Policy for the Birmingham, Sandwell, Solihull and environs (BSSE) Area Prescribing Committee

Document history

Version	Date	Author	Changes
1	10th July 2014	Jonathan Horgan	Consultation with members for version. Approved in APC
2	11th December 2014	Jonathan Horgan	Added section on red drugs in the community (7.3.6)
3	5th February 2015	Jonathan Horgan	Amendments to section 7.3.6 following members' comments, review of appeal process (12.3- 12.6).
4	19th March 2015	Jonathan Horgan	Amendments to section 8 to clarify NICE TA implementation timescale.
5	4th August 2017	Isabelle Hipkiss	Reformat, reference to RMOCs, revision of appeal section, addition of abbreviated application form, new section on guests at meetings and appropriate behaviour.
6	12th July 2018	Kuldip Soora	Amendments to page iii, section 3.3.2, new section on RMOC recommendations (6).
7	14th January 2021	Graham Reader	Amendments to page 12, section 4.7 wording that ESCAs are not necessarily required retrospectively

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Midlands and Lancashire CSU Medicines Management on behalf of:

Clinical Commissioning Groups
Birmingham and Solihull CCG
Sandwell and West Birmingham CCG
South East Staffordshire and Seisdon Peninsula CCG

NHS Trusts
Birmingham Women's and Children's NHS Foundation Trust (incl Forward Thinking Partnership)
Birmingham Community Healthcare NHS Foundation Trust
Birmingham and Solihull Mental Health NHS Foundation Trust
Royal Orthopaedic Hospital NHS Foundation Trust
Sandwell and West Birmingham Hospitals NHS Trust
University Hospitals Birmingham NHS Foundation Trust

Administration support is provided by the Midlands and Lancashire Commissioning Support Unit.
The updated membership lists including local stakeholders are published in the Terms of Reference.

1. Policy statement/Key objectives

The objectives of this policy are to help constituent organisations:

- Commission medicines and related services using the most effective and efficient management of resources
- Provide unbiased but accountable commissioning, leadership and strategic co-ordination of the use of medicines
- Commission services using medicines that focus on achieving improved clinical outcomes.

1.1. Background

The NHS Constitution 2013 states:

> You have the right to drugs and treatments that have been recommended by NICE for use in the NHS if your doctor says they are clinically appropriate for you.
>
> 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.

Secretary of State Directions (Department of Health, 2009) provide the NHS with clear and concise requirements that must be adopted to ensure compliance with the constitutional statements. There is a statutory responsibility set out by the Department of Health (2010) for commissioners to make funding available within 3 months for medicines that are subject to a positive NICE technology appraisal.

This was re-emphasised in 2011: "*Clinicians should be empowered to use these medicines and treatments where they consider their patients would benefit and local processes for pro-active adoption of NICE recommended medicines into local formularies should be in place*". (Innovation Health and Wealth – accelerating adoption and diffusion in the NHS. Department of Health, December 2011)

Healthcare commissioners have a statutory responsibility to ensure that care, including medicines and treatments, is commissioned within available resources (Department of Health, 2010). In order to secure the best value healthcare and the greatest health benefit for their populations, commissioners need to prioritise the allocation of limited resources and balance demands for medicines and treatments against a number of considerations. Commissioners may not always be able to fund all the care that is practically possible.

The local GP led Clinical Commissioning Groups (CCGs) and NHS Hospital Trusts across Birmingham, Sandwell and Solihull work collaboratively to put in place systems to improve the use of medicines supported by an Area Prescribing Committee (APC). The APC will have a number of benefits including improved NHS efficiency in delivering evidence-based advice for clinicians through a collaborative approach, improved transparency, engagement with the public, and more coherent advice for patients across the local area between the hospital Trusts and GPs.

The APC is a strategic group involving lead clinicians from hospitals and primary care, commissioning and specialist medicines advisers, patient/public representation and support staff working together to improve safety and consistent access to medicines across local pathways of care. The APC has a leadership role to support the introduction of new medicines. This means it assesses the benefits, and risks for new medicines, and provides advice to prescribers on the best use of these medicines.

This document describes the framework by which this process will take place in a consistent, predictable, open and transparent manner.

2. Purpose of the APC

2.1. Overview

The APC serves the local community by improving the use of medicines in terms of safety, effectiveness and cost effectiveness across its member organisations. It does this by deciding which medicines are recommended, and not recommended for local use, and supporting the implementation of advice for best use of medicines. Decisions will be made following consensus agreement by stakeholders informed by systematic evidence evaluation and consultation.

The output of the APC will be an on-line joint formulary, defining those medicines commissioned (and therefore funded) by the partner commissioning organisations.

The joint formulary is a list of drugs that are recommended for use across this area. The joint formulary makes recommendations for the use of the individual drugs, for example whether they can be considered as part of a group of first tier drugs, or where they may best be prescribed by a specific clinical group such as a specialist or GP. The joint formulary document may highlight safety aspects for the appropriate use of products, or associated documentation such as prescribing guidelines to support the best use of medicines for patients.

Co-ordination of this activity across Birmingham, Sandwell, Solihull and environs through the APC will minimise unnecessary variation in medicines use and policy across the area ("postcode prescribing") for the benefit of patients, providers and commissioners. Decisions by the Committee will be made in accordance with the Collaborative Commissioning Policy which has been approved by CCGs locally; *Ethical framework for priority setting and resource allocation, October 2014*. A copy is available via the website. www.birminghamandsurroundsformulary.nhs.uk

2.2. Core Principles[1]

Principle 1

The values and principles driving priority setting at all levels of decision-making should be consistent.

Principle 2

The Clinical Commissioning Group has a legal responsibility to commission healthcare, within the areas for which it has commissioning responsibility, in a manner which is consistent with its legal duty not to overspend its allocated budget.

Principle 3

The Clinical Commissioning Group has a responsibility to make rational decisions in determining the way it allocates resources to the services it directly commissions and to act fairly in balancing competing claims on resources between different patient groups and individuals.

Principle 4

Competing needs of patients and services within the areas of responsibility of the Clinical Commissioning Group should have a fair chance of being considered, subject to the capacity of the Clinical

[1] The Core Principles are based on the CCG's Commissioning Policy: Ethical framework for priority setting and resource allocation 2013

Commissioning Group to conduct the necessary healthcare needs and services assessments. As far as is practicable, all potential calls on new and existing funds should be considered as part of a priority setting process.
Services and individual patients should not be allowed to bypass normal priority setting processes.

Principle 5

Access to services should be governed, as far as practicable, by the principle of equal access for equal clinical need. Individual patients or groups should not be disadvantaged or unjustifiably advantaged or on the basis of age, gender, sexuality, race, religion, lifestyle, occupation, social position, financial status, family status (including responsibility for dependants), intellectual/cognitive function or physical functions.

There are proven links between social inequalities and inequalities in health, health needs and access to healthcare. In making commissioning decisions, priority may be given to health services targeting health needs in sub-groups of the population who currently have poorer than average health outcomes (including morbidity and mortality) or poorer access to services.

Principle 6

The Clinical Commissioning Groups are required to assess the cost effectiveness and clinical effectiveness of all interventions and only invest in treatments which are of:

(1) Proven cost-effectiveness; or

(2) Likely cost-effectiveness based on balance of probability; or

(3) Likely cost-effectiveness to the equivalent current treatment, for which there is the intention to continue commissioning the healthcare intervention.

Other forms of service developments must represent value for money.

Principle 7

New treatments should be assessed for funding on a similar basis to decisions to continue to fund existing treatments, namely according to the principles of clinical effectiveness, safety, cost-effectiveness/value for money, and then prioritised in a way which supports consistent and affordable decision-making.

Principle 8

The Clinical Commissioning Group must ensure that the decisions it takes demonstrate value for money and an appropriate use of NHS funding based on the needs of the population it serves.

Principle 9

No other body or individual, other than those authorised to take decisions under the policies of the Clinical Commissioning Group, has the mandate to commit the Clinical Commissioning Group to fund any healthcare intervention unless directed to do so by the Secretary of State for Health.

Principle 10

The Clinical Commissioning Group should strive, as far as practicable, to provide equal treatment to individuals in the same clinical circumstance. The Clinical Commissioning Group should therefore not agree to fund treatment for one patient which cannot be afforded for, and openly offered to, all patients with similar clinical circumstances and needs.

Principle 11
Interventions of proven effectiveness and cost-effectiveness should be prioritised above funding research and evaluation unless there are sound reasons for not doing so.

Principle 12
Because the capacity of the NHS to fund research is limited, requests for funding to support research have to be subject to normal prioritisation processes.

Principle 13
Patients participating in clinical trials are entitled to be informed about the outcome of the trial and to share any benefits resulting from having been in the trial. The responsibility for this lies with the party initiating and funding the trial and not the Clinical Commissioning Group unless the Clinical Commissioning Group has either itself funded the trial or agreed in advance to fund aftercare for patients entering the trial.

Principle 14
Unless the requested treatment is approved under existing policies of the Clinical Commissioning Group, the Clinical Commissioning Group will not, save in exceptional circumstances, commission a continuation of privately funded treatment even if that treatment has been shown to have clinical benefit for the individual patient.

2.3 Responsibilities

- The APC will, on behalf of the health economy, manage the local Joint Formulary.
- It will consider applications for medicines to be added to the Joint Formulary, recommend their adoption or non-adoption, and specify the circumstances under which adopted medicines should be used.
- It will also review the Joint Formulary from time to time to ensure that it is consistent with the aims of safe, effective and cost-effective prescribing, and with national guidance.
- The APC will only approve formulary applications that are within CCG Commissioner budgets or that have an impact across primary care.
- Where inclusion of a product will require additional investment beyond delegated limits (either acquisition costs, or service costs), or has broader commissioning implications (e.g. change in service provision), the APC will pass the recommendation to the relevant Commissioning forum for prioritisation and financial approval.
- The APC will review areas where there is inconsistent formulary status across the health economy and make binding recommendations on their resolution.
- The APC will highlight the impact of joint formulary additions to commissioners.
- The APC will consider the cost-effectiveness of existing treatments and make recommendations for a change in prescribing practice where appropriate.
- The APC will undertake horizon scanning to forecast developments in medicines related healthcare and provide effective introduction of new medicines.
- The APC will ensure the joint formulary is updated in response to national guidance, medicines licence changes, and safety alerts related to medicines. For example by NICE or the Medicines and Healthcare products Regulatory Agency.

- The APC will provide a framework to endorse medicines related guidelines to support better use of medicines across the local area.
- The APC will be cognisant of the outputs of the Regional Medicines Optimisation Committees (RMOCs) and aim to review any relevant advice/ recommendations in a timely manner.
- Where there are financial implications to RMOC recommendations usual commissioner arrangements will apply
- Use of the Joint Formulary will continue to be incorporated into NHS Trust contracts and will be considered best practice in primary care. CCGs will work closely with primary care clinicians to maximise formulary adherence.
- Processes include the use of medicines outside the Joint Formulary for immediate clinical need prior to a formulary application, or for individual patients with exceptionality.

2.4. Documentation

The following documents are used to deliver the functions of the APC:

- The Policy which includes the process for the formulary
- Terms of Reference
- Formulary Application form
- Medicines Independent Review
- Decision making support tool
- Code of practice for declaring and dealing with conflicts of interests

3. Formulary process

3.1 Background

The following section describes the process for the formulary. The formulary process commences via two routes;

- Reactive in response to applications from clinicians supported by their NHS Trust Drugs and Therapeutics Committee or Clinical Commissioning Group.

- Proactive by horizon scanning to identify formulary updates, or to resolve inconsistent formulary status across the health area.

3.2 Process timescale

The committee will operate a process for new applications over 6 weeks. A flow chart of the process is displayed in Appendix 1. This timescale has a number of benefits:

- The timescale allows peer review across the area prior to consideration at the APC. APC members receive the application prior to committee discussion to allow them to share it within their organisations and bring comments to the APC.

- The timescale minimises duplication for formulary development across organisations.

- The timescale enables Applicants to plan to attend the meeting or arrange a representative clinician to present the application.
- The timescale enables development of the Medicines Independent Review, and enables consideration of the financial commissioning impact in advance of the meeting.

3.3 Reactive process: Submitting a formulary request

3.3.1 Applications are submitted using the APC Application Form by email to the APC Secretary via mlcsu.medicines-management@nhs.net.

NHS Trust Clinicians must first apply to their NHS Trust Drugs and Therapeutics Committee (DTC) or Medicines Management Advisory Group (MMAG) using their internal NHS Trust formulary application process. DTC/ MMAG need to be cognisant of the opinion of the locally constituted clinical groups/ networks.
The NHS Trust's DTC or MMAG will consider the application and if considered appropriate for potential adoption on the joint formulary they will allow it to go ahead and be submitted to the APC secretary on behalf of the applicant clinician for APC consideration. This endorsement is provided by the Chair of the Trust DTC/MMAG and a Senior Pharmacist.

Applications from GPs or within primary care will be endorsed by the CCG Medicines Lead or GP Prescribing Lead prior to APC submission.

3.3.2 The full APC application form is used to add a new drug on the joint formulary, add new licensed indications for existing formulary medicines or to remove or amend the use of a drug on the existing formulary. The abbreviated application form may be used in certain circumstances determined by the APC secretary, in conjunction with the APC Chairs.

3.3.3 Applications are required for drugs that will be prescribed in primary care, or funded by Clinical Commissioning Groups, or cause a change in the Tariff related activity such as appointments. Applications will not be considered by the APC for drugs prescribed within hospital tariff and funded by the hospital. These are considered through internal NHS Trust processes. However, NHS Trusts will need to inform the committee of their decision for red formulary status drugs that are taken home with patients as outlined in 3.3.6. Applications are not required through the APC for specialist drugs commissioned by NHS England which may be prescribed in local Trusts.

3.3.4 The application form includes:

- details of the applicant making the request
- NHS organisational approval for the submission
- declarations of interest
- details of the medicines including strength, formulation, therapeutic drug class
- indication, monitoring requirements and cost
- evidence submission with relevant supporting literature including efficacy, safety and cost effectiveness
- comparison with existing treatments
- likely place in therapy
- recommendation for decommissioning of current formulary medicines if applicable

3.3.5 Applicants are encouraged to consult with their peer networks across the NHS Trusts to gain consensus and a joined up approach to the introduction of new drugs. Views from peer networks or other organisations can be reflected in the application form or submitted prior to the APC meeting.

APC members across the NHS Trusts and CCGs will have the opportunity to share applications to seek Area wide views prior to the APC discussion.

3.3.6 Drugs will be included as red formulary status where NHS Trusts maintain prescribing for patients to take in the community outside the hospital.

These are included in the APC formulary to ensure that NHS Trust formularies do not conflict with the APC formulary and to provide transparency on Trust formulary decisions across Trusts and primary care. It should be noted that NHS Trusts' formulary decisions on the use of specialist drugs may vary at a local level.

3.3.7 The APC will not accept applications developed by, or received from the Pharmaceutical Industry.

3.4 Proactive identification of medicines for consideration

3.4.1 Horizon scanning is carried out by a Commissioning Clinical Pharmacist to review medicines that are recently licensed that are not yet subject to NICE review utilising UK Medical Information resources.

3.4.2 Medicines not subject to NICE will be prioritised for review using defined criteria. These will be based on:

- Impact on patient care
- Timeliness for new medicines reaching the market
- Severity of disease and patient numbers affected
- Clinical effectiveness

Patient safety
- Gaps in treatment or other available treatments
- Cost effectiveness or resource impact
- Inappropriate variation in current practice

3.4.3 Assessment is carried out by Commissioning Clinical Pharmacists of local Trust and CCG Formularies to identify inconsistent formulary status across the Area. Submissions to the APC are made to harmonise inconsistencies by the Commissioning Clinical Pharmacists in conjunction with Trust Formulary Pharmacists.

3.5. Exceptional and Immediate Clinical Need

3.5.1 The majority of prescribing should be in accordance with the formulary. However, it is recognized that a formulary will not provide the most appropriate treatment for every patient with all clinical conditions, so processes are required to enable clinical decision making to allow non-formulary prescribing where this is appropriate.

The following principles can be applied for exceptional and immediate clinical need;
- Formulary drugs are preferred for patients.
- Use of drugs outside the formulary requires an established clinical rationale which should be documented.
- If the use of a drug outside the formulary applies to a cohort of patients, then an APC formulary application should be made.

3.5.2 If a non-formulary medicine is required for a patient who has exceptional need, processes are available to request commissioning funding using the Individual Funding Request (IFR) process. This process allows commissioners to consider the funding approval in a fair and transparent way.

3.5.3 If there is immediate clinical need within a secondary care setting, NHS Trusts can utilise their internal one-off non-formulary approval process for urgent use of a drug prior to a formulary application. If a clinician wishes to use a non-formulary drug for a cohort of patients, a full formulary application should be made.

3.5.4 If there is immediate clinical need within a primary care setting, clinicians may if required contact their local medicines management team for advice.

3.5.5 Representatives from NHS Trusts report on non-formulary approvals and the reasons for these to the APC. Applications for formulary are required for subsequent funding.

3.5.6. Patients who have been previously established on non-formulary drugs may normally continue with their treatment. A change to a formulary drug should only be considered where the patient will gain clinical benefit; for example, if the formulary drug is more effective or has improved adherence.

3.6 Receipt of the application

3.6.1 Applications are received by the APC Secretary by email. An acknowledgement will be emailed to the Trust representative submitting on behalf of the Trust DTC/MMAG or the applicant from the CCG.

3.6.2 The application form will be screened by a Commissioning Clinical Pharmacist for completion. For submissions from NHS Trusts, the Commissioning Clinical Pharmacist will liaise with the Trust Formulary Pharmacist for points of clarification. Incomplete forms will be rejected with a request for completion and advice for the Applicant.

3.6.3 A record will be kept of all applications received, date and time, and any returned to the Applicant with reasons. This will be reported to the APC.

3.6.4 Applications will be considered in 6 weeks to allow time for screening, commissioning and peer review.

3.6.5 Applications recommended for any earlier consideration less than 6 weeks hence, will be accepted at Chair's discretion. The Chair will consider the volume of items on the agenda, the urgency for a decision to be made and the ability to produce the Medicines Independent Review, and gain peer review across the Area within the timescale.

3.6.6 Papers will be shared with the members in a digital format.

3.6.7 The APC agenda and final papers are distributed a week before each meeting.

3.7 Preparation for the APC

3.7.1 A Medicines Independent Review produced by the Commissioning Clinical Pharmacists in conjunction with NHS Trust Formulary Pharmacists will be prepared for submission with an application for a new drug. A standard template will be used to collate this information for submission.

3.7.2 The standardised Medicines Independent Review template will be available for all member organisations to use. If these are commenced in NHS Trusts they can be shared with the Commissioning Clinical Pharmacists for the APC.

3.7.3 The process enables members, their associated Trust Formulary Committee and Commissioning Clinical Pharmacists to be aware of what applications have been received, and to avoid duplication of formulary development between organisations.

3.7.4 The Medicines Independent Review will be compiled using recognised sources of medicines information where they are available. The APC will avoid duplicating the production of medicine information where this is freely available for NHS use. The following resources are recommended:

- Electronic Medicines Compendium
- BNF/Children's BNF
- NICE including Evidence summaries: New Medicines
- Specialist Pharmacy Services website
- Scottish Intercollegiate Guidelines Network (SIGN)
- All Wales Medicines Strategy Group (AWMSG)
- NHS evidence
- Cochrane library
- MHRA drug safety alerts and regulatory authority alerts relating to medicines

3.8 Presenting to the APC

3.8.1 The applicant clinician or their NHS clinical representative will be invited and encouraged to attend the meeting by the APC Secretary to present new drug requests or formulary amendments to support the application. This will enable the APC to ascertain answers to any questions during the meeting and ensure all the relevant clinical evidence is clarified to support the members in reaching a decision.

3.8.2 The APC may at their discretion request the views or attendance of other experts to support their understanding.

3.8.3 APC members will advise the committee in the meeting of any comments from their organisations.

3.8.4 The Commissioning Clinical Pharmacist will present the Medicines Independent Review to the Committee.

3.8.5 The Committee will make their decision based on the information they have to hand on the day.

3.8.6 In the absence of the applicant clinician or NHS clinical representative to address any questions or points of clarifications, it is more likely that the application will be turned down and the clinician would need to re-submit the application.

3.8.7 Manufacturers are not eligible to present to the committee.

4. Committee decision making

4.1 The members will assess applications against a range of criteria and record their decision and the rationale on the decision support tool (DST). The decision making criteria will include:

- Patient safety
- Clinical effectiveness
- Cost effectiveness or resource impact
- Strength of evidence
- Place in therapy relative to available treatments
- National guidance and priorities
- Local health priorities
- Equity of access
- Stakeholder views

4.2 The APC Secretary will advise applicant Clinicians of the decision within 5 working days of the meeting.

4.3 Decisions will be categorised using the following:

Formulary Traffic light status	**Definition**
	Initiation and maintenance of prescribing by Specialists only.
	Initiation and maintenance of prescribing by Specialists and transfer to Primary Care prescribing when appropriate, or initiation and maintenance of prescribing in Primary Care following recommendation from a Specialist. Some amber medicines require agreement with the local (internal) medicines committee prior to initiation; others may require a framework to support safe transfer and maintenance of care such as a RICaD or ESCA. The Formulary will be annotated to reflect these requirements.
	Initiation and maintenance of prescribing by Specialists, GPs and other qualified clinicians.
	This has a positive NICE Technology Appraisal and/or is awaiting local clarification on place in therapy.
	Non Formulary; may be prescribed following approval by individual hospital Medicines Management Committees for specific patients

4.4 The decision will provide guidance on the place in therapy, for example whether a first or second tier medicine and any other relevant issues such as high cost or specialist initiation for some Amber drugs.

4.5 The APC is responsible for determining what supporting documentation may be required and determining resources to deliver these, and is responsible for ratification on behalf of the Area. Supporting documentation will be made available via the APC website.

4.6 Supporting documentation can include for example prescribing guidelines or *Rationale for Initiation, Continuation and Discontinuation* (RICaDs). RICaDs share information between the specialist and GP to support safer and appropriate prescribing.

4.7 *Effective Shared Care Agreements* (ESCAs) are developed by a specialist in conjunction with clinical pharmacists. These are used to form an agreement between the specialist and GP to define the responsibilities of each party for jointly managing the care of a patient on a drug. An ESCA is not necessarily required retrospectively for patients who have already previously been prescribed a medication in primary care for a period greater than one year, or who were prescribed a medication prior to the existence of the ESCA. Any referral back to the specialist in these circumstances should be based on clinical need.

4.8 Decisions by the Committee will be made in accordance with the Collaborative Commissioning Policy which has been approved by CCGs locally; *Ethical framework for priority setting and resource allocation, October 2014.* A copy is available via the website.

4.9 The meeting is digitally recorded for the purpose of accurate minute taking and once the minutes are approved, the recording is deleted by the APC secretary.

4.10 Minutes of meetings and any DSTs will be ratified at subsequent meetings and published.

5 Adoption of NICE Technology Appraisals (TA)

5.1 NICE TAs that are relevant to the local health economy within primary care commissioning will be submitted as a standing agenda item for ratification and consideration by the APC. A statement will be published to confirm adoption or decision making as appropriate. If adopted, NICE TAs will be implemented as soon as is practical and within 90 days.

5.2 The APC will engage clinicians to identify the position for therapies in the relevant care pathways in line with NICE recommendations where required.

6. RMOC recommendations

6.1 One of the four Regional Medicines Optimisation Committees (RMOCs) meets every month. RMOC recommendations will be submitted as standing agenda items for consideration by the APC. The RMOC recommendations are accessible within the Specialist Pharmacy Service (SPS) website.

6.2 RMOC recommendations or advice that are deemed relevant to the local health economy will be submitted for further consideration by the APC.

7. Transparency

The documentation and notes will be published on the APC website maintained by Midlands and Lancashire CSU.
The website is: http://www.birminghamandsurroundsformulary.nhs.uk/

The APC will engage stakeholders involving clinicians, patients' representatives and other relevant stakeholders to review the effectiveness of the process at timescales agreed by the committee members. The outcomes will be documented within the minutes and published annually.

8. Monitoring the impact

The APC will audit the impact of the formulary through prescribing measures at agreed times in the year. This may be 6-12 months to allow time for data to become available and change to occur.
As part of the decision making process, the Committee will consider how the impact will be monitored.

An annual report will be published on the overall activity and impact of the Committee. It will also make recommendations on improvement to the process and policy.

9. Resubmission and appeals process

9.1 Resubmission process

9.1.1 Once a formulary review has been completed or a new drug application has been rejected, a resubmission would normally require a minimum interval of 12 months.

9.1.2 The Chair has the discretion to shorten the resubmission period on receipt of significant new information such as trial evidence or appropriate clinical guidance.

9.1.3 Where new published information significantly affects previous decisions, the Chair in agreement with the members can remove recommendations and request a resubmission or a proactive formulary review.

9.2 Appeals process

9.2.1 In line with good practice recommendations that a clinician is best placed to submit a formal appeal on behalf of their patient population[1], the appeals process is open to clinicians involved in the application process and who work within the Birmingham Sandwell Solihull and environs Health Economy for an NHS Commissioned Service. It exists to give those clinicians who feel that the BSSE APC decision may result in a compromise in care to patients, an opportunity to make their case for the decision to be reviewed where it is felt that the APC has either not followed due process or that the committee has not given appropriate consideration to the evidence presented. Appeals from pharmaceutical companies will not be accepted.

9.2.2 Grounds for appeal:

a) Appeal against a decision made by BSSE APC because the APC's procedures and policies were not followed.

b) Appeal against a decision made by the BSSE APC to reject an application for a specific medicine because vital evidence submitted/ presented was misinterpreted or not fully considered or an inappropriate deduction from the evidence presented was made.

Notes:

1. The applicant cannot appeal against a decision just because he/she does not agree with the decision or because new evidence has come to light since the original decision was made. In this case, a resubmission is in order as described in 8.1.
2. The applicant cannot appeal against a decision because a neighbouring APC came to a different decision.
3. The applicant will not be able to lodge an appeal if he/she did not attend the meeting where the application was considered.

9.2.3 An intention to appeal should be made in writing to the APC secretary within 8 weeks of the Committee's decision. A template form has been developed to support the appellant. (See appendix 2)

The appeal must state the following:

- Name of drug/s
- Date of committee decision
- Reason for appeal stating the potential failing

9.2.4 An acknowledgement will be sent the appellant to confirm receipt. The appeal will be screened and reviewed by the APC Secretary and Chair to confirm that it is an appeal in relation to a process issue, or an appeal proposing that a reasonable decision has not been made.

9.2.5 Appeal papers relating to the process and decision making will be presented to an independent APC under a reciprocal arrangement to review the appeal. The appellant is invited to attend the committee to present the case for the appeal. A member of the Birmingham, Sandwell, Solihull and environs APC would also attend the appeal panel to present the APC decision making process.

9.2.6 The role of the appeal panel is not to review the evidence and make a decision, but to decide if the grounds for appeal are valid and the appeal is to be upheld. The fact that the BSSE APC will reconsider does not necessarily mean that it will reach a different decision.

9.2.7 Following review of the appeal, recommendations will be made by the appeal panel to the APC as follows:

- Appeal upheld and the BSSE APC is directed to reconsider the original application in light of procedural failure or misinterpretation of the evidence presented (depending on the grounds for appeal). No new information can be submitted as part of the appeal process.
- Appeal dismissed and reasons why.

The appellant will be informed in writing of the outcome of the appeal within 10 working days of the meeting. The outcomes will be published on the website.

Reference

1. NICE. Developing and updating local formularies. December 2012. Accessed on 4.8.17 at: http://www.nice.org.uk/guidance/MPG1

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10. A code of practice for declaring and dealing with conflicts of interest

A code of practice is available for conflicts of interest for members of the Committee. Formulary applicants are required to declare their interest within the application form and at each meeting.

11. Policy Impact Assessment

A policy impact assessment has been completed as a separate paper.

12. Membership

BSSE APC is a decision making group, and therefore organisations will need to delegate responsibility to their representative members.

The strength of the APC will depend principally upon members working voluntarily together to innovate, solve problems of mutual concern and co-ordinate solutions and implementation plans.

The membership of the APC is detailed in the terms of reference. Each of the member organisations is invited to send one pharmacist and one medical representative. Representatives are also invited from the Local Public Health Network. In addition, Midlands and Lancashire CSU will provide a professional secretary present at all meetings who will organise venues, meeting timetable, agendas and minute-taking on behalf of the constituent organisations.

13. Terms of reference

See separate document.

14. Frequency of meetings

The BSSE APC will meet once per month, with the exception of August.

15. Guests at Meetings

Attendance at the APC groups is governed by the membership. Intended attendance by any guests should be notified to the Chair and/or Professional Secretary in advance of the meeting to seek permission to attend and, if agreed, in order that the attendee can be briefed on the working of the APC.

Guests attending have no voting rights and may only contribute to the committee proceedings at the Chair's discretion.

16. Appropriate Behaviour

All members attending the APC to represent an organisation or present a paper do so in a professional capacity, and all participants should be treated with courtesy, respect and consideration.

Participants should only speak when they are invited to by the Chair and should indicate as having something to say. A person should not be interrupted while speaking or asking a question.

All speakers are asked to be clear and concise, as the APC have busy agendas, and are required to adhere to time.

17. Website

Midlands and Lancashire CSU will maintain the BSSE APC website www.birminghamandsurroundsformulary.nhs.uk/ which will contain all agreed decisions, essential shared care protocols (ESCAs), rationales for initiation continuation and discontinuation (RICaDs), joint formulary, guidelines and other documents agreed by the APC.

Constituent organisations can create links to this site from their websites to aid dissemination of information.