent this, then a nominated deputy may attend. The presentation should be brief (no more than ten minutes), its purpose being to provide an overview and be able to respond to questions raised regarding the application.
- If a product is subsequently approved for use, it is highly likely that guidance on use will be requested, including the products place in therapy. This information will need to be approved by the committee before the product is added to the formulary. If appropriate guidance is submitted with the initial application this may speed up this process.
- Applicants will be informed of the Committee's recommendation at the earliest opportunity following the meeting, up to a maximum of seven working days after the decision has been made.

- If the product is not recommended for local use, an appeal may be made and a further presentation made to the committee, by arrangement with the professional secretary.
- An Individual Funding Request (IFR) should be dealt with in line with the local IFR policy and supporting operating procedures.
- IFRs within Worcestershire Acute Hospitals Trust (WAHT) or Worcestershire Health and Care Trust (WHACT) will be considered initially within the respective Trust:
    - If the request is less than £2500 per patient per year, and there are considered to be no similar patients, the Trust will consider the available evidence and approve or decline accordingly.
    - If the request is more than £2500 per year, there is likely to be no similar patients and there is supporting evidence of clinical and cost-effectiveness the Trust will ask the clinician to complete the IFR pro-forma and submit it to local commissioners for consideration.
    - If there are considered to be similar patients the request will not be considered as an IFR. The applicant will be encouraged to submit an application to APC, for the routine use of the medicine.

4.3.1 Decision-making process and criteria

- Completed application forms and supporting information will be circulated electronically to the APC members at least five working days prior to the meeting.
- A search for relevant supporting information, including national guidance (NICE, SMC, AWMSG), other health communities' recommendations [for example the London Cancer New Drugs Group (LCNDG)] and critical appraisal of the supporting evidence (as available) will be undertaken. A template used to provide any supporting information is shown in Appendix 3. This will be updated with the rationale for the recommendation made by the committee, once the application has been considered.
- APC members will consider the application form, supporting evidence, presentation from applicant and answers to specific questions raised, specifically taking into account the following criteria:
    - nature of health outcomes/benefits to be gained & impact on the patient group, community or service
    - clinical effectiveness
    - level of confidence in the evidence underpinning the application
    - cost-effectiveness/value for money
    - safety
    - assessment of risks
    - alignment to DH or local priorities
    - equity/access
    - patient choice
    - budgetary impact
- Clinical decisions will be reached through a voting system that may require individual votes/views being recorded.
- Decisions will be agreed on a majority vote, providing that a consensus is reached.
- If the Head of Medicines Commissioning is not present at the meeting, they will be asked to approve any decision(s) made by the committee after the meeting. This will be recorded in the minutes.

- In order to manage agendas for APC meetings, certain decisions will be agreed by email, for example final approval of local guidance or on those occasions when a decision is required more rapidly than waiting for the next APC meeting. In these circumstances the final decision will be fed back to the committee at the next available APC meeting and recorded in the minutes.
- If the APC's decision is that the new medicine/treatment should not be routinely funded, the applicant will be informed of the decision within seven working days of the decision being made. (Note, the decision is made if the Head of Medicines Commissioning agrees with the consensus view of the committee).
- If APC's decision is that the new medicine/treatment should be routinely funded, the applicant will be informed of the decision within seven working days of the decision being made. (Note, the decision is made if the Head of Medicines Commissioning agrees with the consensus view of the committee)
- If the APC clinically supports the use of a new medicine/treatment and there are significant unplanned cost or risk, financial approval will be required from the CCG Boards.
  N.B. No requested service development shall be approved unless Worcestershire APC can reach a clear conclusion that the requested treatment satisfies the following tests:

    - The proposed service development would have been highly likely to have been supported in the last annual commissioning round, in priority to those service developments which were not funded;
    - The proposed service development is both clinically effective and cost effective; and
    - The proposed service development is affordable in the current financial year.

Local guidance to support the applicant through the new medicines application process is shown in Appendix 4. A quick reference guide is available in Appendix 6.

4.3.2 Pharmaceutical Industry Schemes

The pharmaceutical industry is increasingly offering schemes within primary care, which pay a retrospective discount based on sales of a particular product within the community. Such discounts may provide significant efficiency savings, however there is also a risk that they may alter local prescribing adversely.

This information seeks to address this risk, by outlining the process within Worcestershire for considering participation in such schemes.

Details of proposed schemes may be submitted to GPs or pharmacists within the CCG by the pharmaceutical industry; these should be forwarded to the Head of Medicines Commissioning for consideration by the Worcestershire Area Prescribing Committee (APC). The NHS Midlands and East Pharmaceutical Industry Scheme Governance Review Board undertakes clinical and financial assessments for a range of these schemes. Their assessments and recommendation will be used by the APC, when considering whether the scheme should be adopted locally.

A scheme will only be considered if the medicine it relates to has already been approved for addition to the local formulary; where a medicine application is being considered by the Worcestershire APC, the final decision of whether the medicine is

approved will be based on the full cost price of the medicine rather than a discounted price, that is the scheme will not be considered in the decision-making process.

When considering whether a scheme should be adopted locally, the APC will consider the following:
Benefit:

- Does the scheme make the agent the most cost-effective intervention?
- What thresholds are included? How easy will it be to achieve any thresholds?
- What is the payback?
- Are the benefits clear and transparent?

Burden:

- Is the scheme simple to operate/administer?
- Are the benefits guaranteed?
- What is the length of the scheme? Are there any market uncertainties?
- Are there significant penalty clauses?

4.4. Documentation

Policies and processes for local decision making for medicines and treatments, including the role of advisory bodies, need to be clear to patients and clinicians and publicly available. The following commissioning policies and operating procedures are currently available via the Worcestershire CCGs or electronically at: http://www.worcestershire.nhs.uk/about-us/publications/policies-and-procedures/

- Supporting the decision-making process within Worcestershire: Worcestershire Area Prescribing Committee Operating Procedures.
- In-Year Service Developments and the PCT approach to treatments not yet assessed and prioritised policy.
- Managing In-year Service Developments – Operating Procedures.
- Ethical framework
- Individual Funding Requests policy.
- Individual Funding Request - Operating Procedures.

Reasons for general policy on whether a particular medicine or treatment is available are also be available in writing from the Worcestershire CCGs.

Each new medicine application is supported by a checklist detailing other available information relevant to the application. Once the application has been considered by the APC the rationale for the recommendation is recorded on this checklist. Copies of new medicine application checklists are available from the APC on request.

To aid consistency in the consideration of new medicine applications a variety of templates are available, including an application form, supporting checklist, local policy/guidance and minutes.

4.5. Timeliness

The APC will adhere to the following timescales:

- Upon receipt of a completed application at least two weeks before the next APC meeting, members will consider the application and supporting information at the next available meeting. On those occasions when the agenda is already full the applicant will be contacted and an alternative date agreed.
- If an application form does not contain sufficient information it will be returned to the applicant for completion.

- Once the application has been considered the applicant will be informed as shown below:
    - Recommendation not to fund: within seven working days of when decision made.
    - Recommendation to fund (no financial implications): within seven working days of when decision made.
    - Recommendation to fund (financial implications): within seven working days of when application considered by all three CCG Clinical Executive/Management Teams.

  Urgent requests:

  Urgent Individual Funding Requests are managed by the IFR Team. If an 'urgent' service development for a new medicine or indication is necessary, the request may be considered electronically by the APC members, providing sufficient information is made available for an informed decision to be made. The APC application should be completed as fully as possible and supporting evidence provided.

  If the supporting evidence is equivocal or a unified clinical decision is not supported, the application will need to be reconsidered at the next face-to-face APC meeting.

4.6. Engagement

The involvement of stakeholders within the APC is a key factor in supporting the committee to achieve its aim of managing medicine use effectively across the Worcestershire health economy.

Patient and public involvement (PPI) is an essential element of the functioning of the APC; a PPI representative will be invited to each APC meeting. Copies of the approved minutes for each meeting are provided to each of the PPI representatives who link with the APC.

4.7. Communication

There is a general feeling that the understanding of Provider Trusts and clinicians, regarding the role and functions of the Worcestershire APC, could be improved. This operating framework has been developed to raise awareness amongst clinicians and support them in submitting new medicine applications.

A variety of methods are used for communicating recommendations to relevant stakeholders, as detailed in appendix 6 and in the Terms of Reference.

4.8. Implementation and process improvement

Decisions made by the Worcestershire APC will be communicated back to the original requesting clinician and any supporting guidance requested/agreed. Worcestershire guidance will be sent to all relevant providers for implementation.

New evidence, which relates to local guidance, will be reviewed as it emerges. Existing guidance will be reviewed on a three year rolling programme.

The APC will undertake a self-assessment activity once every two years, using the resources provided by the Medicines and Prescribing Centre. An action plan will be agreed to address any areas for improvement.
The internal functions of the APC will be monitored using the following key performance indicators:

- Meeting is quorate – standard 100%
- New medicine applications completed and supporting information provided – standard 100%
- Resources checklist completed – standard 100%
- APC papers circulated at least five working days before meeting – standard 100%
- Decision-making criteria applied to all new medicine applications – standard 100%
- Rationale for decision made documented within checklist for new medicine applications – standard 100%
- Applicant informed of the APC decision within seven working days of final decision being made – standard 100%

Adherence to the APC local guidance will be monitored by:

- Analysis of prescribing data (primary and secondary care)
- Specific audit of identified guidance

A KPI report will be included with the quarterly report to the CCGs.

5.0. References

1. Department of Health. High Quality Care For All - Next Stage Review Final report; June 2008.
http://www.official-documents.gov.uk/document/cm74/7432/7432.pdf

2. Department of Health. The Handbook to the NHS Constitution; March 2013. http://www.nhs.uk/choiceintheNHS/Rightsandpledges/NHSConstitution/Documents/2013/handbook-to-the-nhs-constitution.pdf

3. Department of Health. Defining Guiding Principles for Processes Supporting Local Decision Making About Medicines Final Report; January 2009. http://www.npc.nhs.uk/local_decision_making/resources/guiding_principles.pdf

4. National Prescribing Centre. A Handbook of Good Practice Guidance - Supporting Rational Local Decision Making about Medicines (and Treatments); February 2009.
http://www.npc.co.uk/local_decision_making/resources/handbook_complete.pdf

Other documents used to inform this guidance historically in version 1:

- NHS Confederation Priority Setting Series, 2008.
- West Midlands Strategic Commissioning Group – Commissioning Policy Individual Funding Requests W/M 9, Version 2; February 2012.
- West Midlands Strategic Commissioning Group – Commissioning Policy In-Year Service Developments and the PCT's approach to treatments not yet assessed and prioritised W/M 8, Version 2; February 2012.

- West Midlands Strategic Commissioning Group – Ethical Framework to support priority setting and resource allocation within collaborative commissioning arrangements W/M 1, Version 2; February 2012.

- NHS Worcestershire Commissioning Policy. Prioritisation Framework for Commissioning Health Services; July 2010.

Appendix 1: Worcestershire Area Prescribing Committee Terms of Reference

The Area Prescribing Committee (APC) is a strategic decision-making committee of Trust representatives across Worcestershire operating in a partnership capacity.

AIM

The aim of the committee is to manage medicines usage across the Worcestershire Health Economy. This requires that the committee is pro-active; taking a strategic approach by co-ordinating and directing policy across primary and secondary care, between Trusts and between clinical networks where possible.

The central principles of equitable, rational prescribing and medicines use, namely clinical and cost effectiveness, appropriateness (including convenience), safety and financial management, will guide the thinking and outputs of the committee.

SCOPE

The APC will undertake work on behalf of the three Worcestershire Clinical Commissioning Groups (CCGs), Worcestershire Acute Hospitals NHS Trust (WAHT) and Worcestershire Health and Care Trust (WHACT), relating to the use of medicines identified through analysis of individual funding requests, contract review meetings, NICE programme of work and other issues identified as they arise. This will include the introduction of new medicines/indications, funding considerations and development of local guidance. **Medicines which are within the remit of NHS England Prescribed Specialist Services will not be considered by the APC.**

Local policies developed by the APC will be subject to an Equality and Diversity Impact Assessment.

The Worcestershire APC will undertake work on behalf of the three Worcestershire Clinical Commissioning Groups (CCGs), Worcestershire Acute Hospitals Trust and Worcestershire Health and Care Trust. (see Collaborative Arrangements)

Clinical decision-making will be based on the consensus[2] view of the members of the APC. Financial decision-making will be via delegated authority. The Head of Medicines Commissioning in South Worcestershire CCG has delegated authority for all three CCGs for decision making associated with operation of the APC in accordance with its Terms of Reference. The Head of Medicines Commissioning will make decisions relating to the use of medicines within Worcestershire, on the basis of the consensus[2] view of the members of the APC.

Where clinical agreement is not reached by members of the APC, the application will be reconsidered at a future meeting together with further supporting information. Should members still not reach a consensus view, the decision will be to reject the application. Financial approval is required from each CCG Governing Body where significant, unplanned cost or risk is identified.

[2] For the purpose of this document, consensus is defined as: 'a group decision making process that seeks the consent of all participants; it may be defined professionally as an acceptable resolution, one that can be supported, even if not the 'favourite' of each individual'. The term 'consensus' describes both the decision and the process of reaching a decision. Consensus decision-making is thus concerned with the process of deliberating and finalising a decision, and the social and political effects of using this process.

Any policy development requests for new non-medicine technologies will be considered via the Worcestershire Clinical Policy Collaboration.

Medicines in the context of this document include prescribable (FP10) appliances.

MEMBERSHIP

- Clinical Commissioning Group x 8 representatives, including:
  - GP representative from each CCG
  - Head of Medicines Commissioning
  - Primary Care Medicines Lead
  - Secondary Care Medicines Lead
  - Clinical Effectiveness Pharmacist (APC secretary)
  - Commissioning Manager
- Consultant in Public Health
- Worcestershire Acute Hospitals Trust (clinical and pharmaceutical) x 6 representatives
- Worcestershire Health and Care Trust (clinical and pharmaceutical) x 4 representatives
- PPI representative
- Nursing/allied healthcare professional representation as required
- Representative clinicians for discussions around specific medicine requests

TERMS OF REFERENCE

Clinical

1. To act as a focus for developing and refining local professional opinion on medicines, therapeutics and associated pharmaceutical issues in consideration of the financial implications, and to convey such opinions to all relevant organisations and bodies, including those not directly represented on the committee.
2. To inform the commissioning process, based on the available evidence, regarding the place in treatment locally of relevant new medicines / formulations, or of existing medicines with new indications.
3. To develop a unified approach to the introduction of new treatments, local policies and national guidance involving medicines across Worcestershire.
4. To lead formation, development and implementation of medicines management policies, formularies and guidelines for Worcestershire.
5. To assist resolution of problems relating to prescribing at the interface between primary, secondary, tertiary and social care.

Commissioning/Finance

6. To forecast developments in healthcare which involve the use of medicines and provide effective advice on the local clinical and financial implications of such developments and their management.
7. To consider the financial implications of new medicines and agree appropriate levels of funding, advising local commissioners and provider trusts as appropriate.
8. To respond promptly to local, regional and national changes in NHS policy that will affect prescribing and medicines management locally, including NICE guidance, outlining the financial implications.
9. To contribute to the commissioning process to ensure that prescribing and medicines use issues are given due weight in wider healthcare planning and service delivery agreements locally.
10. To monitor the decision-making process and expenditure by the WAHT and WHACT for unexpected costs incurred without prior APC authorisation e.g. where an immediate funding decision is required.

11. To manage expenditure on new medicines/developments and changes in health care policy that involve medicines, within the allocated resources.
12. To monitor WAHT baseline expenditure and review prescribing practice, advising as appropriate in the interests of the health economy.

MEETING FORMAT

- A quorum is defined as a minimum of 8 members present, including at least one CCG GP representative, at least one representative from each of the WAHT, the WHACT and the Medicines Commissioning Team SWCCG.
- If any member of the APC is unable to attend they should provide comments on agenda items before the meeting where possible.
- Meetings will be held monthly.
- The committee will democratically elect the Chairman and deputy and this appointment will be reviewed on an annual basis in December.
- South Worcestershire CCG hosts the administration of the meetings and associated correspondence with additional clinical support from all other organisations. This is detailed in the Collaborative Arrangement (see end).
- Papers will be circulated electronically at least five working days before the meeting.
- Documentation should be kept for a minimum of six years.
- Decisions will be reached through a voting system that may require individual votes/views being recorded. Decisions will be adopted on a majority vote, providing that a consensus is reached.
- If the Head of Medicines Commissioning is not present at the meeting, they will be asked to approve any decisions made by the committee after the meeting. This will be recorded in the minutes.
- Where there is a divergence of opinion between the consensus view and the Head of Medicines Commissioning with delegated authority, the application will be reconsidered at a future meeting. Should the divergence of opinion remain, the issue will be referred to CCG Management Teams/Clinical Executive for a final decision to be made.
- Where the committee fails to reach a consensus view, further discussions will be held at a future meeting. If a consensus is still not reached, the application will be rejected.
- The committee will hold a register of interests with new declarations recorded at the start of each meeting from members present.

AUTHORITY

CCG Boards are required to authorise the APC to undertake any activity falling within its terms of reference.

Quarterly reports to CCG Clinical Executive/Management Teams will include details regarding any financial arrangements associated with decisions made by the APC.

Where the APC members fail to reach a consensus view following two considerations (meetings) the application will be rejected.

Where an APC guidance/policy has significant and unplanned financial implications or represents a high risk to organisations involved, this will be referred to CCG Boards for a final decision to be made.

Resources will be allocated following consideration of the horizon scanning/budget planning document as part of the annual commissioning process. Allocated resources will be managed either through delegation to the WAHT or held by the CCGs. This will be defined as part of the horizon scanning/budget planning process.

RESPONSIBILITY OF MEMBERS

- All members should have nominated deputies who can attend in their absence.
- If any member has financial or personal interests, whether pecuniary or otherwise, in any related matter that is the subject of consideration, they should declare such interest, in advance. All declarations of interest made as a result of this provision, and any action taken, will be noted in the minutes of the meeting.
- Resignation from the committee may be made at any time by notice to the Chairman, in writing.
- Nominated organisation representatives should agree a standard approach for dissemination of information.
- WAHT: feedback is via the Medicines Safety Committee (MSC), with specific information on new medicine requests/introduction of new medicines directed at relevant clinicians/departments.
- WHACT: feedback is via the Medicines Management Safety Sub-Committee (MMSSC).
- South Worcestershire CCG: feedback is via the Prescribing Newsletter; liaison with GP colleagues.
- Redditch & Bromsgrove CCG: *as above*
- Wyre Forest CCG: *as above*
- All members should ensure that organisational colleagues are aware of how, when and to whom they should feed in issues for consideration by the APC.
- All organisations are expected to follow the APC operating procedures entitled: 'Supporting the Decision-Making Process within Worcestershire'.
- Organisation representatives are responsible for ensuring timely dissemination of decisions made by the committee.

MONITORING

- The APC will undertake a self-assessment activity once every two years, using the resources provided by the Medicines and Prescribing Centre. An action plan will be agreed to address any areas for improvement.
- The internal functions of the APC will be monitored using the following key performance indicators:
    - Meeting is quorate – standard 100%
    - New medicine applications completed and supporting information provided – standard 100%
    - Resources checklist completed – standard 100%
    - APC papers circulated at least 5 working days before meeting – standard 100%
    - Decision-making criteria applied to all new medicine applications – standard 100%
    - Rationale for decision made documented within checklist for new medicine applications – standard 100%
    - Applicant informed of the APC recommendation within 7 working days of final decision being made – standard 100%
- Adherence to APC local guidance will be monitored by:
    - Analysis of prescribing data (primary and secondary care)
    - Specific audit of identified guidance

A KPI report will be included with the quarterly report to the CCGs.

COLLABORATIVE ARRANGEMENT

The details of the collaborative arrangement for operation of this group are summarised in the following table:

Name of Joint Group/ Arrangement	**Area Prescribing Committee**
CCGs Involved	South Worcestershire (SW) Redditch and Bromsgrove (R&B) Wyre Forest (WF)
Other Organisations / Groups Involved	Worcestershire County Council Worcestershire Acute Hospitals NHS Trust (WAHT) Worcestershire Health and Care Trust (WHACT) Patient and Public Interest representative (PPIs)
Role of Group / Arrangement	The Worcestershire Area Prescribing Committee (APC) is a strategic decision-making committee of health care provider representatives across Worcestershire operating in a partnership capacity. The overall aim of the committee is to manage medicines usage across the Worcestershire health economy. This requires that the committee is pro-active with its health economy partners, taking a strategic approach by co-ordinating and directing policy across primary and secondary care, between Trusts and between clinical networks where possible.
Nature of Group/ Arrangement	**Lead Commissioning**
Responsibilities of Group/ Arrangement	1. The Medicines Commissioning team hosted by SW CCG are responsible (through the SLA) for the administration and operation of this committee across Worcestershire in accordance with the Terms of Reference, with additional clinical support provided by all other organisations as appropriate. 2. The operation of the Committee will be in accordance with the APC Terms of Reference. 3. All CCGs will be responsible for ensuring attendance at meetings in accordance with the APC Terms of Reference; it is the responsibility of individuals to appoint a deputy as their representative at the meeting if they are unable to attend. 4. The County Council Public Health team are responsible for ensuring attendance at all meetings and providing the necessary clinical input (in accordance with the Public Health/CCG Memorandum of Understanding, April 2012). 5. The APC has delegated authority, via the Head of Medicines Commissioning, to make decisions relating to the use of medicines within Worcestershire. 6. Where there is a divergence of opinion between the consensus view and the Head of Medicines Commissioning with delegated authority, the application will be reconsidered at a future meeting. Should the divergence of opinion remain, the issue will be referred to CCG Management Teams/Clinical Executive for a final decision to be made. 7. Where the committee fails to reach a consensus view, further discussions will be held at a future meeting. If a consensus is still not reached, the application will be rejected. 8. Financial approval is required from CCG Boards where significant, unplanned, cost or risk is identified. 9. Medicines in the context of this document include prescribable (FP10) appliances.
Duration of Arrangement	The arrangement made is valid for three years or less if Department of Health or legal advice suggests the need for earlier review.
Pooled Resource	None
Annual Budget 2012/13	Some medicines are funded through the excluded Payment by Results (PbR) budget by CCGs (per capita 2012/13 with a plan to move to actual allocation of CCG expenditure 2013/14). The majority of resource for medicine procurement will be allocated directly from CCGs to Provider Trusts (growth allocation will be in accordance with the advice of the APC following the annual horizon scanning event).

Name of Joint Group/ Arrangement	Area Prescribing Committee
Budget Management Arrangement	The excluded PbR resource is managed by the Medicines Management Team South Worcestershire CCG. The APC will hold an annual Horizon Scanning event to determine budgetary requirements for the following year. Worcestershire Acute Hospital NHS Trust is responsible for managing the annual prescribing allocation.
Budget Reporting Arrangements	The APC will receive a monthly report by Worcestershire Acute Hospitals NHS Trust detailing the PbR excluded and tariff medicine expenditure for the month with projections for the year end position. NICE costing templates for published Technology Appraisals when available are used to inform local commissioning estimates and are compared with previous estimates within the horizon scanning exercise or existing expenditure. Quarterly reports to CCG Clinical Executive/Management Teams will include details regarding any financial arrangements associated with decisions made by the APC.
General Management Arrangement	1. All organisations involved will be expected to follow the APC operating procedures entitled: Supporting the Decision-Making Process within Worcestershire. 2. Decisions will be made by consensus view of all members present and supported by the HMC with DA for the 3 CCGs; where this is not reached (after consideration at 2 meetings), the application will be rejected. 3. If the Head of Medicines Commissioning is not present at the meeting, they will be asked to approve any decisions made by the committee after the meeting. This will be recorded in the minutes. 4. Where there is a divergence of opinion between the consensus view and the Head of Medicines Commissioning with delegated authority, the application will be reconsidered at a future meeting. Should the divergence of opinion remain, the issue will be referred to CCG Management Teams/Clinical Executive for a final decision to be made. 5. The joint decision making ensures equity for patients and appropriate management of resources. 6. Where an APC guidance/policy has significant and unplanned financial implications or represents a high risk to organisations involved, this will be referred to CCG Boards for a decision to be made.
Operational Responsibility	SW CCG
Operational Policy	Worcestershire Area Prescribing Committee - Supporting the Decision-Making Process within Worcestershire: Operating Procedures. August 2013.
Risk Management arrangement	➢ Medicines expenditure incurred against the excluded PbR budget or provider contract will be charged directly to the CCG concerned. ➢ The process is set up to ensure that new and appropriate medicine developments are funded in-year where possible.
Dispute Resolution	Issues of dispute will be managed in accordance with the Memorandum of Understanding "CCG Collaboration in Worcestershire".
Termination Arrangements	A decision to terminate may be made by all parties at any time and should be made in writing. However the decision to terminate can only apply at the end of the three year period; this decision should be communicated no later than 31st December in order to take effect from 1st April of the following year.
Communication of Decisions	A written report on the outcomes of the APC, including a KPI report, will be presented to CCG Clinical Executive/Management Teams quarterly. Verbal updates will be made as necessary for significant decisions made.

Appendix 2: New Medicine Application Form.

Medicine Details and Usage Information

- Medicines include prescribable (FP10) appliances

Approved Name, Strength and Form	
Trade Name and Manufacturer	
Proposed Indications	
Is the medicine licensed in the UK?	Yes / No
Is the medicine licensed for the proposed use?	Yes / No
Will the medicine replace an existing medicine on the existing formulary? If yes, please detail which medicine(s). If no, please detail how you currently manage these patients	Yes / No
Will the medicine compliment existing treatments? If yes, please give details.	Yes / No
What is the recommended dosage range for this treatment?	
What is the expected duration of use i.e. acute (state days) or long term?	
Who will initiate prescriptions?	Consultant / Hospital Doctor / GPs / Specific Consultant / Non-Medical Prescriber
Who will undertake maintenance prescribing?	Consultant / Hospital Doctor / GPs / Specific Consultant / Non-Medical Prescriber
Who is responsible for monitoring?	Consultant / Hospital Doctor / GPs / Specific Consultant / Non-Medical Prescriber
What are the monitoring requirements?	
When will this medicine be used in the treatment pathway? ***Please attach a copy of the proposed treatment pathway or proposed service development business case***	
Is this medicine recommended by any National organisations?	Yes / No

If yes, please provide details.	
Please give a brief summary of why you think that this medicine should be approved for local use.	

Evidence for Efficacy and Safety

Please give a brief summary of published evidence available to support the application.	
To support this summary, please give details and provide copies of up to 4 key references or reviews, ideally not older than five years.	1. 2. 3. 4.
If the product is an alternative brand to an existing formulary product, please give evidence of why this product should be used instead.	
Summarise the safety and tolerability of the medicine, compared with comparator medicine(s) or placebo.	

Expected Level of Use and Financial Implications

Cost of the medicine	£…… per treatment course/annum (365 days in year i.e. 13 x 28) Source:…… Date:…….		
Comparative cost of existing treatment	£…… per treatment course/annum (365 days in year i.e. 13 x 28) Source:…… Date:…….		
	Primary Care	Secondary Care	Total
Product Cost by Sector (X)			
Comparative cost by Sector (Y)			
Estimated additional cost by sector (X-Y = A)			
Estimated number of patients to be treated per annum (based on Worcestershire population of approx. 550,000, giving consideration to incidence, prevalence and expected place in therapy) (B)			
Annual cost implication (A x B)			
Are there any expected activity changes associated with this medicine? If yes, please provide details	Yes/No		
Are there any differences in non-medicine costs (or savings) associated with use of the new product, for example diagnostic tests, monitoring?			
Do any of the published papers give details of NNT? (C) If yes, please give details (including level of benefit over given time period)	Yes / No		
Based on the NNT, what is the estimated cost benefit? (C x cost over given time period)			
Can the cost of this be covered by a reduction in expenditure on anything else?			

If yes, please give details.	
Within your area of practice, what else would you like to spend this amount of money on? Which provides the greatest level of benefit to patients?	

Applicant Details and Declaration

Name	
Job Title	
Status	
Work Base	
Wish to attend the APC to discuss application?	Yes / No In-person / Representative
Has a pharmaceutical company been directly involved in completing this application?	Yes / No
If yes, please state which sections the pharmaceutical company has helped to complete.	
Please state any personal conflicts of interest.	
Has this application been discussed and supported by an MDT/GPCC (for primary care) meeting on all sites?	Yes / No
If not, which sites support this application?	
Name of person completing the application form	
Signature of Applicant	*
Name and signature of Clinical Director/Clinical Lead	Name: …… Signature*:……
Pharmacy check: Name and signature of clinical pharmacist Name and signature of Chief/Director pharmacist) / Consortia pharmacist lead	Name:…….. Signature:…… Name:…… Signature*:…….

*Please note that unsigned application forms will be returned to the applicant for completion. This may delay the application being considered.

Appendix 3: Checklist template for new medicine applications.

New Medicines Application
Resources Checked Record Form

Completed by:	**Applicant:**	**Date:**
Application details:		

Resources Checked

Include: medicine, dose, side effects, cost, national guidance, summary of evidence found.

Sources used	BNF		EMEA		WAHT MI		OTHER please list
	SPC		Previous Enq		Regional MI		
	Drug Tariff		APC Minutes		RPSGB		
	NICE		APC Guidelines		ARIF		
	MHRA		WAHT Guidelines		Industry		
	MTRAC		NICE inc. NHS Evidence/MPC		NHS library		
	AWMSG		UKMI new drugs Online				
	SMC		NIHR Horizon Scanning Centre				
	DoH						

Outcome of Application for:

Name of Applicant:
Date Application Received:
Date Considered:
Date of Decision:

	Yes/No	Details/comments
Checklist of additional information completed		
Application, checklist & relevant supporting papers circulated		
Applicant invited to attend the APC		
Applicant attended the APC		
Sufficient information to enable a decision to be made		
If unable to make a decision, additional information required		

Decision made: Approve
Approve with restrictions
Decline
Further information needed

Rationale for Decision:
Clinical-effectiveness -

Cost-effectiveness -
Equity -
Other -

Supporting Information required:

	Yes/No	Details, including by whom and when:
Guidelines		
Feedback		
Audit		
Other		

Date applicant/s informed of decision:
Review date (if relevant):

Appendix 4: Guidance on completing a new medicines application form.

Please discuss application and completed form with appropriate member of your pharmacy team, as indicated below, prior to submitting it to the Worcestershire Area Prescribing Committee (APC). This is to ensure that the application has sufficient evidence to progress it through the APC:

- Worcestershire Acute Hospitals Trust (WAHT): Nick Hubbard, Alan Catterall
- Worcestershire Health and Care NHS Trust (WHACT): John Morrison, Andy Down
- Primary Care: Anne Kingham
- Clinical Networks: Mandy Matthews

Please note that incomplete application forms will be returned to the applicant for completion.

An application to the Worcestershire APC should not be made for any medicine which is within the remit of the NHS CB Prescribed Specialist Services.

Medicine Details and Use

- Medicines include prescribable (FP10) appliances.
- Please specify the main indications for which you or others will be using the product. Consider how this product will be used in relation to existing products. For example, those not tolerating first line treatment.
- Please consider who will be responsible for managing the patient from initiation to on-going treatment, including any necessary monitoring requirements. In some cases a Shared Care Protocol may be desirable in order to facilitate continuing supply by GPs of a hospital initiated product.
- Please include a copy of the suggested treatment pathway, supporting local guidance or proposed shared care guidance as appropriate.
- If the application is part of a proposed service development, include a copy of the accompanying business case/service development proposal.
- Please express use relative to other medicines or in terms of clinical status if applicable. For example, 'the 10% of patients who do not respond to medicine X' or patients who meet the following criteria for disease severity…..'

Evidence for Efficacy and Safety

- This section is designed to establish the evidence base available to support acceptance of the product onto the Worcestershire Joint Medicines Formulary.
- Please list and include, if possible, no more than four references to support your application. These should be the most recent and relevant available. If there is a good systematic review you need not include the original papers. We are looking for references from reputable sources that are unbiased with good methodology. Reviews from expert groups will also be considered.
- Where evidence is equal to other agents, has only been compared with placebo, or there is no long term outcome data published, it may be useful to provide quality of life data if it is available
- Comparative safety of the product is obviously of great interest. Many new medicines arrive on the market with as few as 1500 patients having been exposed. The Summary of Product Characteristics (SPC) or clinical trials are a good source of adverse event reports.

Level of Use and Financial Implications

- Please provide costs for different doses where applicable.
- Consider where the costs will be incurred i.e. primary or secondary care.
- Estimate the number of patients who are likely to be treated.
- Consider use in relation to the whole Worcestershire population (556,000).
- Consideration should be given to incidence, prevalence and place in therapy, in terms of estimating the likely numbers of patients.
- Where possible provide an indication of cost-benefit, cost-effectiveness (for example numbers needed to treat, NNT) or cost utility (for example cost per QALY).
- When calculating annual costs please incorporate 365 days which equates to 13 x 28 day packs.

Applicant Details and Declaration

- Applications will only be accepted from consultants, general practitioners or lead prescribing practitioners
- It is essential that we are made aware of the extent of interest in prescribing the product. Please obtain Directorate support in the WHAT or WHACT, or have MDT approval. If one product is to be replaced with another, this must be a Trust wide switch. There will be no confidence in financial predictions if all potential users have not been consulted before the application.

- Ensure that both applicant and Clinical Director have signed the application form.
- It is important that any conflicts of interest are declared on the form.

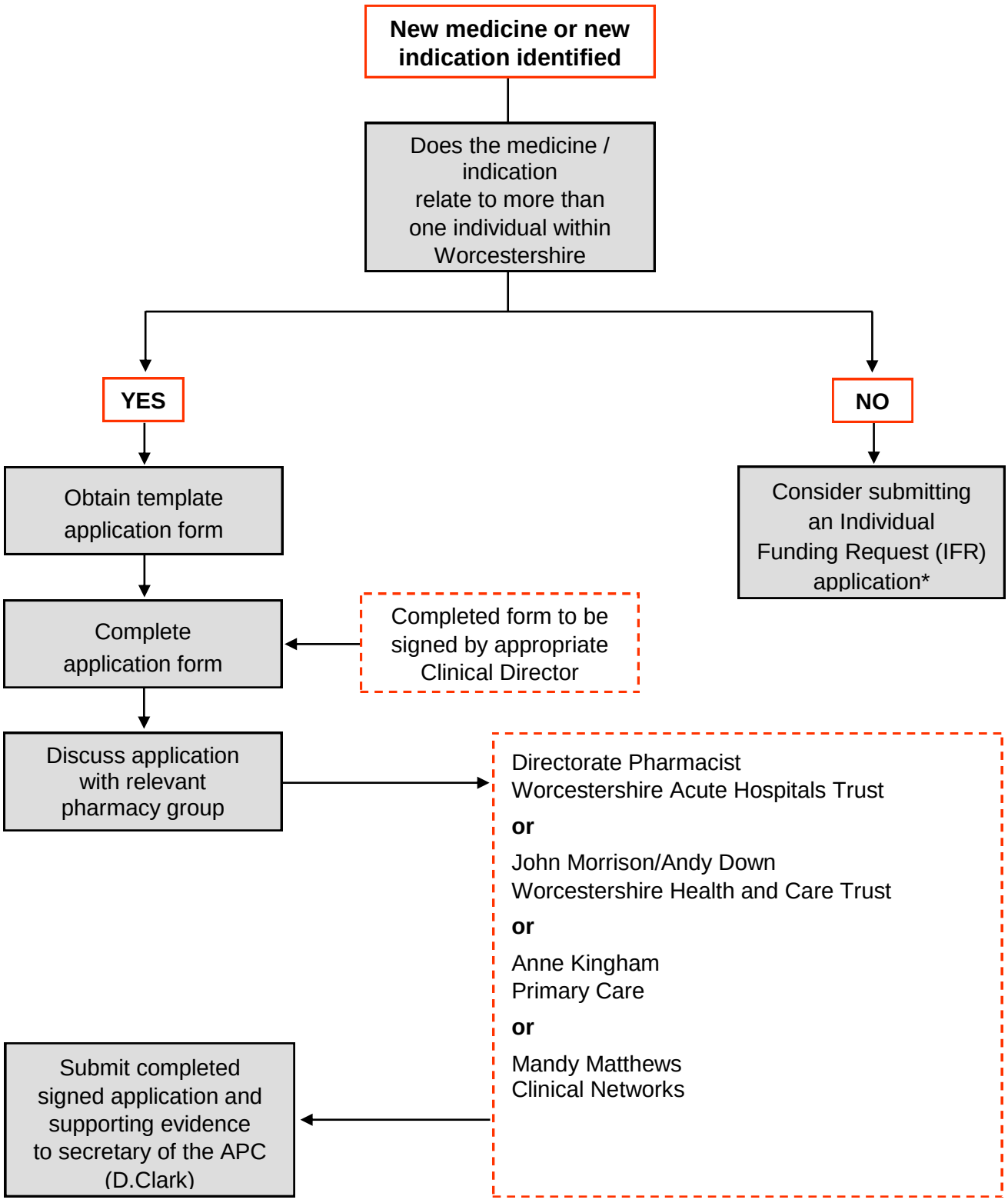
Contacts:
Area Prescribing Committee
Chairman: Dr Charles Ashton – via secretary on 01905 763333, ext 34530
Professional Secretary: Danielle Clark – Clinical Effectiveness Pharmacist
via - Danielle.clark@worcestershire.nhs.uk

Worcestershire Acute Hospitals NHS Trust Medicines Safety Committee (MSC)
Chairman: Dr Steve Graystone
Director of Pharmacy Mr Nick Hubbard 01905 763333 ext 30230

Worcestershire Health and Care NHS Trust Medicines Management Safety Sub-Committee (MMSSC)
Chairman: Dr David Lewis *(interim)*
Chief Pharmacist Mr John Morrison 01905 733397

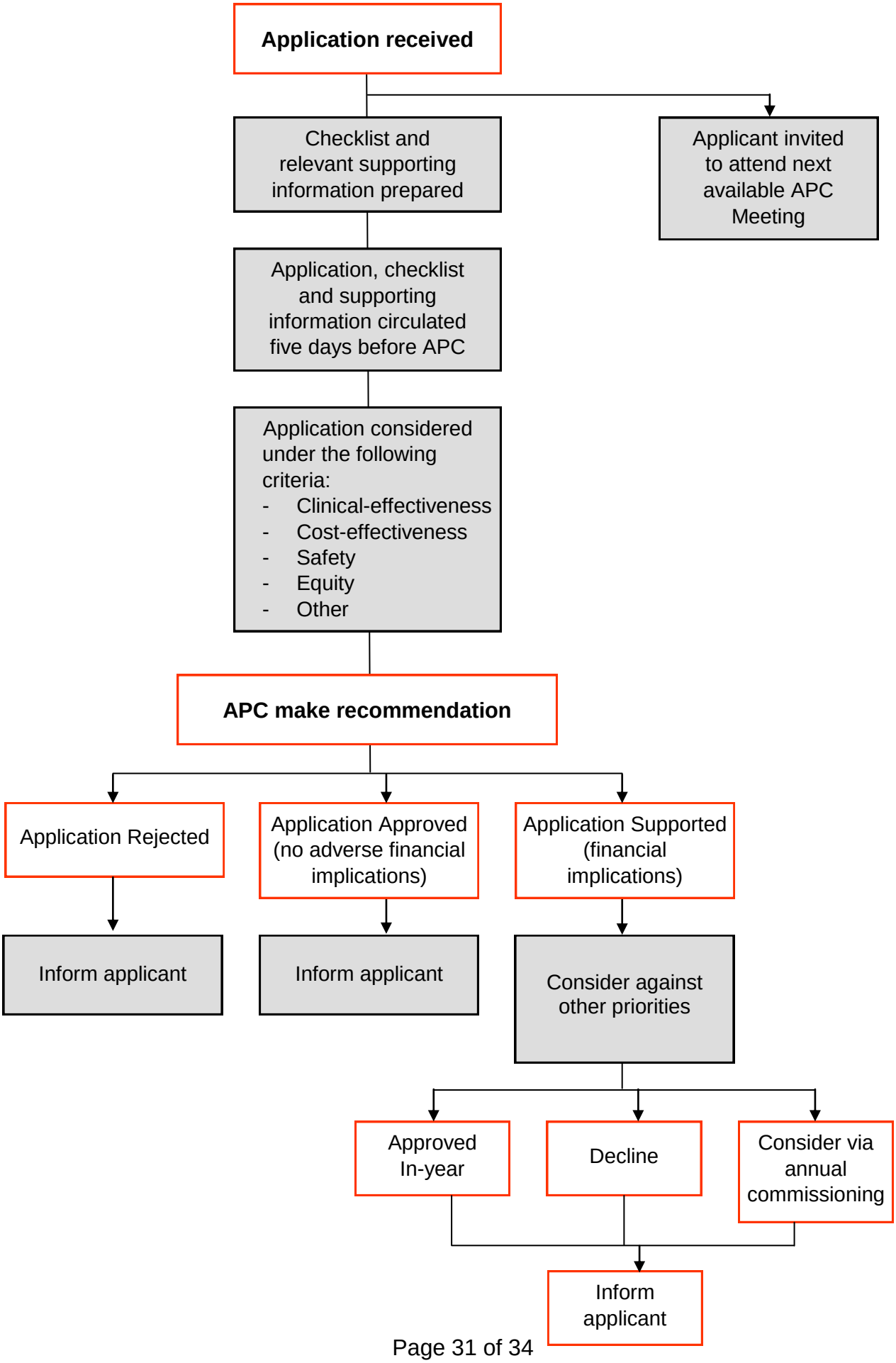
Appendix 5

New Medicine / Indication Applications - Quick Reference Guide



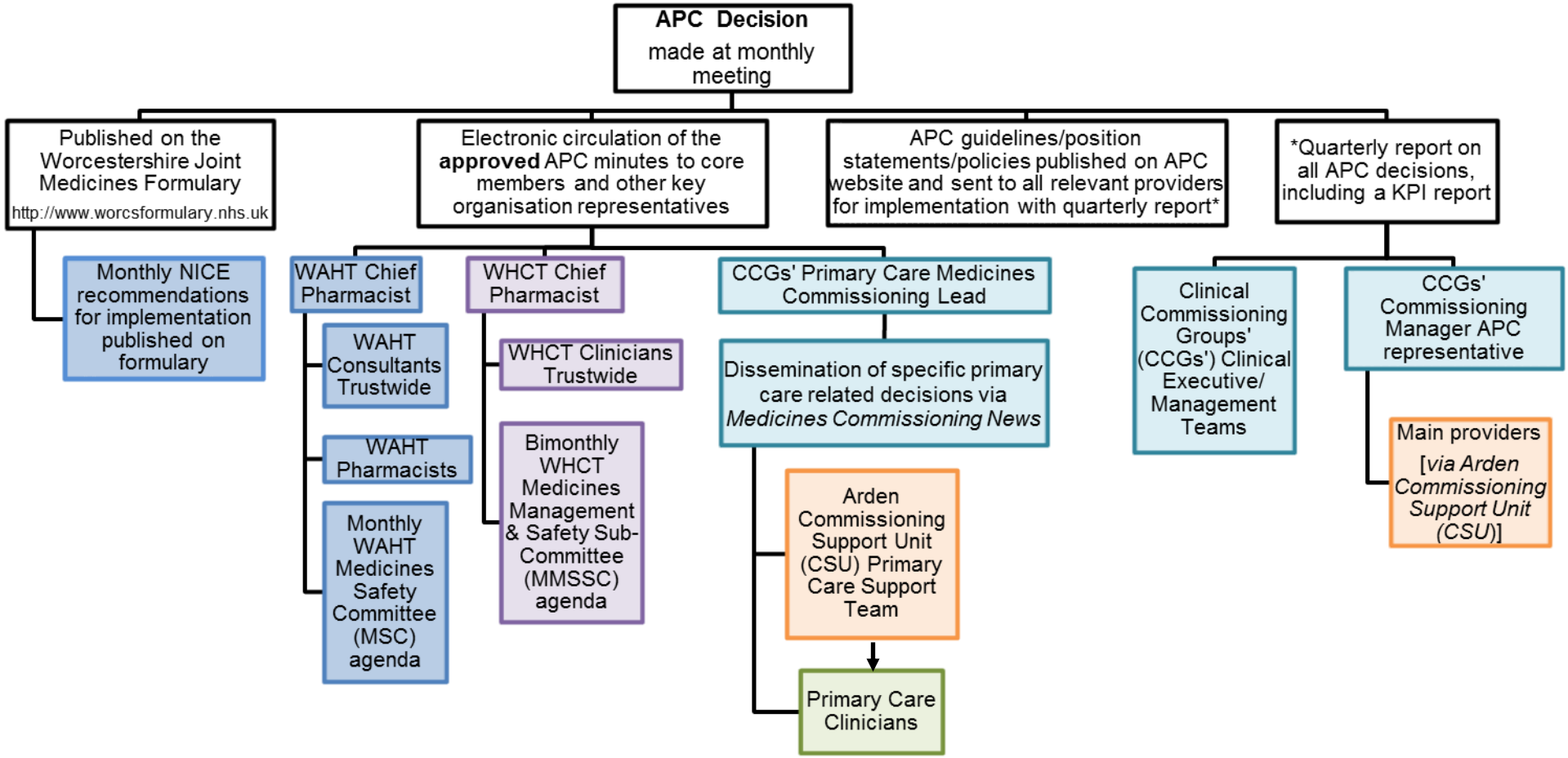
* Refer to Commissioning Individual Funding Requests policy

New Medicine / Indication Applications - Quick Reference Guide



APPENDIX 6:
APC Decision Dissemination

Nominated organisation representatives are responsible for agreeing a standard approach for dissemination of information and decisions made by the APC in a timely fashion.



Responsibilities: Area Prescribing Committee Professional Secretary

South Worcestershire Clinical Commissioning Group (SWCCG)

Worcestershire Acute Hospital Trust (WAHT)

Worcestershire Health and Care Trust (WHCT)

Arden Commissioning Support Unit (Arden CSU

APPENDIX 7: Worcestershire Area Prescribing Committee: Horizon Scanning Framework

Aim:
The Worcestershire Area Prescribing Committee (APC) undertakes horizon scanning to identify medicines likely to become available to the NHS in the next twelve to twenty-four months. This includes new medicines and new indications or formulations of existing medicines.
The aim of effective horizon scanning is to identify those medicines that may have a significant impact on:

- Clinical practice
- Service design
- Finance

Purpose:
Horizon scanning is used to inform commissioners and providers of potential new medicines/indications so that they can plan more effectively for their use in the local health economy. This includes:

- Anticipate pressures, including potential financial risks and changes in service delivery.
- Identify and plan for services, whether new or redesign of an existing service.
- Inform budget setting for medicine expenditure.
- Support the managed entry of medicines in the local health economy.
- Identify potential areas for disinvestment.

Outcomes:

- A 'live' horizon scanning document which provides information on those medicines likely to impact the NHS in the next twelve to twenty-four months; this includes:
    - Medicines approved by NICE with anticipated further impact, e.g. full year effect, additional growth.
    - Medicines to be considered by NICE in the current financial year, in the next financial year and beyond (or date not yet confirmed).
    - New medicines, which are not to be considered by NICE.
    - Existing commitments.
- Annual horizon scanning event.
- Report on potential financial implications to commissioners and providers.
- Budget setting for next financial year.
- Support budget monitoring in-year.

Process:
A 'live' horizon scanning document has been developed, which is updated monthly with the following information:

- New published NICE Technology Appraisals (TA) – to include anticipated numbers and costs, taken from the NICE costing template and the views of local experts. If a TA is supported by a Patient Access Scheme (PAS) details of this are also included. During the annual event the APC identifies any additional funding required to fully implement the TA in the next financial year.
- NICE updates to TA consultation documents and timescales.
- Advance planning notifications received from the pharmaceutical industry.
- Details from other resources, including UKMI, NELM, networks, Medicines and Prescribing Centre New Drugs events.

The 'live' document includes medicines commissioned by CCGs or by NHS England; the APC focus on those medicines to be commissioned by CCGs.

Medicines to be considered by NICE:

As commissioners are required to provide funding for the implementation of NICE TAs within three months of publication of a TA, the APC focuses on those medicines being appraised by NICE. From April to October, details are collated to provide an indication of the likely impact for the Worcestershire population if a medicine receives a positive TA in the next financial year; this begins with the information provided as part of the NICE TA appraisal process and is reinforced with advance planning and budgetary information provided by the Industry. Local experts are contacted for their views on whether a medicine is likely to have a significant impact and an estimate of potentially eligible patients. All of this is included in the 'live' document to inform discussion at the annual horizon scanning event.

The annual horizon scanning event takes place in November; an agenda and a copy of the most up-to-date 'live' document are circulated to members a week before the meeting. Highlights from the UKMI 'Prescribing Outlook' document are also circulated. Details included on PAS are often commercially sensitive so members are required to treat them as confidential.

During the annual horizon scanning event, each medicine is considered, taking into account the information provided and any relevant views of the APC members; as a result those medicines considered to be likely to have a significant impact in the next financial year are highlighted and associated potential costs agreed. The APC may identify a number of medicines which, at the time of the event, do not look likely to receive a positive NICE TA but if they subsequently do the financial implications would be considerable; a proportion of the total likely costs for such medicines is included as a contingency.

Medicines not being considered by NICE:

The default position is that a new medicine, or new indication for an existing medicine, is not routinely funded unless it is supported by a NICE TA or an APC new medicines application has been considered and prioritised by the APC. Therefore, new medicines included in the 'live' document, which are not being considered by NICE, will not be routinely funded. At the annual event, members review these medicines to identify if any are likely to be requested by local clinicians and if so, whether any additional funds should be approved.

Existing commitments:

This section relates to medicines provided as non-contracted activity within the current financial year. APC consider whether there is likely to be any growth and include additional funds if required. Insulin pumps are also considered here.

Where funds are identified for any of the above, the APC will then determine which providers (Worcestershire Acute Hospitals Trust or 'others') those funds are likely to be required by. An updated 'live' document, detailing likely funds required, is shared with commissioners and providers.

A report is submitted to the CCGs' finance teams summarising the advice on likely financial implications for the next financial year, based on the discussion at the annual event. This includes additional funds required for the following:

- Full implementation of a published NICE TA, where a part year effect has occurred when the TA was published.
- Part year costs for medicines likely to be approved by NICE.
- Funds identified as a contingency for those medicines currently not supported in the appraisal process but would pose a significant financial risk if subsequently approved by NICE.
- Growth for existing commitments.

The report is then used to inform the annual budget setting process with individual Trusts.