Supporting rational local decision-making about medicines (and treatments)

A handbook of good practice guidance

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About the National Prescribing Centre (NPC)

The NPC is an NHS organisation formed in 1996.

Its aim is: to promote and support high-quality, cost-effective prescribing and medicines management across the NHS, to help improve patient care and service delivery.

The NPC work programme is designed to support the specific needs of commissioners, providers and individuals with an involvement in prescribing. In order to improve the flexibility, accessibility and timeliness of its support, the NPC provides key NHS audiences with a range of choices for accessing outputs. This includes making use of opportunities provided by electronic learning environments, as well as more traditional approaches. Enhanced versions of many of the NPC materials included in this Handbook are available through the NPC websites: www.npc.co.uk and www.npci.org.uk

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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.

From the *NHS Constitution*
Executive summary

1 This Handbook gives initial good practice guidance and provides tools to help Primary Care Trusts (PCTs) begin to review current decision-making processes about the funding of medicines, with cooperation from Provider Trusts and other stakeholders. It was commissioned by the Department of Health (DH) primarily to support the development of decision-making processes around medicines, however much of the content will apply equally to decision-making about other treatments and interventions.

2 The NHS Constitution is a declaration of rights that are underpinned in law. It confirms that patients have the right to expect local decisions about the funding of medicines and treatments to be made rationally following a proper consideration of the evidence.

3 PCTs need to work with their clinical networks and Specialised Commissioning Groups (SCGs), along with Provider Trusts and clinicians such that decision-making policies and procedures are consistent with the requirements of the NHS Constitution.

4 To support the NHS Constitution, the DH has commissioned the development of DH guiding principles for decision-making about medicines which are relevant to all NHS organisations. This Handbook should help organisations to develop processes consistent with these guiding principles.

5 PCTs have the statutory responsibility to commission care including medicines, for their populations, within available resources. The funding of medicines should not be viewed in isolation from the funding of other health services. Decisions on whether to fund medicines should be taken in the context of the PCTs available resources to ensure that care is fairly allocated to all patients and, where appropriate, measured against the PCT’s other service development priorities, National Institute of Health and Clinical Excellence (NICE) guidance and national priorities.

6 Robust, transparent processes, along with sharing of information and appropriate collaboration should help to improve the consistency of decision-making. This should help reduce the ‘postcode lottery’ where different funding decisions are made due to inconsistent or incomplete processes and policies. However, even with robust processes in place some legitimate variation will remain because PCTs make commissioning decisions based on local priorities, which will vary. PCTs should proactively engage with the public about local prioritisation and why geographical variances in funding decisions may result.

7 Decision-making policies and procedures require appropriate capacity and resources to implement, maintain and monitor. PCTs, with the cooperation of Provider Trusts and other stakeholders, should review their needs and ensure they have appropriate resources in place, including access to training. In order to make best use of resources, PCTs should consider working together to jointly develop or commission the necessary support activities.

8 PCTs are likely to be faced with decisions about a range of medicines and treatments for rarer and more complex conditions where they and their local Provider Trusts cannot reasonably be expected to have the full range of expertise or the resources to support decision-making. Where appropriate, PCTs should consider the development of processes to enable collaborative decision-making. The NHS Chief Executive has asked Strategic Health Authorities (SHAs) to review the way in which PCTs in their area collaborate to support effective decision-making on new medicines.

9 The way in which PCTs structure themselves to support, make and deliver decisions may vary reflecting care configurations and other local factors. PCTs, with Provider Trusts and other stakeholders, should develop a whole system map of their decision-making processes and ensure that all the key steps and decision points are clear, and appropriate policies and procedures are in place. In particular, there should be clarity about the advisory, or decision-making status of any constituted committees.
Most decisions about the funding of medicines and treatments should be taken proactively on a population basis by PCTs, with the cooperation of Provider Trusts and other stakeholders. Proactive horizon scanning and early identification of potential service developments, or disinvestments are crucial to achieving this aim.

Requests for funding on an individual patient basis usually occur for medicines or treatments which fall outside existing commissioning arrangements. If an individual funding request (IFR) is submitted that would apply to a population of patients, it should normally trigger the development of a new policy or a possible modification to an existing policy. These requests should not, routinely, be considered by an IFR panel.

PCTs and Provider Trusts need to have clear, agreed policies and procedures in place for the consideration of IFRs. All IFR policies should allow for an initial triage of requests to ensure that any submitted inappropriately are referred to the relevant policy-/decision-making group, or back to the requester as appropriate.

There are specific circumstances, relating to medicines where PCTs should develop, with cooperation from relevant stakeholders, general policies around how requests for funding are managed; for example, funding for patients coming out of clinical trials.

PCTs currently have a range of different names for the decision-making and advisory groups which support decision-making processes. When sharing information and/or developing collaborative approaches, it is important to have clarity about definitions. PCTs may wish to consider greater standardisation of terminology and names.
# Executive summary

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Introduction

What this Handbook is all about

This Handbook represents initial good practice guidance and resources to help PCTs to review current decision-making processes about the funding of medicines, with cooperation from Provider Trusts and other stakeholders. This first edition of the Handbook will be updated in light of feedback from users. In addition, as part of an ongoing package of support to PCTs and other stakeholders, further resources will be developed. More information about these developments can be found on the National Prescribing Centre (NPC) website.

The Handbook was commissioned primarily to support the development of decision-making processes around medicines; however much of the content will apply equally to decision-making about other treatments. The Handbook will refer to medicines and treatments where it is considered likely that the good practice guidance will apply to both.

Using the Handbook to support and develop decision-making processes should help PCTs develop their systems and enable decision-making consistent with the following right in the NHS Constitution:

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.
What the Handbook contains

Section one sets the overall context in which this Handbook has been developed. It points to the other policy drivers and key work streams about which PCTs and Provider Trusts need to be aware.

Section two of the Handbook outlines the key steps involved in local decision-making, which may include supra PCT collaboration. Individual organisations and health economies as a whole are likely to have a range of different structures in place for making decisions about whether to fund or routinely recommend medicines or treatments. However, there are some key steps that all organisations will wish to consider. These steps are outlined in a generic flow chart and each step discussed in detail with links to additional information and examples of current practice.

Section three of the Handbook provides a series of checklists and frameworks that can be used as a starting point to review and develop existing systems. Each of these resources can be downloaded separately from the NPC website; as a result, there may be some repetition between the sections.

Section four of the Handbook contains some additional factsheets that give more detail on specific issues raised in the Handbook.

Definitions, abbreviations and references are included in the Appendices at the end of the Handbook.

Additional resources

A quick diagnostic tool which focuses on key aspects of the DH guiding principles for decision-making and some of the key steps recommended in the Handbook, is available to be used electronically or in printed form. It gives a starting point from which to review whole system decision-making about medicines and to identify potential development areas. It should be used in conjunction with the full Handbook.

In defining processes for decision-making, it is important that PCTs develop locally the systems which work best for them and their local care structures (taking into account the DH guiding principles for decision-making and the key steps highlighted in this Handbook). This will help to ensure that systems have good local buy-in and that the processes developed are fully understood. Because of this, the Handbook gives short examples of current practice but does not provide any standard policies, procedures or templates to be adopted wholesale. All the examples of practice in the Handbook can be found on the NPC website mapped by SHA area.

The NPC website also contains a ‘Sharing Practice Library’ of some existing locally defined policies and procedures that have been developed by PCTs or Provider Trusts and reflect their local context. It is envisaged that the library will be added to and updated in light of feedback. Also found on the NPC website are Podcasts from individuals who are sharing their experiences of working in practice on some of the key issues covered in the Handbook.

Core audience for the Handbook

• PCTs (see route map for Chief Executives)
• Provider Trusts (see route map for Chief Executives)
• SCGs
• Local clinical networks
• SHAs

The Handbook will also be of interest to a range of other stakeholders, including:

• Patient groups
• Local Involvement Networks (LINks)
• Private healthcare providers
• Pharmaceutical industry
A route map for PCT Chief Executives

Why read this Handbook?

- Your organisation will have a responsibility to ensure that decisions made about the funding of medicines and treatments are consistent with the rights outlined in the NHS Constitution (Section 1.1) and relevant statutory frameworks
- Rational local decision-making supports at least five of the World Class Commissioning (WCC) competencies (Section 1.2)

What should your organisation do next?

- Map out your existing decision-making structures and processes, including any supra PCT collaboration, against the key steps in Section two to develop a whole system map of decision-making. Include to which Boards any decision-making or advisory committees are ultimately accountable
- Identify where there may be gaps, duplication or lack of clarity in your processes
- Use the relevant checklists and frameworks in Section three as a starting point to review and develop your systems
- Commit the appropriate resources and funding needed to review, develop and maintain your systems. Consider collaboration with other PCTs where appropriate
- Work with your Provider Trusts, Specialised Commissioning Groups (SCGs) and clinical networks to develop a common understanding of the need for triage requests and to define decision-making routes
- Ensure that primary care prescribers are aware of how whole system decision-making processes work. In particular, the difference between population decisions and IFRs

A route map for Provider Trust Chief Executives

Why read this Handbook?

- Your organisation will have a responsibility to ensure that decisions made about the medicines and treatments used within your organisation are consistent with the rights outlined in the NHS Constitution (Section 1.1)

What should your organisation do next?

- Map out your internal decision-making processes against the key steps map in Section two. Identify where there may be gaps or lack of clarity
- Cooperate with your PCTs as they develop a whole system map of decision-making about the funding of medicines and treatments
- Consider establishing a central ‘hub’ in your organisation through which funding requests are triaged and managed before submission to a PCT
- Ensure that your clinicians and directorate management teams are fully aware of how whole system decision-making processes work. In particular, the difference between population decisions and IFRs, and the need to proactively horizon scan to identify medicines and treatments which are potential service developments
1.1 The Next Stage Review and the NHS Constitution

The way in which decisions are made about access to effective medicines (and other treatments) is under increasing scrutiny. The Next Stage Review and the NHS Constitution have laid out plans for the future direction of the NHS.\(^1\)^\(^2\) This includes a recognition that patients should have access to the most clinically and cost-effective medicines and treatments. The Next Stage Review recognises the concerns of patients and the public due to ‘unexplained variation in the way local decisions are made’ and proposes that patients have the right, through the NHS Constitution, to ‘expect rational local decisions on funding of new drugs and treatments’.

NICE assesses a range of new, licensed drugs and medical technologies to determine clinical and cost-effectiveness. Where NICE appraises a medicine positively through its technology appraisal mechanism, PCTs have a legal duty to make funding available for the indications for which it has been approved, without reinterpretation or modification. As a result of the Next Stage Review, NICE is increasing capacity which is aimed at reducing the time it takes to produce technology appraisals once a medicine has marketing authorisation. This should mean that clear national guidance is available about the funding of more medicines (in particular those used to treat cancer) nearer the time of their launch.

However, there will always be situations where PCTs need to make funding decisions about medicines or treatments, for example:

- In the absence of NICE guidance, either before guidance becomes available, or because it is not in the NICE work programme. The DH has made it clear that it is not acceptable to cite a lack of NICE guidance as a reason for not providing a medicine or treatment\(^3\)
- Where a medicine or treatment has been given a positive recommendation by NICE for defined clinical criteria but the request is for usage outside those criteria
- Where a medicine or treatment has not been recommended by a NICE technology appraisal but it is being requested for an individual patient (see Section 2.4)
Patients have the right to expect rational local decisions on the funding of these medicines, and an explanation of the reasons for decisions (see Box one). Draft directions to PCTs (and NHS Trusts) made under the National Health Service Act 2006, and intended to come into force on 1st April 2009, make explicit the responsibilities to have arrangements in place for making decisions, to give reasons for decisions and to publish written information on PCT arrangements.

1.2 World Class Commissioning

PCTs have a statutory responsibility to commission care (including medicines) for their populations, within their allocated resources. WCC provides guidance for PCTs around commissioning of services. The WCC Assurance Framework outlines the key commissioning competencies that PCTs need to develop. Use of this Handbook will support commissioners in meeting WCC competencies, particularly:

- ‘recognised as the local leader of the NHS’ (Competency 1)
- ‘proactively build continuous and meaningful engagement with the public and patients to shape services and improve health’ (Competency 3)
- ‘lead continuous and meaningful engagement of all clinicians to inform strategy and drive quality, service design and resource utilisation’ (Competency 4)
- ‘prioritise investment according to local needs, service requirements and the values of the NHS’ (Competency 6)
- ‘promote and specify continuous improvements in quality and outcomes through clinical and provider innovation and configuration’ (Competency 8)

1.3 DH guiding principles for local decision-making

To support decision-making about medicines, DH guiding principles have been developed for PCTs and other relevant stakeholders and published on the DH website. These DH guiding principles are applicable to decision-making about medicines not, or not yet, appraised by NICE, and are laid out in Box two. They should be used to inform decision-making processes and are aimed at providing organisations with a starting point to address the requirements of the NHS Constitution (Box one). They lay out the context of PCT decision-making in a scoping statement and give some high-level specific guidance on how such decisions should be made.

The DH guiding principles aim to support PCT decision-making on a population basis, within the overall framework of the PCTs approach to the commissioning of treatments and services. In addition, the DH guiding principles should help support decision-making for IFRs, in the context of other decisions made on a population basis. Increasingly, there are likely to be some instances when PCTs choose to make decisions about medicines or other treatments on a collaborative basis.

This Handbook has been produced to help support the review and development of decision-making processes in line with the DH guiding principles.

It is important for PCTs to take reasonable steps to engage with patients, Provider Trusts, SCGs, clinical networks and clinicians to ensure that the context in which the PCT is making decisions about medicines and treatments is understood and supported locally.
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 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 WCC and 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.

Box two

The DH guiding principles for processes supporting local decision-making about medicines
Similarly, Provider Trusts will need to ensure that their decision-making processes are consistent with the DH guiding principles when making decisions about medicines funded through their budgets and when requesting funding from PCTs.

1.4 NHS patients who wish to pay for additional private care

Following Improving access to medicines for NHS patients, a review by the National Clinical Director for Cancer, the DH published Guidance for NHS patients who wish to pay for additional private care.

In line with the aim of this Handbook, both the guidance and the review emphasise the importance of PCTs having processes in place to make rational decisions in the absence of NICE guidance and to proactively collaborate where appropriate. The importance of transparency in all decision-making processes, including decisions made on an individual patient basis is also highlighted.

The guidance document clarifies that when the NHS has made a decision not to fund a medicine or treatment, patients who choose to pay privately for that medicine or treatment can do so alongside their NHS care.
Section two
Key steps in local decision-making

The purpose of this section of the Handbook is to outline the key steps involved in local decision-making. Whilst PCTs may have different structures in place which contribute to the decision about whether to commission or routinely use a medicine or treatment, there are some key steps for all organisations to consider. These steps are outlined overleaf (Figure one) and each step discussed in more detail in this section of the Handbook.

2.1 Identification
2.1.1 Proactive identification
PCTs and Provider Trusts need to have systems for effective horizon scanning to identify new medicines or treatments, or developments in the uses of existing medicines or treatments. These systems are crucial to informing the selection of topics for proactive consideration. Early development of commissioning policies by PCTs, with the cooperation of Provider Trusts and clinicians, will help to ensure that rational, timely decisions are made. This should also help PCTs to avoid instances of inappropriate reactive decisions made on an individual patient basis (see Section 2.4).

There may also be issues which emerge, where PCTs need to proactively develop general policies, with the cooperation of Provider Trusts where appropriate. Current examples include the following:

- Pick-up funding for patients coming off clinical trials (see Sharing Practice Library: Commissioning Intentions)
- Continued funding for medicines or treatments started privately or overseas
- Decisions inherited when patients move into the PCT
- Funding of unlicensed medicines and/or off-licence medicines (see Sharing Practice Library: Commissioning Intentions)
- Funding of experimental medicines and treatments (see Sharing Practice Library: Commissioning Intentions)

There are already widely available, national information sources which should inform activities around horizon scanning (Factsheets 4.1 and 4.2) topic selection (Factsheet 4.3) and assessment of the evidence base (Factsheet 4.4) supporting the use of a medicine or treatment (see also Box three). To ensure effective use of resources, PCTs need to use recognised, national sources of information and avoid
**3 Population decisions/recommendations (Section 2.3)**

PCTs are likely to have a range of committees to which medicines and treatments can be referred for consideration:

- PCT Priorities Committees and/or Area Prescribing Committees (APCs) (see Section 2.3.1)
- Collaborative commissioning committees/groups that span PCTs (see Section 2.3.2)
- Drug and Therapeutics Committees (DTCs) in Provider Trusts (see Section 2.3.3)

It is important to be clear about whether these committees are decision-making or advisory and, if advisory, where the decision will ultimately be taken.

**4 Individual funding requests (Section 2.4)**

(Not to be confused with prior approval for named patients - see Definitions)

**5 Medicine (or treatment) commissioned (Section 2.5)**

**Medicine (or treatment) not routinely commissioned (Section 2.5)**

**Funded**

**Not funded**

**6 Communication, implementation, monitoring and feedback (Section 2.6)**
duplicating effort. This will be facilitated in 2009 by the introduction of NHS Evidence - a single portal for information relating to health and social care. One component of the information available through NHS Evidence will be synthesised assessments of evidence relating to new medicines not covered by NICE technology appraisals. PCTs will have access to these national assessments which can be used to inform their own local decision-making processes (see Section 2.3). In addition, in 2010, it is expected that there will be a single national database highlighting medicines in clinical development which will inform the work of national groups supporting NHS decision-making.

Box three

**Synthesised assessments of evidence**

Whether considering policy development (Section 2.3), or looking at requests for individual funding (Section 2.4), committees will need to have access to an assessment of the evidence base for a medicine or treatment. Synthesised assessments of the evidence base should ideally describe the clinical effectiveness relative to existing treatments, comparative safety data, cost impact, clinical impact and, where available, an appropriate independent cost-effectiveness analysis. This information can then be used, along with other relevant factors, to inform local decision-making (see Box four).

Evidence synthesis requires clarity about the methods used in accessing, appraising, assessing, and then interpreting and contextualising evidence. Evidence synthesis is a specialist activity and requires individuals with a specific range of skills and competencies. To ensure best use of resources, PCTs should utilise nationally recognised assessments where they are available.

As well as national information, PCTs will need to have processes in place to give local context to proactive identification of medicines and treatments. Working with clinical networks, Provider Trusts and clinicians, is important to ensure that local stakeholders inform and support these processes from an early stage; for example, Provider Trust clinicians identifying potential requests for new medicines or treatments early in the PCT planning cycle (see Definitions).
2.1.2 Reactive response

While the proactive consideration of medicines or treatments via the policy development route is preferable, there are still likely to be circumstances where PCTs receive requests to fund medicines or treatments for individual patients. Typically this happens where:

- The PCT has no commissioning policy in place
- There is a policy which means that the PCT would not normally fund a medicine for that patient, but the clinician and their patient still want to use it

Generally speaking, these requests are considered via the PCT's IFR process. There are currently a wide range of names for IFRs and the systems that PCTs have to manage them. Not all requests that are made for individual patient funding will necessarily be 'appropriate' so it is important for PCTs and Provider Trusts to effectively triage requests to ensure that they are processed correctly (see Section 2.4.2 and Definitions).

IFRs are discussed in more detail in Section 2.4 and resources to help develop IFR processes are included in Section 3.4 and Section 3.5 of the Handbook.

2.2 Triaging Processes

The early and explicit triage of requests for medicines or treatments into the appropriate decision-making process should help PCTs to make more timely, transparent and rational decisions. Triage will already be happening to some extent, implicitly if not explicitly. However, PCTs should work with relevant stakeholders to explicitly identify the routes that decisions can and should take. Stakeholders might include: Provider Trusts, clinical networks and, for collaborative approaches, other PCTs and SCGs.

Figure two gives a generic overview of how a triaging system might work. The triaging of IFRs is discussed in more detail in Section 2.4, Section 3.4 and Section 3.5 of the Handbook.

Effective triage of requests for medicines and treatments requires:

- A locally developed map of the routes that decisions might take
- Processes and procedures for triaging requests
- Individuals who are trained and competent to triage
- Clear and widely communicated polices against which requests are triaged

A comprehensive triage system for requests will involve input and management from both the PCT and their SCGs and clinical networks, along with Provider Trusts. Section 3.4 contains a generic triage framework for Provider Trusts and clinicians to use as a starting point to help identify the routes that decisions might take.

2.3 Population decisions/recommendations

As already highlighted, PCTs are likely to have a range of different structures in place to facilitate decision-making about the commissioning and use of medicines and treatments. Most organisations use committees to support decision-making. A typical arrangement is illustrated in Figure three.

The NHS Constitution underscores the importance of rational decision-making processes which are transparent to clinicians and patients. All PCTs and Provider Trusts therefore need to ensure that they have processes, policies and procedures for all their constituted committees which are in line with the DH guiding principles for decision-making (Section 1.3). This includes groups involved in collaborative decision-making.

A comprehensive checklist for all advisory and/or decision-making groups, which allows them to review themselves against the DH guiding principles, is included in Section 3.2.

2.3.1 PCT policy-/decision-making groups

Priorities committees or equivalents

Medicines and treatments that have significant resource implications, and are therefore competing for resources against other possible service developments, require explicit and transparent prioritisation by PCTs. Horizon scanning, topic selection and an assessment of the evidence base (Section 2.1) should support the annual commissioning round by identifying, ahead of time, which medicines are likely to need prioritisation.

Prioritisation recommendations or decisions are generally made by PCT priorities committees to feed into the annual commissioning round. There may be different names for
Section two  Key steps in local decision-making

TRIAGE
(see also (Section 2.6)

Request may be referred back; for example,
- No documentation/information to support request for consideration as an IFR

Service development (Triage into population decision-making)

TRIAGE
(see also (Section 2.6)

Pro-active referral
(for population decision-making)

Request for funding
(for individual patients) (Section 2.6)

No Policy in place
PCT policy-/decision-making committee
(e.g. APC or priorities committee)
(Section 2.4)

Supra PCT policy-/decision-making
(e.g. SCG, other supra PCT configurations)
(Section 2.5)

Policy in place
Policy needs review (refer to the appropriate group)

Policy Stands
(communicate details of the policy to the referrer)

Appropriate IFR
Refer request into the IFR process
(Section 2.6)
Figure three: Typical arrangement of committees involved in population decision-making processes

**Supra PCT group (Section 2.3.2)**
Collaborative commissioning committee/group established across PCTs
Specialised Commissioning Group (SCG)
Usually advisory but sometimes have delegated decision-making responsibility

**Decisions/recommendations**

**Priorities Committee or equivalent (Section 2.3.1)**
Can be advisory or decision making

**Area Prescribing Committee or equivalent (Section 2.3.1)**
Usually advisory but can be decision-making

**Provider Trust Drug and Therapeutics Committee (Section 2.3.2)**
Can feed into, or act as, an APC
Advisory

**Communication, implementation, monitoring and feedback (Section 2.6)**
Link back to identification (Section 2.1) to ensure the decision is revisited, if necessary
these groups; for example, clinical effectiveness committees, clinical priorities committees, effective use of resources groups. Typically, the PCT develops a policy where treatments are given a priority. Low-priority treatments are generally not recommended for commissioning, high-priority treatments are considered with other potential service developments and prioritised as part of the PCT’s annual commissioning round.

New medicines and treatments regularly come on line within the financial year. For medicines given a positive assessment by a NICE technology appraisal, PCTs must make funding for the medicine available. This contingency should have been planned for in the commissioning round (see also Section 2.5). In-year requests for the funding of other, unplanned for, medicines can be a more difficult issue and it is important that PCTs develop a consistent policy on how these requests will be managed. The specific criteria, which need to be satisfied in order for a case to qualify for consideration as an in-year service development, are typically established locally and can vary across PCTs. The investment decision in these cases is made outside of the annual prioritisation processes, typically where an immediate need arises, which could include:

- The introduction of a newly available intervention of high strategic importance
- The introduction of a new product with an improved cost-effectiveness profile
- The avoidance of a significant risk
- The need for immediate compliance with newly introduced legal requirements
- The need for urgent remedial action

The NHS Confederation have published a series of briefings about priority setting. In particular, Priority setting: managing new treatments describes key considerations for developing priority setting in relation to new treatments including medicines.

NHS Suffolk’s Clinical Priorities Group uses an horizon scanning process with their providers to identify new medicines, and then uses a ranking tool to prioritise which to submit into the annual commissioning round. The group will evaluate in-year developments at a mid-year meeting which uses the same ranking criteria. The ranking criteria derive from the PCTs ethical framework. Email: christine.bower@suffolkpct.nhs.uk or p.badrinath@suffolkpct.nhs.uk and see Sharing Practice Library.

East Midlands SCG considers requests for medicines in-year for local PCTs through a Budget Management Group chaired by a non-executive director from one of the member PCTs. The criteria on which decisions are based are reflected in a standard application form. As far as possible, medicines that may require in-year consideration are identified ahead of time through a confirm and challenge meeting with clinicians and providers, which is part of the annual commissioning process. The funding requests are prioritised by a multidisciplinary group and final uplifts are agreed by PCT Boards, following verification of level of investment required by the specialised commissioning team. Email: malcolm.qualie@lcrpct.nhs.uk

Area Prescribing Committees or equivalents

Many PCTs have a committee whose members include; primary, secondary and tertiary care clinicians, representatives from commissioner and Provider Trusts and other stakeholders, working together to develop a consistent health community approach to medicines management. These committees have a wide range of remits but generally consider the implementation of NICE guidance and manage the introduction of medicines across a health economy. There are a wide range of names used locally for these committees and considerable variation in the way that they are structured. This Handbook uses Area Prescribing Committees (APCs) as shorthand for these groups.

Many medicines used in primary and secondary care will be evaluated by either an APC, and/or a Provider Trust DTC (see Section 2.3.3) to establish the medicines’ clinical and cost-effectiveness. It is important that these groups are clear about the wider context in which their decisions and/or recommendations are being made. This can be facilitated by the use of an explicit ‘ethical framework’, which links decision-making to the wider context in which funding decisions are taken (see Box 4 and Definitions) or aligning the groups closely with priorities committees. In particular, clarity is required on whether APCs are advisory (so recommendations need further consideration through...
another group or process) or, whether they have a budget and can make binding decisions.

In 2007, the National Prescribing Centre produced a fitness for purpose framework for APCs which will be updated later this year.\(^\text{14}\)

### 2.3.2 Collaborative approaches to decision-making

Some services are designated ‘specialised’ services (see Definitions). For these services (typically for rare, and/or complex/chronic conditions) PCTs group together to collectively commission. Since 2007, specialised services are either commissioned on a regional basis, by the 10 SCGs or, in the case of particularly rare conditions, on a national basis by the National Commissioning Group (NCG). Each SCG acts on behalf of a population of about five million people, usually through a pooled budget allocated from PCTs. SCGs formally designate specific providers of specialised services, based on a nationally agreed set of criteria. As with all committees, SCGs need to ensure that their decision-making is consistent with the DH guiding principles (see Checklist Section 3.2); that policies and procedures for SCG commissioning fit with those of their constituent PCTs; and that there is clarity around responsibility for decision-making and how decisions will be taken.

Not all rare conditions have been designated as requiring specialised commissioning. PCTs are likely to be faced with decisions about a range of medicines and treatments for rarer conditions, where they, and their local Provider Trusts cannot reasonably be expected to have the full range of expertise.

To ensure equitable access for patients and to avoid inconsistencies, PCTs should consider, where appropriate, the development of processes to enable collaborative decision-making. Collaborative commissioning has already been used for a range of medicines and treatments; for example, high-cost medicines for rarer conditions used in tertiary centres, or for cancer medicines. There are also examples of retrospective collaboration where PCTs, through their priorities committees, work to harmonise their existing commissioning policies across an SHA area.

There have been different approaches to the coordination and funding of collaborative commissioning. Configurations so far have been on a sub-regional, or regional level, taking into account natural patient flows. Equally, funding has been arranged in a variety of ways, with some medicines and

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**Box four**

**Examples of criteria for local decision-making**

The criteria for local decision-making may be encapsulated within a guiding, or ethical, framework (see Sharing Practice Library for examples). These state explicitly the wider issues that the PCT needs to consider when making decisions for their populations; for example, taking into account the other healthcare investment opportunities that will be lost when a particular option is prioritised (i.e. opportunity cost - see Definitions).

Criteria against which medicines/treatments should be evaluated are likely to include as a minimum:

1. Patient safety
2. Clinical and cost-effectiveness and strength of evidence
3. Place in therapy relative to available treatments
4. Affordability
5. National guidance and priorities
6. Local priorities

The best available evidence should be used to inform decisions (see Box three and Factsheet 4.4).

**Warwickshire PCT** developed a framework to facilitate decisions about funding of treatments, under the following headings: health outcome, clinical effectiveness, cost-effectiveness, equity, inequalities, access, patient choice, disinvestment, quality and affordability.\(^\text{10}\)

**South Central PCTs.** The PCTs in South Central SHA have developed a common ethical framework which supports decision-making using the following principles: evidence of clinical and cost-effectiveness, equity, health care need and capacity to benefit, cost of treatment and opportunity costs, needs of the community, policy drivers and exceptional need. [www.oxfordshire.nhs.uk/documents/southcentraletethicalframework.pdf](http://www.oxfordshire.nhs.uk/documents/southcentraletethicalframework.pdf) and see Sharing Practice Library.
treatments being funded through risk-sharing arrangements between PCTs, with others funded on a cost-per-case basis by individual PCTs.

Where PCTs decide to collaborate, they will need to identify a group through which recommendations can be made, and decision-making processes should be consistent with the DH guiding principles. The status of recommendations needs to be well defined within governance and accountability mechanisms. This may involve making use of existing groupings; for example, SCGs, clinical networks or sub-regional clusters (where it is indicated by natural patient flows and the configuration of services). Some groupings may cross SHA boundaries. However groups are configured, there must be clarity about their remit and status which is formally acknowledged by the relevant boards and widely communicated to clinicians, Provider Trusts, clinical networks and all other decision-making/advisory groups.

Given that collaboration should always add value to existing systems, once PCTs have a forum for collaboration, there needs to be a mechanism for determining for which medicines or treatments it is appropriate to collaborate, (see Section 3.3 for an example of a framework which may be used as a starting point for discussion).

**South East London** collaboratively commissioned cancer medicines across six PCTs for 2007/08. The South East London Cancer Network undertook a horizon scanning exercise which identified 34 potential new treatments. A scoring tool was developed and used to rank them at a joint seminar with clinicians and commissioners. As a result, nine treatments were prioritised and the PCTs agreed to fund these following detailed costing of drug acquisition cost, service delivery costs and offset costs. This system will be used for 2008/09 across the London SHA.

Email: jaimie.ferguson@lambethpct.nhs.uk

**North of England Cancer Drug Approval Group (NECDAG).** NECDAG was established in May 2006 to provide NHS commissioners with clear advice. Its function is primarily to approve or reject requests for the clinical approval and funding of new cancer medicines. It aims to ensure patients with cancer in the North East receive equitable access to a clinician-defined, appropriate range of cancer medicines.

Email: steve.williamson@nhct.nhs.uk and see Sharing Practice Library.

**North East Treatment Advisory Group (NETAG).** A regional subgroup of the North East Specialised Commissioning Group, that brings clinical decision-making and commissioning together to make recommendations on low-volume but high-cost treatments, excluding NICE and cancer treatments. Representation is drawn from throughout the North East SHA, ensuring a wide variety of experience and expertise. Email: william.horsley@newcastle-pct.nhs.uk. Decisions on other non-cancer treatments are made in local groups across the SHA, such as the North of Tyne Area Prescribing Committee. This group also brings clinical decision-making and commissioning together and covers six primary and secondary care organisations across the North of Tyne health economy. Committee decisions and meeting minutes are available for viewing on www.northoftyneapc.nhs.uk or Email: david.cook@nhct.nhs.uk

**Yorkshire and the Humber SCG.** Used as a forum to discuss collective commissioning of treatments regardless of their specialised status. Provider Trusts, SCGs, PCTs and clinical networks horizon scan to identify when collaborative commissioning may be appropriate. When agreement is reached in principle, a commissioning framework with audit requirements is developed. At least one Acute Trust DTC must have positively assessed the evidence base before funding will be considered. Support for decision-making is commissioned through a local Excellence in Decision-Making (EDM) process. Email: kevin.smith@barnsleypct.nhs.uk or see www.yhscg.nhs.uk

**Greater Manchester (GM) Medicines Management Group.** Accountable to the Association of Greater Manchester PCTs, the group coordinates decision-making on behalf of all 10 PCTs around medicines and in particular high-cost medicines. Support activities for decision-making are commissioned from the Regional Drug and Therapeutics Centre (Newcastle) www.nyrtdc.nhs.uk/gmmmg

**Greater Manchester (GM) Effective Use of Resources Group** share information to facilitate decision-making on non-medicine treatments and interventions (typically high-cost, low-volume). Support activities for decision-making are commissioned from the Public Health Practice Unit. Work is ongoing to integrate the processes supporting the two groups to provide commissioning guidance to GM PCTs individually and to the Association.

**West Midlands** has five local collaborative commissioning boards which support specialised commissioning. In addition to the specialised commissioning agenda, the Boards provide a forum for developing other regional commissioning policies and provide a single process for assessing proposals and developing consensus. For policy related to a regional specialist service, the final policy-making body is the SCG. If related to another service, it is the Regional Chief Executive Group. The local collaborative commissioning board boundaries reflect network boundaries and is, therefore, a vehicle for collaborating at a sub-regional level.

Email: daphne.austin@wmcs.nhs.uk

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Section two  Key steps in local decision-making

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2.3.3 Provider Trust committees

Most Provider Trusts have committees to make recommendations on the use of medicines within their own budgets. Typically the DTC makes an assessment of the clinical effectiveness of a medicine and recommends whether it can be prescribed, often using a formulary to ensure that decisions are implemented.

For medicines that have an impact across primary and secondary care (financial or clinical), many Provider Trusts have a joint APC-type arrangement with their PCTs to enable the development of coordinated recommendations. In some cases this is a single joint committee (see Section 2.3.2).

Provider Trusts will also want to ensure that their decision-making processes are consistent with the DH guiding principles for decision-making.

To facilitate whole system decision-making, it is important that Provider Trusts have the processes in place to enable clinicians to access advice about, and support in, identifying funding for medicines and treatments. It may be helpful to use a ‘hub’ approach within a Provider Trust to ensure that all requests are rapidly managed and directed to the appropriate decision-making process. This approach will help contribute to proactive decision-making and gives PCTs and the Trust a single communication point.

A generic flow chart for Provider Trusts and clinicians to begin the development of a triage process for funding requests is included in Section 3.4.

Clinicians at the Leeds Teaching Hospitals who want to use a medicine which is not covered by routine commissioning policies or existing contracts, are referred to the Provider Trust’s pharmacy department, from which all requests to PCTs are coordinated. The finance and commissioning pharmacists work with the clinical teams to identify if the request should be directed to a PCT and, if so, where it needs to go. The pharmacists ensure that the request has followed Trust procedures, such as having DTC support, and work with Commissioners to identify where there are service developments which require a commissioning position rather than IFRs. A regular newsletter (Medicines funding update) is published to inform clinicians about funding processes and issues (see Sharing Practice Library for examples).

Email: catherine.hughes@leedsth.nhs.uk

2.4 Individual Funding Requests (IFR)

It needs to be emphasised that most decisions about the funding of medicines and treatments should be taken on a population basis by PCTs, with cooperation from Provider Trusts and other stakeholders. Proactive horizon scanning and early identification of potential service developments is crucial to achieving this aim.

An IFR is a request to fund, for an individual patient, a treatment or medicine which falls outside existing contracts or policy. An IFR should not be used to bypass usual commissioning processes.

This section discusses some of the key issues for PCTs to consider in the development of an IFR policy. For a more detailed policy review, the IFR policy health check in Section 3.5 should be utilised.

The NHS Confederation has also published guidance on the management of IFRs.11

2.4.1 Submission of IFRs

It is important that PCTs and Provider Trusts work with clinicians to ensure that only appropriate IFRs are submitted (see below and Definitions). Those that are submitted should have been through the Provider Trust’s own triage and management systems (Section 2.3.3) and have all the information necessary to enable the PCT to make a decision.

To avoid delays for patients in the processing of requests, PCTs should have standard submission forms which facilitate decision-making, and Provider Trusts and clinicians should ensure that all the required information is present prior to submission.

2.4.2 Triage

It is unlikely that all requests made for individual funding will need to be reviewed by an IFR panel. PCTs and Provider Trusts should have a process for the initial triage of requests to ensure that requests that can be, or need to be, considered through other decision-making routes are referred rapidly. The triage process can also ensure that all the information necessary to support appropriate IFRs has been submitted with the request in order to avoid any delays later in the
process. **It is important that the triage process does not delay the time taken to consider appropriate IFRs.**

See **Section 3.4** for a flowchart that can be used to help with the initial triage process.

Any triage system needs clear policies and processes in place and an individual, or group of individuals, competent to triage requests.

**Bedfordshire PCT has a designated Commissioning Manager to review all requests for individual patients and advise whether the request is covered by the existing portfolio of Service Level Agreements (SLAs) or current commissioning policies.** If the Commissioning Manager has reason to consider that simple application of SLAs and/or commissioning policies would be inappropriate, the case is then considered by the weekly Case Review Panel. The group has three options: agree the request without reference to the Individual Case Panel, refuse the request without reference to the Individual Case Panel, or refer to the Individual Case Panel. Refusing the request is an option where there is a clear policy concerning the situation and where there is no evidence that the individual would constitute an exception to the policy.

Email: ash.paul@bedfordshire.nhs.uk and see Sharing Practice Library.

Generally, requests that are appropriate for consideration on an individual patient basis are:

- When a patient and their clinician requests funding for a treatment which is outside existing generic or treatment-specific policies on the basis of an exceptional circumstance (exceptionality) which applies specifically to that patient (see **Box five**)
- The PCT has no commissioning policy in place and the request is so rare that the PCT is unlikely to receive another request

Requests that are not appropriate for consideration by an IFR panel include:

- Requests which represent service developments (e.g. a group of IFRs relating to a newly licensed drug) and therefore need to be triaged into the appropriate population decision-making process (see **Section 2.3**)
- Requests where no information is submitted in support of the individual’s exceptionality (see **Box five**)

### 2.4.3 IFR panel membership

Members of an IFR panel should together have the skills and expertise necessary to enable them to make effective decisions. The group needs a clear statement of purpose and terms of reference.

Currently, IFR panels often comprise: directors of commissioning, directors of public health, heads of medicines management, GPs/GP prescribing leads and PCT board members (including non-executive members).

The composition of the panel should have an appropriate mix of clinical and managerial members. PCTs may also wish to consider lay membership and the potential value of individuals attending with ‘observer’ status.

For a given case, where the IFR panel does not have the expertise necessary to make a decision, there needs to be a mechanism in place to access relevant specialist expertise.

In addition, members will need ongoing training to undertake this role, in particular to enable them to comprehend and interpret complex data, and also in the legal and ethical aspects of the panel’s work.

### Box five

**An example of a PCT’s policy on exceptionality**

The PCT does not offer treatment to a named individual which would not be offered to all patients with equal clinical need.

In making a case for special consideration, it needs to be demonstrated that:

- The patient is significantly different to the general population of patients with the condition in question.
- The patient is likely to gain significantly more benefit from the intervention than might be normally expected for patients with that condition
- The fact that a treatment is likely to be efficacious for a patient is not, in itself, a basis for exceptionality.

The NHS Confederation have published more detailed guidance on exceptionality in *Priority setting: individual funding requests.*

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*Note: *Page numbers and references have been adjusted for coherence and consistency. The original text is copyright protected and not subject to alteration.
2.4.4 Framework for IFR decisions

The IFR panel needs to have, and consistently apply, a framework against which to make decisions. Decisions should be taken in the context of the need to maintain the equity and consistency of NHS provision. As a general rule, ethical frameworks or local guidelines for decision-making which underpin PCT population decision-making processes should also apply to IFR processes. The framework is likely to include a requirement to consider:

- The nature and extent of the evidence base for a treatment. For IFR requests, there may be a limited evidence base which falls short of accepted gold standards (see Factsheet 4.4). The panel does not need to assess the evidence base themselves; this could be achieved by using a nationally available assessment or a review by another competent group.
- The evidence that the patient’s clinical circumstances might mean that they should have access to a particular medicine or treatment when other similar patients do not (See Box five).

London & South East Medicines Information Service, in common with many other regional medicine information centres, supports the work of IFR panels. The service either produces an independent review of the evidence using an agreed template or, provides a quality assurance service for PCTs that undertake their own evidence reviews. Email: david.erskine@gstt.nhs.uk

2.4.5 Appeals process

Patients and their clinicians should have the ability to appeal the decision made by an IFR panel. In line with DH guiding principle 6 (Section 1.3), this process should be open to input from the patient and/or their clinician.

The appeal is generally considered by an appeals panel, whose membership is different to the IFR panel members who reviewed the original case. The appeals panel needs to have access to all relevant documentation, including any correspondence, a synthesis of the evidence base, and minutes which summarise the basis for the original decision. This documentation should also be available to the requesting clinician and patient.

Appeals panels do not, in general, consider new evidence emerging after the request has been considered. Typically, if new evidence emerges, the request is considered again by the original IFR panel.

IFR policies therefore need to clearly define the grounds for appeal. This is generally on the basis of a procedural review, and can include:

- Was due process followed, did the PCT follow its own policies and procedures?
- Did the panel take into account all relevant information available at the time?
- Was the decision reasonable and in line with the evidence?

PCTs need to be clear about what happens if the appeals panel finds in favour of the patient. Can the appeals panel reverse the decision of the IFR panel by giving a ruling of its own, or only overturn it and refer it back to an IFR panel for reconsideration. Given that many cases need a speedy clinical response, it may be preferable that appeals panels should normally have power to adjudicate in their own right and so avoid the further delay and frustration of referring the patient back to an IFR panel.

As with the IFR panel, the appeals panel needs a clear statement of purpose and should together have the skills and expertise necessary to enable them to make the decisions being asked of them. In addition, members will need training to undertake this role, not least in the legal and ethical aspects of the panel’s work.

However the process works, decisions need to be timely and the patient and clinician kept fully informed.

2.4.6 Patient involvement in the process

It is important that IFR policies and processes are clear to patients. Locally, PCTs may want to investigate the possibility of working with patient organisations and their LINks to ensure that there is clarity about the IFR process. PCTs should also seek patient and public involvement in the development and review of IFR processes.

PCTs need to ensure that their policies consider appropriate communication with patients; for example, setting timescales, how patients can input into the process, how the basis for decisions is communicated etc. (see IFR policy checklist, Section 3.5).
Patients should understand why they are being considered for individual funding, what the purpose of an IFR panel is, the framework for decision-making and what the process will involve. Publishing policies and procedures on PCT websites should be standard practice. In addition, some PCTs have produced patient information leaflets (See Sharing Practice Library for an example from Oxfordshire PCT) and others have a dedicated officer to guide patients through the process.

The IFR process can be extremely stressful for patients and their families. IFR processes need to be as smooth as possible to ensure that patients are fully informed and, where appropriate, supported.

Shropshire PCT has a designated officer for the IFR process to give initial consideration to all requests. Once a request has been identified as appropriate for consideration by an IFR panel, the designated officer contacts the patient and guides them through the process and the nature of the decision being taken. The patient is given the opportunity to attend their panel. Once a decision has been made, the designated officer contacts the patient. Email: su.green@shropshirepct.nhs.uk and see Sharing Practice Library.

2.4.7 Documentation and monitoring of the process
It is important to ensure that the IFR process is fully documented, from initial receipt of the request, through to initial triage of requests, consideration by an IFR panel and in some cases appeal. The rationale for decisions taken should be documented, as well as the decision itself with clear action points where necessary.

The IFR process needs to be monitored and reviewed both to ensure that decision-making is fair and consistent, and to make sure that the panels are making decisions about the right sort of cases; for example, where a number of requests of a similar nature are considered this should generally trigger the development of a commissioning policy. Evaluation of the process by patients and requesting clinicians will also contribute to ongoing process improvement.

As part of the review and development of its IFR process NHS Birmingham East and North asked the Audit Commission to give an independent view of the PCT’s systems and processes, including surveying clinicians from provider units and panel members. The results of this review will be used to refine and develop the IFR process along with the guidance in this Handbook. Email: andrew.donald@benpct.nhs.uk

The South East Coast Health Policy Support Unit (HPSU) is commissioned by the South East Coast (SEC) PCTs to support prioritisation decisions where consistent policy across the region is called for. The HPSU website contains details of the work of the unit and all their policy recommendations. The website also has a secure area where anonymised details of IFRs made to SEC PCTs are recorded and shared with other PCTs in the SEC. All SEC PCTs are registered with the website and are therefore able to view the IFR register and contribute to an online discussion forum. IFR panel leads meet at a regional group to share best practice and identify topics arising from IFRs that require consistent policy across the region www.sechealthpolicysupportunit.nhs.uk or Email: hpsu@bhcpct.nhs.uk

2.5 Medicine or treatment commissioned/not commissioned
Once a policy has been developed and a decision taken to commission a medicine or treatment it is important to ensure that funding flows are clear. For medicines prescribed in primary care, funding flows are likely to be relatively straightforward coming from the primary care prescribing budget.

For medicines prescribed in secondary and tertiary care and not included in (or excluded from) the Payment by Results (PbR)* tariff, there may need to be an explicit discussion about funding flows. In particular, there can be a lack of clarity or agreement across organisations about what monies are included for new medicines and new developments within annual contract arrangements. To help clarify this, some SHAs and PCTs have included in their commissioning intentions the starting point for discussions with their Provider Trusts about funding flows. Provider Trusts may also have groups that discuss the annual targeting of monies allocated for in-year NICE developments and the uplift allocated for new drug developments.

Increasingly, schedules to the standard NHS contracts are being used to capture and formalise the detail around the

* In 2009, the National Prescribing Centre will be publishing a more detailed user guide to PbR
funding for high-cost medicines. These schedules can also discuss the monitoring and audit requirements for high-cost medicines, using, for example, prior approval mechanisms (see Definitions) and minimum datasets for invoicing.

Where collaborative commissioning arrangements are used, it is important to ensure that there is clarity between all PCTs and all relevant Provider Trusts about the contracts and funding flows for medicines and treatments.

Directors of Commissioning for East of England (EoE) PCTs, with EoE SHA, published a schedule of commissioning intentions for 2008/09 which was included as a schedule to the standard NHS contract for all their providers. The schedule detailed how high-cost drugs and technologies would be commissioned. This included explicit guidance about the funding of PbR-excluded medicines and clarification of the scope of PbR mandatory and indicative tariffs. Email: sue.ashwell@cambridgeshire.nhs.uk and see Sharing Practice Library

North Central London (NCL) PCTs’ 2009/10 Acute Commissioning Intentions, reflect those agreed by the London-wide Commissioning Intentions, but with a focus on what they consider to be the most important contractual requirements. One area identified is the funding of new medicines and extensions of indications. Explicit guidance is given on, for example, PbR-excluded medicines, PbR uplift for in-year NICE medicines, new drug developments and IFRs. Throughout 2009/10 these areas will be subject to intense performance management to ensure Trusts are complying with NCL commissioners’ requirements. Email: pauline.taylor@haringey.nhs.uk and see Sharing Practice Library

East Midlands SCG on behalf of local PCTs manages budgets for high-cost medicines commissioned as part of annual commissioning arrangements but not covered by the PbR tariff. Expenditure is monitored monthly by the SCG which also holds a mid-year review meeting with Provider Trust clinicians to identify and address any issues regarding potential in-year cost pressures. Email: malcolm.qualie@lcrpct.nhs.uk

Where a decision is made not to commission a medicine or treatment this needs to be clearly documented, with action points where appropriate. Where a medicine or treatment is not commissioned as part of the commissioning cycle but still remains a candidate for funding, a system should be in place to allow for re-consideration the following year.

Similarly all decisions, whether to commission or not to commission, need to be subject to review in light of emerging evidence, which may support usage or indicate disinvestment. This should be part of the proactive identification processes (Section 2.1) which identify issues for consideration.

2.6 Communication, implementation, monitoring and feedback

Effective communication is crucial to the successful functioning of any decision-making process, whether making a policy decision on the use of a medicine, or considering an IFR (see also Section 2.4). It is important that committees have resources identified and a structure in place to communicate recommendations or decisions in a timely and effective way.

Some practical points:

- Develop a communication framework to disseminate concise, targeted information to the key individuals and groups who need to know about the decision. Remember that communication is a two-way process
- Routinely communicate with neighbouring PCTs to share practice, particularly where there are cross-boundary patient flows and shared Provider Trusts; for example, using email discussion groups
- Target communication; for example, use email alerts, newsletters, individual communication by medicines management teams and press releases
- Make decision-making processes and procedures, and criteria on which decisions are made, publicly available. For the IFR process, information should be proactively given to patients at the start of the process (see also IFR policy health check Section 3.5)
- Make decisions and the basis on which they were made publicly available (without compromising patient confidentiality)
- Use a standard format for notes/minutes which ensure that for all decisions the key points are summarised
- Produce an annual report about the committees’ work and processes for the relevant boards. Report the number of medicines considered proactively, and the number of medicines considered as IFRs, along with the numbers approved/declined
- Ensure all patient communication is in clear language and in an appropriate form
The Avon and Wiltshire Cancer Network has a Drug Policy Forum which provides information and formulates advice to help PCT commissioners make policy decisions about new cancer drugs or about existing drugs where new indications are proposed. The Network has a web page aimed at patients and the public on which it publishes its advice www.aswcs.nhs.uk/DPF/default.htm

Overseeing the implementation, monitoring and feedback on decisions should be a core function of committees or a central part of the activities that support them. In reality these are often overlooked and/or under-resourced.

Some practical points:

- When decisions are made, responsibility for the implementation and monitoring of that decision should be allocated and a mechanism for feedback on progress specified
- Requirements for ongoing monitoring and audit of decisions can be included as part of the decision to recommend or fund the medicine
- Ensure that there is a proactive work programme supporting the ongoing review of the evidence base supporting decisions so that they can be revisited where appropriate
- Clear arrangements for audit and evaluation should be set out in the terms of reference for the decision-making group and lessons learned incorporated into practice
- Consider devoting a standing agenda item or part of the group’s annual report, to the implementation and monitoring of decisions
- Use contracts with Provider Trusts to encourage the monitoring and audit of the use of high-cost medicines
- In primary care, there are a wide range of initiatives and incentives that can be used to facilitate the implementation and monitoring of decisions about the usage of medicines. Medicines management teams in PCTs can advise\textsuperscript{15}
This section of the *Handbook* contains some practical resources to help PCTs, SCGs, clinical networks and Provider Trusts to put appropriate systems and processes in place consistent with the *DH guiding principles* for decision-making outlined in Section 1.3 of the *Handbook*.

Taken together, these resources can help the development of whole system decision-making. The high-level indicators in Section 3.1 can be used in conjunction with the diagnostic tool on the NPC website as a starting point to develop a baseline for the system as a whole. The more detailed checklists and flowcharts in Sections 3.2-3.5 can be used to review key components of the system.

Each of the resources in this section can be downloaded separately from the NPC website.

This section contains:

3.1 Indicators for whole system decision-making

3.2 DH guiding principles checklist for all decision-making or advisory committees/groups

3.3 Framework to help identify medicines/treatments for collaborative commissioning

3.4 IFR triage tool for Provider Trusts and clinicians

3.5 IFR policy health check
The NHS Constitution outlines the need for PCTs, their SCGs and clinical networks along with Provider Trusts to make local decisions about the funding of medicines and treatments rationally, following a proper consideration of the evidence. The DH has published guiding principles, to help improve local decision-making processes and to reassure patients that there will be a common, overarching framework within which such decisions should be made.

Due to local care configurations, PCTs are likely to use a range of different structures to develop policy, and make decisions about medicines and treatments. PCTs, with cooperation from Provider Trusts and other stakeholders, need to develop some indicators against which they can evaluate their whole system decision-making. As a starting point, included below are some examples of high-level indicators, based on key aspects of the DH guiding principles for local decision-making (Section 1.3) and the key steps in this Handbook (Section 2).

The indicators need to be refined for local use in order for them to be a meaningful tool to evaluate progress toward whole system decision-making. This will involve an initial baseline assessment of current practice and a clear view of how the system is developing in order to evaluate progress. These indicators can be used in conjunction with the diagnostic tool which helps PCTs to evaluate their current performance in some of these areas.

### 3.1 Indicators for whole system decision-making

<table>
<thead>
<tr>
<th>Scope</th>
<th>Do you have documentation describing how decision-making processes are linked into the PCT WCC assurance process?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effectiveness of horizon scanning</td>
<td>Did you proactively horizon scan to identify new medicines and treatments? How many unexpected ‘in-year’ funding requests did you have for new medicines or treatments? Could these have been predicted?</td>
</tr>
<tr>
<td>Triage to relevant groups</td>
<td>How were decisions separated into those for the whole population of the PCT and those dealing with individual patients?</td>
</tr>
<tr>
<td>Collaboration</td>
<td>How many commissioning policies were developed/decisions taken on a supra PCT (collaborative) level? Is this in line with expectations?</td>
</tr>
<tr>
<td>Speed of decisions</td>
<td>How many (what percentage of) commissioning policies took longer to develop than agreed timescales? Where delays occurred, what caused them? How many (what percentage of) IFRs were not decided within agreed timescales? Where delays occurred, what caused them?</td>
</tr>
<tr>
<td>Engagement and communication</td>
<td>Have reasonable steps been taken to engage with the public and patients about local decision-making processes and the need for prioritisation? How was feedback solicited? Are all relevant policies and decisions publicly available on the PCT website? Have you got a communication framework? Has the success of the framework for decisions/recommendations been evaluated? Can you demonstrate that commissioners and clinical teams are aware of, and act upon, decisions?</td>
</tr>
<tr>
<td>IFR processes</td>
<td>How many requests for IFRs were submitted? What percentage was appropriate for consideration through the IFR route? What percentage of IFR panel decisions was appealed? How many original decisions were overturned?</td>
</tr>
</tbody>
</table>
3.2 DH guiding principles checklist for all decision-making or advisory committees/groups

The DH guiding principles give a starting point against which decision-making or advisory groups can review their policies and procedures. The checklist here is based on these principles and should be used by PCTs and the following groups to review the policies and processes which support their defined functions.

- Priorities Committees or equivalent (see Section 2.3.1)
- APCs or equivalent (see Section 2.3.1)
- SCGs making recommendations about medicines or treatments (see Section 2.3.2)
- Supra PCT collaborative committees or groups making recommendations about medicines or treatments (see Section 2.3.2)
- Clinical Networks making recommendations about medicines or treatments
- Provider Trust DTCs or equivalent (see Section 2.3.3)

A separate health check for groups considering IFRs can be found in Section 3.5.

Overall picture (SCOPE of DH guiding principles)
The DH 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 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 WCC and 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.

☐ Is there a clear map of where the group fits in the overall structure (whole system) for PCT decision-making and policy development around medicines and treatments?

☐ Is the group clear about the context in which decisions/recommendations are being made?

☐ Are existing and potential collaborative arrangements understood by the relevant Boards and the individual decision-making/advisory groups?

Governance and accountability (DH guiding principle 1)
PCTs should: 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.

☐ Has the relevant Board formally agreed the remit of the group? Is there clarity about the status of decisions made, i.e. is the group decision-making or advisory?

☐ Is the authority and accountability for decision-making clearly defined and fully communicated?

☐ If the group has delegated authority, is it operating within the PCTs governance framework?

☐ Does the group have a clearly designated remit, lines of accountability and governance arrangements? Does the group have clear terms of reference?

☐ Does the membership of the group appropriately reflect the decisions it is being asked to take? Is there an appropriate mix of clinical and managerial professionals?

☐ Do members have the appropriate range of skills? Is there access to adequate ongoing training and resources to support the committees’ work? Do members have designated time?

☐ If necessary, how are additional specialist skills accessed?

☐ Is there a defined quorum? How is decision-making formalised (e.g. voting for consensus)?
Does the group have a policy which defines conflicts of interest, how to declare them and what happens if interests are not declared? Is this open to public scrutiny?

Are governance arrangements and resources in place to support audit of the group’s activities, both in terms of internal functions and outcomes of decisions/recommendations?

**Procedures (DH guiding principle 2)**

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

Does the group have a set of standard procedures? Would they enable a group of competent people to make the best decision, based on the available information at that time?

What provision is there for identifying and meeting the training and development needs of group members?

Have decision-making procedures been agreed by the relevant Board(s)?

Are there resources to support/commission the activities which underpin effective decision-making; for example, horizon scanning, evidence appraisal? Do these activities have procedures and policies in place?

How are agendas set? What does the group consider? Is there provision for proactive and reactive agenda items?

Does the group accept submissions, how are they structured, who can submit?

Are there procedures for re-visiting decisions based on subsequent evidence; for example, where treatment outcomes are poor, or new clinical trials emerge? How is this highlighted?

Are there procedures to manage urgent requests clearly linked to other groups where appropriate?

**Criteria for decision-making (DH guiding principle 3)**

PCTs should: 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.

Does the decision-making group have a set of defined criteria to be considered in decision making? Are these publicly available?

How are ethical considerations incorporated into decision making?

Are there policies on other potential influencing factors; for example, innovation, precedents, weak/insufficient/conflicting evidence?

Does the group have access to the best available evidence? How is the evidence base for decisions identified, accessed and used?

**Documentation (DH guiding principle 4)**

PCTs should: Document thoroughly the application of decision-making procedures and the rationale for each decision.

Does the group have publicly available and accessible documentation which describes how decisions are made?

Are decisions minuted with clear rationale, decision points and action required?

Is the validity and relevance of the clinical evidence base clearly documented?

Are there standard templates for agendas, minutes, submissions (with supporting notes)?

Is the minimum documentation for urgent requests defined?

Is there a record of how decision-making procedures were applied, and the rationale for each decision which can be reviewed and/or audited?
TIMELINESS (DH guiding principle 5)

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

☐ Does the group have a policy which defines timely decision-making and communication of outcomes? Does this vary depending on the nature of the decisions?

☐ Where, due to unusual or unexpected circumstances, defined timeframes are unlikely to be achievable, is this explained to the relevant stakeholders and a realistic timeframe proposed?

IFR APPEALS PROCESS (DH guiding principle 6)

**PCTs should:** Establish an appeals process for decisions made on individual funding requests, including clearly defined grounds for appeal, independent of the original process and open to patients and their clinicians.

See IFR policy health check, Section 3.5 for detailed guidance.

ENGAGEMENT (DH guiding principle 7)

**PCTs should:** 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.

☐ How does the group engage with stakeholders about prioritisation, the different decision-making processes and how they can best provide input?

☐ How does the group engage with wider stakeholder groups including, for example, local authorities and the pharmaceutical industry?

☐ How are patients and the public involved in the development of decision-making processes?

COMMUNICATION (DH guiding principle 8)

**PCTs should:** 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.

☐ Is the remit of the group and how it functions well understood by Provider Trusts and clinicians likely to be using it to request medicines and treatments for their patients? How is this evaluated?

☐ Is there a framework for the timely and effective dissemination of decisions; for example, detailing method, frequency, format and recipients?

☐ Is responsibility assigned for communicating decisions (including where appropriate to patients, the NHS community and the public)?

☐ Is communication in a style and format that is appropriate to the target audience? How is this evaluated?

IMPLEMENTATION AND PROCESS IMPROVEMENT (DH guiding principle 9)

**PCTs should:** Establish assurance processes to monitor the application and performance of decision-making arrangements and to enable learning to be incorporated into future process improvements.

☐ Is there a clear process for ensuring funding decisions are incorporated into contracting and procurement procedures?

☐ Is there a framework for the implementation and monitoring of decisions? Does the group assign responsibility for implementation and/or monitoring?

☐ How does the group monitor decisions to ensure that criteria for decision-making are being consistently applied? What is the feedback mechanism?

☐ How are decisions/policy kept up-to-date as new evidence emerges?

☐ Is there an assurance process to monitor the effectiveness of the committee and to enable learning to be incorporated into future process improvements?

☐ Does the group have performance indicators? How are these developed and reviewed?
3.3 Framework to help identify medicines/treatments for collaborative commissioning

As highlighted in Section 2.3.3 PCTs with a committee for collaborative commissioning need to develop a framework to help identify for which medicines or treatments it may be appropriate to collaborate. An example of a framework which can be used as a starting point for discussions is given below.

The framework proposes three steps:

1. Define **triggers**. Identify criteria that are likely to trigger collaboration (see below). The triggers in themselves may not be enough to indicate that collaborative commissioning is appropriate.

   **Examples of triggers for possible supra PCT collaboration:**
   - A number of PCTs are likely to require a policy for the same medicine or treatment
   - A medicine/treatment is high cost or high risk
   - The evidence base for the medicine/treatment is equivocal and there is a higher risk of neighbouring PCTs making different decisions
   - There is uncertainty about the medicine’s/treatment’s cost-effectiveness
   - Medicine/treatment is highly specialised and no PCT could reasonably be expected to have the full range of expertise to make a decision
   - The medicine/treatment is likely to significantly change the ways that services are configured for patients across multiple PCTs
   - PCTs (where they share information) have received multiple IFRs for the same medicine or treatment
   - Medicines coming onto the market where PCTs and providers want to develop an early policy decision
   - Other specific medicines-related factors; for example, pricing differentials between licensed and unlicensed medicines, off-license indications
   - Other specific provider issues; for example, the need to designate providers

2. Identify the **advantages** and **disadvantages** of collaboration for this medicine or treatment.

3. Make an assessment of relative **impact** by identifying the benefits associated with collaboration compared with commissioning individually. Steps 2 and 3 are summarised in **Figure four**.

**Figure four: Summary of steps 2 & 3**

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Factors which may shift the balance (rank low, medium or high)</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Consistent access for patients</td>
<td>• Clinical factors</td>
<td>• Decision distanced from the budget holder</td>
</tr>
<tr>
<td>• Avoids duplication of effort</td>
<td>• Financial factors</td>
<td>• Bypasses PCT prioritisation</td>
</tr>
<tr>
<td>• Clarity for providers</td>
<td>• Reputational factors</td>
<td>• May be sub optimal decision for some PCTs</td>
</tr>
</tbody>
</table>
It is important that Provider Trusts have the processes in place to enable clinicians and managers to identify clearly the most appropriate route that decisions about the funding of medicines or treatments need to take. Greater clarity for clinicians should help ensure that proactive decisions can be taken without the need for inappropriate reactive IFRs. This may be facilitated by using a ‘hub’ approach within a Provider Trust to ensure that only appropriate IFR requests are submitted to PCTs (see Section 2.3.3). A generic triage tool is outlined in Figure five.

**3.4 IFR triage tool for Provider Trusts and clinicians**

If appropriate, refer to IFR process (see Section 2.4 and Section 3.5).

---

**Figure five: Generic IFR triage tool**

- **Is the funding of this medicine or treatment already included in Provider Trust funding streams?**
  - **YES**
    - Provider Trust manages request (see Section 2.3.3)
  - **NO**

- **Do the PCT and Provider Trust have existing contracts and/or policies that cover the funding of this medicine?**
  - **YES**
    - Fund through existing arrangements with the PCT
  - **NO**

- **Does the PCT have a generic or treatment-specific policy in place which means that the medicine is not routinely funded?**
  - **YES**
    - Treatment not funded
  - **NO**

- **Does the patient have clinical differences which mean that they are likely to benefit from the treatment more than the normal range of response?** (see Section 2.6.2)
  - **YES**
    - Is the patient representative of a subgroup of patients?
      - **YES**
        - Refer to IFR process (see Section 2.4 and Section 3.5)
      - **NO**
        - If a potential service development (see Definitions), then refer for consideration via the PCT policy development process and annual commissioning mechanism (see Section 2.3).
  - **NO**

- **If no policy or contract exists, is the clinician likely to request this medicine for a group, or subgroup of patients?**
  - **YES**
    - If appropriate, refer to IFR process (see Section 2.4 and Section 3.5).
  - **NO**
Section three Checklists and frameworks

3.5 IFR policy health check

As highlighted throughout the Handbook the majority of decisions about the funding of medicines and treatments should be taken on a population basis by PCTs in cooperation with Provider Trusts and other stakeholders. Only a small minority of decisions should be considered on an individual patient basis. It is, however, important that PCTs have a process in place to manage these requests.

The checklist in this section considers each step in the generic IFR process illustrated in Figure six. PCTs can use it to review their own policies and identify areas for development/consideration. The majority of questions posed in this checklist should have been considered in the development of any comprehensive IFR policy.

1 IFR submitted (see also Section 2.4.1)

☐ Do you have a policy and process for IFRs? Does this include a submission form outlining all the information normally required to make a decision? Is this available on the PCT website and on request?

☐ Are the processes and the timelines for communication with the patient and clinician clearly defined?

☐ Do you have information and guidance for clinicians and patients explaining when IFRs are appropriate?

☐ Do you have appropriate forms of patient information explaining the individual funding process; for example, leaflets in multiple languages or Braille?

☐ Who can submit a request for individual funding; is this clearly defined? Can the patient submit a request or is a clinical sponsor required?

☐ Who can clinicians or patients contact for advice in deciding whether an IFR is appropriate, or for help completing a submission form?

☐ Who receives IFRs for the PCT? Is there a standard letter acknowledging receipt and a description of the process? Are timescales for acknowledging clear?

☐ Who routinely receives correspondence? Do the requesting clinician and the patient both receive copies of correspondence?

☐ How has the patient’s GP been involved in the process?

2 Triage (see also Section 2.4.2)

☐ Who screens requests initially? What competencies do they need? How are they trained and supported?

☐ How are existing policies, SLAs and contracts, and records of previous IFRs (possibly on a supra PCT level) accessed?

☐ What criteria are used for triage?

☐ How soon are requests triaged after receipt of a request?

☐ Do you have a mechanism for identifying urgent requests? What are the criteria that differentiate urgent from non-urgent? Is there a separate procedure for fast tracking these requests? Does this include minimum procedural requirements?

☐ What happens if the IFR request is incomplete/more information is needed? How is this communicated to the clinician/patient? What happens if requested information is not received?

☐ Do you have a process for managing requests which are not appropriate? How is this communicated to the patient or clinician? To where is the request referred?

☐ If the request is appropriate, do you have a process for referring it for consideration by the IFR panel?

3 Request considered (see also Sections 2.4.3 and 2.4.4)

☐ What is the membership of the IFR panel? Does it accurately reflect the role it is being asked to undertake?

☐ Do you have terms of reference that include membership of the panel, whether deputies are permitted, how a quorum is achieved (number and mix), how decisions are formalised (e.g. voting for consensus)?

☐ Do panel members have a ‘job description’? What training is available for members? How are they supported? Do you have an induction process for new members and deputies?

☐ Do you have a decision-making framework? Is it freely available? Do you have an ethical framework? How is the evidence base considered; for example, where evidence is limited? Does the PCT have a definition of exceptionality?

☐ What is the mechanism for obtaining further input if necessary; for example, evidence appraisal or ‘expert’ advice?
Do you have a mechanism for recording and minuting the meeting? Who agrees the minutes? Can they be clearly understood by those outside the panel; for example, the appeals panel or the patient?

Do you have processes that maintain the confidentiality of all participant parties where appropriate?

**4 & 5 Funding agreed/not agreed**

- Do you have a process/procedure for what happens if funding is agreed/not agreed?
- What are the timescales for informing the patient/clinician?
- How is the patient informed about the decision; for example, does the patient/clinician receive the minutes of the meeting/a summary letter?
- Who contacts the patient and referring clinician? Is this by letter, telephone, email, or face-to-face? How are they trained and supported?
- Are processes in place to ensure that the decision and the basis for the decision inform any future decision-making?

**For agreed**

- What processes are in place to ensure that the patient receives the treatment in a timely manner?
- How is feedback received on the outcome of the treatment? What processes are in place for stopping treatment if no benefit is shown?

**For not agreed**

- Is the patient informed about the possibility of appeal?

**6 Patient appeals decision (see also Section 2.4.5)**

- Do you have a process/procedure for what happens if a patient appeals a decision? How does the patient lodge an appeal?
- Are timescales for the appeals process clearly defined?
- Do you have a mechanism for identifying urgent requests? What are the criteria that differentiate urgent from non-urgent? Is there a separate procedure for fast tracking urgent requests? Does this include minimum procedural requirements?
- Is the role of the appeals panel clearly defined? Do you specify on what grounds the patient can make an appeal? Do you specify what the appeals panel does not consider? Are these criteria freely available?
- Do you have an organisational framework that specifies where the panel’s authority sits?
- What is the membership of the appeals panel? Does it accurately reflect the role it is being asked to undertake? Is it independent of the IFR panel?
- Do you have terms of reference that include the membership of the appeals panel, whether deputies are permitted, how a quorum is achieved (number and mix), how decisions are formalised (e.g. voting for consensus)?
- Do panel members have a ‘job description’? What training is available for members? How are they supported? Do you have an induction process for new members and deputies?
- How is the appeal process open, giving the patient and/or their clinician opportunity to input? How are patients and panel members supported? Do you have a mechanism for recording and minuting the appeals panel meeting? Who agrees the minutes?
- Do you have processes that ensure confidentiality of all participant parties, where appropriate?

**7 & 8 Original PCT decision overturned/upheld**

- Do you have a clear process in place for what happens if the PCT decision is either overturned or upheld?
- What are the timescales for informing the patient/clinician?
- Who contacts the patient and referring clinician? Is this by letter, telephone, email, or face-to-face? How are individuals trained and supported?
- How is the patient informed about the decision; for example, does the patient/clinician receive the minutes of the meeting/a summary letter?
- How does the decision feed back to the IFR panel so that lessons can be learnt?

**For decision upheld**

- Is the patient informed about what their next options are?
Figure six: Generic IFR process

1. IFR Submitted

2. Triage process. Refer to panel? NO
   - Document how the request was managed

   YES

3. Request considered (by IFR panel)

4. Communicate decision not to fund

5. Communicate decision and authorise treatment

6. Patient/clinician appeals decision

7. Decision communicated. Appropriate action taken

8. Decision communicated. The patient may still use the NHS complaints procedure

Appeal upheld? NO

YES

Feedback loop

Section three Checklists and frameworks
Section four
Factsheets
4.1 Horizon scanning

**What is horizon scanning?**
Horizon scanning aims to identify in advance treatments (not just medicines) that may have significant implications for clinical practice, service design or finance that are likely to become available to the NHS. Horizon scanning should also identify potential disinvestments by reviewing evidence on an ongoing basis.

**Why do it?**
Horizon scanning is crucial to ensure that developments and cost pressures are identified early. By carrying out horizon scanning for medicines and treatments, providers and commissioners may be able to make proactive commissioning decisions and minimise problems created by in-year requests. This could include making interim policy decisions and financial provision for in-year developments, if necessary.

**Who should do it?**
Horizon scanning can be undertaken in a range of ways. There are already national organisations undertaking this on behalf of the NHS (see Factsheet 4.2). In addition, in 2010, it is expected that there will be a single national database highlighting medicines in clinical development which will inform the work of national groups supporting NHS decision-making.

PCTs and Provider Trusts need to ensure that they use these national resources and do not duplicate effort locally. Horizon scanning for medicines needs to be part of, or linked into, the wider PCT horizon scanning process for all new treatments and will involve working with Provider Trusts, clinicians and clinical networks.

**How should it be done?**
The national sources of horizon scanning intelligence need to be linked into the local context. For example, networks with local specialists, provider DTCs or APCs can all contribute to horizon scanning particularly around the PCT’s individual priorities. PCTs need to decide how this is achieved and whether they have the resources to do this alone or should collaborate with other PCTs.

**When should it be done?**
Horizon scanning should be a regular part of the activities of both clinical and commissioning teams. It should be an ongoing process that informs the PCT’s annual commissioning round.
4.2 Examples of sources of national horizon scanning information on medicines

The National Horizon Scanning Centre, the National Prescribing Centre (NPC), and the UK Medicines Information Network (UKMI) contribute to national horizon scanning for medicines. Resources produced can be divided into ‘evaluated’ information and ‘current awareness’.

**Evaluated information includes:**

- **National Horizon Scanning Centre monographs** - published up to 5 years before a drug is likely to be marketed. They inform the NICE work programme [www.pcpoh.bham.ac.uk/publichealth/horizon/](http://www.pcpoh.bham.ac.uk/publichealth/horizon/)

- **On the Horizon - Future Medicines bulletins** sensitise the NHS to significant new medicines. They are published approximately 6 months pre-launch for medicines either not currently covered in the NICE programme or where no NICE guidance is planned near launch. [www.npc.co.uk/ebt/nm/publications.htm?type=all](http://www.npc.co.uk/ebt/nm/publications.htm?type=all) (NHSnet connection required).

- **On the Horizon - Post Launch Update bulletins** are produced when significant additional information has emerged since the publication of the related On the Horizon - Future Medicines bulletins. Published within 6 weeks of a key product being marketed. [www.npc.co.uk/ebt/nm/publications.htm?type=all](http://www.npc.co.uk/ebt/nm/publications.htm?type=all) (NHSnet connection required).

- **New medicines profiles** - published shortly after launch for a selected number of medicines. They appraise key clinical trials and assess potential NHS impact [www.nelm.nhs.uk](http://www.nelm.nhs.uk)


**Current awareness includes:**

- **A daily news service** on the National electronic Library for Medicines website [www.nelm.nhs.uk](http://www.nelm.nhs.uk) highlights FDA and EMEA regulatory decisions, studies of drugs in development and published appraisals.

- **New drugs online database** comprises information on drugs in clinical development including details of development phase, ongoing and completed studies and links to evaluated information on new drugs up to 1 year post-launch. It can be used as a dynamic tool to produce reports based on a number of criteria including possible launch date, pharmaceutical company pipelines or developments, in particular therapeutic areas [www.nelm.nhs.uk](http://www.nelm.nhs.uk)

**The Prescribing Outlook series** is published annually in autumn. [Prescribing Outlook - new medicines](http://www.npc.co.uk) highlights around 30 drugs that may be licensed in the next 18 months and which are considered will have an impact (financial, service or other) on the NHS. [Prescribing Outlook – national developments](http://www.nelm.nhs.uk) estimates the impact of National Service Frameworks, NICE guidance and the outcome of major clinical trials on clinical practice and prescribing budgets.

It is intended to inform discussions between commissioners and providers, and highlight issues around implementation of national guidance. [Prescribing Outlook – cost calculator](http://www.nelm.nhs.uk) is an Excel spreadsheet tool to facilitate estimates of potential prescribing changes for a local population. [www.nelm.nhs.uk](http://www.nelm.nhs.uk) - registration required.

- **On the Horizon - Stop Press and Rapid Reviews blogs** highlight short ‘news’ items or major primary research relating to medicines in development, or recently launched and adds relevant context [www.npci.org.uk/blog/](http://www.npci.org.uk/blog/)

- **E-mail discussion group on new medicines** provides an opportunity to share good practice among people involved in managing new medicines into local healthcare economies. Membership is restricted to relevant NHS employees in England, involved in this process. Members are invited to three face-to-face workshops each year. Matters shared relate to horizon scanning, budget planning, decision-making and implementation. Members can also receive a CD recorded after each workshop that provides information and advice on key drugs that may reach the market within 12 to 18 months. For more information about the discussion group and details on how to join go to [www.npci.org.uk](http://www.npci.org.uk)/blog/

- **Patents database** highlights patent expiry dates of proprietary medicines. The availability of generic medicines provides a potential for disinvestment [www.ukmi.nhs.uk](http://www.ukmi.nhs.uk)
4.3 Topic Selection

What is topic selection?
Horizon scanning will identify a range of potential developments in the pipeline. Topic selection filters and prioritises those treatments most likely to have significant future impact and therefore in need of further assessment. This may also involve selection of topics to review for disinvestment.

Why do it?
Not all developments identified through horizon scanning will need a detailed evaluation of the evidence. Resources need to be concentrated on the timely evaluation of those medicines, or treatments most likely to have significant impact, in order to help prepare PCTs and their Provider Trusts.

Who should do it?
National horizon scanning organisations select topics for further evaluation based on a range of criteria (see below) before producing evidence appraisals for NHS organisations. Topic selection following local horizon scanning activities will depend in part on how the PCT has structured horizon scanning. It is important that the topics selected are those that help the PCT to make timely and effective decisions.

How should it be done?
There are a range of criteria that can be used in selecting topics for further consideration. The criteria need to reflect the PCT’s priorities and the requirements of WCC. A number of organisations have produced medicines specific criteria, for example, NPC, UKMI and NICE. The NPC and UKMI criteria include the following, some of which may also apply to treatments:

- The medicine is expected to provide a significant improvement in disease management
- The medicine is first in class, or has a major new indication
- There are limited other medicine/non-medicine treatment alternatives
- The medicine cost will be high
- The target population is large
- There is likely to be a significant effect on service configurations; for example, method of delivery, diagnostics or follow-up
- The medicine or disease area is considered an NHS priority
- The medicine has significant additional indications in the advanced pipeline stage
- There is likely to be significant media interest

When should it be done?
Topic selection should be linked to the PCT’s decision-making processes to ensure that any further evaluation necessary is completed in time to inform PCT commissioning decisions.
The strength of the evidence base supporting the use of a medicine or treatment is one factor that advisory and decision-making committees need to consider. It is important that members of these groups use the best available evidence to inform their decisions and recognise the relative strength of different levels of evidence.

Studies that are conducted retrospectively (i.e. after an event of interest has occurred), as in case-control studies and some cohort studies, are susceptible to bias from a number of sources. The selection of cases and controls, the accurate recording of exposure to an intervention and the reporting of events of interest may all influence the outcome of the study and can be difficult to control. In contrast, double-blind randomised controlled trials (RCTs), in which subjects are truly randomly allocated to the study interventions and neither the investigators, nor the subjects, are aware of which intervention the subjects will receive, can control for some of the possible biases encountered with retrospective studies. Therefore, well-conducted, prospective, double-blind RCTs are considered more reliable (less open to bias) than unblinded prospective studies, which are considered more reliable than retrospective studies.

This helps create a hierarchy of evidence that describes the validity of different sources of evidence for interventions (Box six). In general, well-conducted systematic reviews and meta-analyses of robust, double-blind RCTs are considered the gold standard of evidence for making decisions about interventions.

However, for information about diagnosis, prognosis and harms, other sources and data may be more appropriate. In addition, there may be occasions where no relevant RCT has been conducted and the next best available evidence will need to be considered.

**Box six**

**A hierarchy of evidence**

- Well-conducted meta-analysis of several, similar, large, well-designed RCTs
- Large well-designed RCT
- Meta-analysis of smaller RCTs
- Case-control and cohort studies
- Case reports and case series
- Consensus from expert panels
- Individual opinion
Appendices

Definitions

**Provider Trusts**
Provider Trusts is used throughout the document to mean NHS Trusts, Foundation Trusts and all other organisations providing services in or for the NHS.

**Annual Operating Plan**
The Annual Operating Plan is one of the planning tools utilised by PCTs. It sets out the developments planned over the following 12 months to improve local health and wellbeing in response to local and national priorities in line with the overall Strategic Commissioning Plan. As part of this planning process, each PCT carries out a population-based relative benefit value assessment of all available interventions, including medicines without positive NICE guidance, in order to prioritise interventions and optimise the use of the available budget. According to the WCC assurance framework, PCT Boards are expected to select health outcomes from the assurance toolkit and submit their choices to the SHA. The selected outcomes should reflect the health needs of the local population and the PCT’s strategic priorities, and should have been agreed with their partners and stakeholders (including the public, patients, clinicians, and community colleagues). The approved health outcomes then become the basis of the annual funding prioritisation (commissioning round), which informs both investment and disinvestment decisions, and against which all newly available interventions are considered.

**Opportunity cost**
Opportunity cost is an economic concept that underlies healthcare priority setting and relates to physical resources such as qualified staff or money. It is derived from the understanding that investing such resources in a particular way means they cannot be invested elsewhere. In the context of finite healthcare budgets, for example, this means that any new development results in the loss of opportunity or benefit from not doing something else. It is, therefore, key that during priority setting, the costs and benefits of interventions are considered in relation to those of the other possible alternatives.
Ethical framework

Criteria for local decision-making may be encapsulated within an ethical framework. These state explicitly all the principles that a PCT needs to consider when making decisions for their populations. They usually include clinical and cost-effectiveness but also, the wider issues that PCTs need to consider; for example, health inequalities, equity and opportunity cost.

Specialised Services

Specialised services are high-cost, low-volume interventions, provided in relatively few specialist centres (usually in larger hospitals). There are currently 36 services defined as being specialised — typically complex/chronic conditions, which require a critical mass of patients to make treatment centres cost-effective and to optimise the level of patient care. These services are therefore best planned for catchment populations greater than one million people. As a result, PCTs group together to commission such services collectively, which allows them to share the financial risk of funding expensive and unpredictable activity. Specialised services are either commissioned on a regional basis, by the 10 SCGs, or on a national basis by the NCG, in the case of particularly rare conditions. Each SCG acts on behalf of a population of about five million people and formally designates specific providers to provide specific specialised services, based on a nationally agreed set of criteria.

Clinical Networks

The Carter Review defines managed clinical networks as linked groups of health professionals and organisations from primary, secondary and tertiary care, working in a coordinated manner, unconstrained by existing professional and Health Board boundaries, to ensure equitable provision of high-quality clinically effective services.18

Service Development

A service development is anything that needs investment. It refers to all new developments, including: new services; new treatments, including medicines; changes to treatment thresholds; and quality improvements, such as reduced waiting times. It also refers to 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.

Individual funding request (IFR)

An IFR is a request to fund, for an individual, an episode of healthcare that currently falls outside existing contracts. The funding request may be asking for any type of healthcare: a service, a piece of equipment or aid, a specific treatment or medicine. In contrast to annual prioritisation and in-year service development decisions, appropriate IFRs are considered on an individual patient, rather than population, basis. There are two main categories of appropriate IFR: first, where patients fall outside an existing generic or treatment-specific policy where an unusual circumstance applies to the individual; second, for patients with a very rare clinical condition. Using the IFR process is inappropriate where they represent requests for service developments (e.g. effectively a group of IFRs relating to a newly licensed drug), or in cases where there is no evidence that a particular individual will gain comparatively greater clinical benefit. Evidence for additional clinical benefit needs to accompany requests that fall outside an existing PCT commissioning policy not to provide a treatment. The question for consideration is then whether the evidence is sufficient to justify the patient receiving funding when others have been excluded. This is usually decided based on clinical differences and evidence that the patient will benefit from the treatment more than the normal range of response.
Prior Approval

For high-cost medicines PCTs may choose to use prior approval policies. These policies, usually agreed as part of the Operational Planning process, define the clinical criteria which patients need to meet before treatment is initiated and the arrangements for starting and monitoring treatment. Prior approval should not be confused with an Individual funding request (IFR), (see also Definitions). Once policies have been developed and agreed, these can be revisited as new evidence becomes available.

Group Prior Approval

Some PCTs use group prior approval. This is for groups of patients with defined clinical criteria for whom additional funding has been agreed. Group prior approval arrangements set out the pathway and/or clinical criteria that Provider Trusts must use (in this they are similar to clinical thresholds for referral). Approval for groups will normally be given by individual PCTs who will specify the values for activity and costs that are covered by the group prior approval. Where a group prior approval arrangement has been established, prior approval for individual patients is not required. However, PCTs will normally require Provider Trusts to notify the patient’s PCT of each new patient starting treatment and where treatment is discontinued.20

PbR

PbR is a system for paying Provider Trusts for services. It sets a tariff for all treatment episodes, including medicines. Most medicines (by volume) are included in the tariff. However, there are a number of medicines, often high cost, not covered by the tariff. These are: specialist medicines explicitly excluded from tariff; medicines used to treat conditions not yet included in the tariff; and recently launched medicines. Inclusion in the PbR tariff does not necessarily mean the medicine will be commissioned by a PCT.

Orphan Drug

The term orphan drug is used in EU legislation to describe a drug indicated for a rare disease (orphan disease). The definition of an orphan disease is one with a prevalence of less than 50 per 100 000 of the population. A potential product can be granted orphan drug status if it is proposed for use to treat an orphan disease. The wide range of conditions that fall within the definition of orphan diseases has led to the emergence of an informal subcategory — called ultra-orphan diseases — to describe extremely rare conditions. The term has no formal legal definition but treatments for these very rare — ultra-orphan diseases — have become known as ultra-orphan drugs.20

Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>APC</td>
<td>Area Prescribing Committee</td>
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<tr>
<td>DH</td>
<td>Department of Health</td>
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<td>DTC</td>
<td>Drug and Therapeutics Committee</td>
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<tr>
<td>GP</td>
<td>General Practitioner</td>
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<tr>
<td>IFR</td>
<td>Individual Funding Request</td>
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<tr>
<td>LINkS</td>
<td>Local Involvement Networks</td>
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<tr>
<td>NCG</td>
<td>National Commissioning Group</td>
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<tr>
<td>NICE</td>
<td>National Institute for Health and Clinical Excellence</td>
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<tr>
<td>NPC</td>
<td>National Prescribing Centre</td>
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<td>PBR</td>
<td>Payment by Results</td>
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<td>PCT</td>
<td>Primary Care Trust</td>
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<tr>
<td>SCG</td>
<td>Specialised Commissioning Group</td>
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<td>SHA</td>
<td>Strategic Health Authority</td>
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<td>UKMI</td>
<td>United Kingdom Medicines Information network</td>
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<td>WCC</td>
<td>World Class Commissioning</td>
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References


Available from: www.npc.co.uk/ebt/merec/mastery/mast2/resources/merec_briefing_no30.pdf
[last accessed 3rd March 2009]

[last accessed 3rd March 2009]

[last accessed 3rd March 2009]

19 East of England SHA. Commissioning intentions 07/08 www.npc.co.uk/policy/local/sharing_library.htm

[last accessed 3rd March 2009]
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How the *handbook* was developed

The *NHS Constitution* gives patients the *right* to expect local decisions about the funding of medicines and treatments to be made rationally following a proper consideration of the evidence. The DH website contains *DH guiding principles* for decision-making about medicines and treatments. The *purpose of this Handbook* is to help organisations put appropriate systems and processes in place consistent with the *DH guiding principles*.

The development of the *Handbook* was undertaken in parallel with two related work streams: the development of the *DH guiding principles* and a baseline survey of PCT local decision-making processes. Both these work streams informed the development of the *Handbook* throughout the process. The output of both these work streams can be found on the NPC website.

An *Expert Group* provided ongoing input and guidance into the structure and content of the *Handbook* and provided advice as issues arose during development.

Before beginning development of the *Handbook*, data were gathered about existing decision-making processes, stakeholders involved and the key issues PCTs, Provider Trusts and patients faced. This involved literature review, interviews, data and insight from the baseline survey and issues emerging from the development of the *DH guiding principles*.

The expert group and a first *User* group developed an initial map of the key steps involved in local decision-making which was refined throughout development; this forms the backbone of the *Handbook*. The outline content underpinning each of the key steps was identified and the broad structure tested with a second *User* group. At the same time an outline of the resources that PCTs and their Provider Trusts might need to help review and develop their systems was developed.

The provisional content of the *Handbook* was developed by the project lead and subsequently tested by *four validation* groups. All four groups commented on the key steps and underpinning content. In addition, the first two groups tested the checklists and resources developed to help PCTs and Provider Trusts review their systems. The third group focused on putting the *Handbook* into practice and the fourth on the development of a high-level diagnostic tool for PCTs to assess their existing systems. All the groups’ inputs led to a further refinement of the content.

Once validated, the *Handbook* was circulated to a range of stakeholders, and back to the user and validation groups, and comments used to refine the content of the *Handbook* for publication.

Throughout the development of the *Handbook*, examples of practice are cited which illustrate key aspects of the *Handbook*. In addition, policies, processes and procedures were collected from across a range of NHS organisations. Some examples are included in a *sharing practice library* and are a reflection of how organisations have developed their own systems locally.

The ‘Acknowledgements’ section of the appendices provides a list of individuals who have contributed to the development of the *Handbook*; their input into the process has been invaluable.