Item Number: 11

NHS VALE OF YORK CLINICAL COMMISSIONING GROUP

GOVERNING BODY MEETING

NHS
Vale of York
Clinical Commissioning Group

Meeting Date: 7 March 2013

Report Sponsor:	**Report Author:**
Rachel Potts Chief Operating Officer	Gill Fox Commissioning Support Unit Policy Implementation and Assurance Manager – Individual Funding Request Lead

1. Title of Paper: Individual Funding Request Panels post 1 April 2013

2. Strategic Objectives supported by this paper

- Improve healthcare outcomes
- Reduce health inequalities
- Improve the quality and safety of commissioned services
- Improve efficiency
- Help to achieve financial balance/value for money

3. Executive Summary

This paper outlines the arrangements to be agreed by the CCG for fulfilling the CCGs' responsibilities for managing Individual Funding Requests (IFRs) post 1 April 2013. An IFR process and decision-making panel will be established as a formal decision making body empowered to make commissioning decisions on grounds of 'exceptionality' in specific circumstances.

4. Evidence Base

Not applicable

5. Risks relating to proposals in this paper

Individual Funding Requests are a high risk area in terms of:

- Potential financial risk
- Potential setting of clinical precedence
- Potential legal challenge (including to Judicial Review) leading to financial costs
- Potential reputational risk

6. Summary of any finance / resource implications

This paper does not include a financial summary. The costs of administratively supporting the IFR process are within CCG resource envelope agreed with the Commissioning Support Unit (CSU). The costs incurred by GPs sitting as panel members are for CCG to consider through internal mechanisms.

7. Any statutory / regulatory / legal / NHS Constitution implications

The requirement to have an Individual Funding Request process is a statutory obligation. Consideration of potential legal considerations and challenges when approval for patients to access specific treatments is declined.

8. Equality Impact Assessment

Not directly applicable to this paper – contained within existing Treatment Advisory Group Policy. All individual commissioning policies will be assessed for impact.

9. Any related work with stakeholders or communications plan

Consultation with all North Yorkshire CCGs and CSU Communications

10. Recommendations / Action Required

The Governing Body is asked to:

- Note and accept the Joint Committee arrangements for Panel membership
- Note and accept delegated authority for Individual Funding Requests
- Note and accept that the provision for IFRs is a statutory duty and an area of risk
- Approve the IFR Panel and Appeal Panel Terms of Reference, including the membership and GP Clinical Decision Maker role.
- Approve the attached amendment to the Scheme of Reservation and Delegation which is in line with the CCG Constitution to secure appropriate delegated decision making in relation to the IFR process.

11. Assurance

By regular interim reports, and annual report to Strategic Collaborative Commissioning Committee.

NHS VALE OF YORK CLINICAL COMMISSIONING GROUP

INDIVIDUAL FUNDING REQUEST PANELS POST 1 APRIL 2013

1. Introduction

This paper outlines the arrangements to be agreed by the CCG for fulfilling the CCGs' responsibilities for managing Individual Funding Requests (IFRs) post 1 April 2013. An IFR process and decision-making panel will be established as a formal decision making body empowered to make commissioning decisions on grounds of 'exceptionality' in specific circumstances.

2. Risk

Individual Funding Requests are a high risk area in terms of:

- Potential financial risk
- Potential setting of clinical precedence
- Potential legal challenge (including to Judicial Review) leading to financial costs
- Potential reputational risk

3. Background

From April 2013, as a result of the Health and Social Care Act, the responsibility for the Individual Funding Request process rests with CCGs as the local NHS commissioning body. As part of this responsibility, each CCG is required to establish arrangements for an IFR Panel and an Appeals Panel to consider cases when the IFR process has been exhausted.

4. IFR Panel

4.1 The IFR Panel is responsible for giving due consideration to, and making decisions on, funding requests for individual cases in which a drug, intervention or treatment is 'not routinely commissioned' as covered by an extant policy. Where there is no extant policy – for example where a treatment is new or experimental - the default commissioning position is taken to be 'not routinely commissioned'. A treatment may be 'not routinely commissioned' because it is considered to be not clinically effective and/ or cost-effective, or where the patient has a rare condition where there is unlikely to be an extant policy or strong evidence base. In these cases, consideration needs to be given to the relevant evidence base for both the clinical and cost-effectiveness of the proposed drug or intervention. In all cases considered by panel, a range of specialist advice and expertise is available to assist members to reach a considered view. Advice may be received from senior pharmacists, legal adviser, subject matter experts, therapists, mental health managers etc. This list is not

exhaustive. The Terms of Reference of the IFR Panel are attached at Appendix A.

4.2 In the Humber area, each CCG has elected to run its own IFR panel in-house, administratively supported by the CSU. For North Yorkshire, discussions have been progressed with the North Yorkshire and Humber Commissioning Support Unit (CSU) via the North Yorkshire Strategic Collaborative Commissioning Committee to support Vale of York, Scarborough and Ryedale, Harrogate and Rural District and Hambleton, Richmondshire and Whitby CCGs in working collaboratively to ensure an efficient and effective way of managing the IFR and Appeals process across the area. At the meeting in December 2012 of the Strategic Collaborative Commissioning Committee, an Option Paper was discussed when it was agreed that the CSU would facilitate and undertake the administration for both IFR and Appeal Panels on behalf of the four CCGs. Fifteen GPs have now put their names forward for consideration, covering all the North Yorkshire and York CCGs. Interviews/competency and training are currently being organised.

5. Appeal Panel

5.1 Occasionally, cases which have been declined are further considered by an Appeal Panel, where the patient/referring clinician wishes to pursue the matter. Good practice* suggests that for cases already considered by clinicians through an IFR panel, a review of due process should be undertaken by an Appeal Panel formed by clinicians who have not previously been involved in the original decision-making process. Appeal Panels are held infrequently (approx 8 per year) and are currently chaired by the Chairman of the PCT, Kevin McAleese. This arrangement will also need to be reviewed prior to 1st April 2013. **NYY CCGs are asked to consider how they would like to deal with the Chairman's role/and or lay representation, going forward.** *(DH Local Decision making Competency Framework, 2012)

5.2 Panel clinicians may be required to attend Appeal Panel where they have not previously been involved in decision-making for the case concerned. Time required would be similar to (or less than) that needed for the IFR panel as a one-off involvement. The Terms of Reference for the Appeals Panel are attached at Appendix B.

6. Responsibilities Associated with IFR

6.1 Key CCG responsibilities are to:

- Own the delegated decisions made by the IFR panel GP members
- Assure attendance of at least one GP member for IFR panel (on rota basis, as required)
- Approve general CCG commissioning policies which underpin the IFR process through the agreed mechanisms (ie Recommendations

from Treatment Advisory Group through the general horizon scanning process, signed off through Service Specifications)

- On an annual basis consider amendments to the over-arching Treatment Advisory Group policy which includes Terms of Reference for the CSU Impact Assessment Group, the Treatment Advisory Group and the IFR/Appeal panel. This policy provides a comprehensive view of the entire process of the circumstances in which commissioning decisions are made for drugs/treatments/interventions outwith the usual Payment by Results tariff, or for treatment of rare conditions
- Agree that the delegated GPs may be called upon, on infrequent occasions, to interface with either requesting clinicians or patients or to provide comment relating to a media enquiry, MP query or similar

6.2 To assist the CCG in delivering its responsibilities a service specification has been agreed with the CSU to include a range of support including:

- Expert advice re national specialist commissioning policies.
- Assimilation of regional/national guidance.
- Storage/recall of local commissioning policies.
- Storage/recall of national commissioning policies.
- Response to related Freedom of Information, MP letters, Ombudsman enquires.
- Case management of exceptional treatment requests.
- Co-ordination of IFR and Appeals Panels.
- Liaison/correspondence with clinicians, patients and families.
- Management of appeals processes.
- Management of judicial reviews.

6.3 More detailed information is provided within the service specification and relevant process maps. Attached at Appendix C. NB: these documents remain draft until approved through the usual mechanisms.

7. Changes in scope of local IFR function of CCGs

From April 2013, a number of specialised/high cost treatments (including for example, all requests subject to the national Cancer Drugs Fund) will be transferred to NHS Commissioning Board, through the National Specialised Commissioning Group. There will be a separate NHS Commissioning Board IFR process to consider these requests.

7.1 The work of the IFR panel has been increasing steadily over a number of years and indications are that this will continue. There are several reasons for this, the main one being that the general public are becoming more aware of their right to challenge decisions about their health, particularly with the introduction of clinical thresholds which

patients often view as a restriction. As more potential treatments become available, particularly increasing use of drugs such as biologics to treat more conditions/clinical indications, there has been considerable cost pressure to accommodate these innovations within a tight financial envelope. From 1 April 2013, all cancer treatments and a number of other high cost/low volume treatments will no longer be considered by CCG IFR panels as the remit moves to the NHS Commissioning Board. Whilst this will cause some reduction in number of high cost/low volume cases received, the NHS Commissioning Board will work to a definitive list and there will remain many other treatments outwith that list which will still need consideration by CCG IFR panels. Although the case mix may change, many of these cases have a level of complexity around the individual case details which will still require CCG IFR panel consideration.

8. Changes in role of Public Health supporting local IFR process

8.1 The former Primary Care Trust IFR Panels were supported by medically qualified public health consultants who provided both healthcare public health/ population science advice as well as the decision-making role. From 1 April 2013, under the new arrangements whereby PH moves to the Local Authority, this decision-making will cease and the decision-making role will pass to the delegated CCG Clinical Decision Makers.

8.2 As part of the LA Core Offer, a healthcare/PH advisor role will be provided across North Yorkshire and York to support the CSU including in the delivery of IFR panels. The exact remit of the role has yet to be confirmed, but may include supporting policy development and any advice requested by IFR panels to offer public health/ population science advice, particularly on the epidemiology of conditions, the evidence if effectiveness and cost-effectiveness of interventions and the criteria and outcomes that are important to consider in considering exceptionality.

9. Joint Committee Arrangements and Panel Membership

9.1 CCG constitutional guidance states that a CCG cannot delegate a commissioning decision (which includes an IFR decision) to a joint committee or panel. The statutory position for CCGs for commissioning decisions is different to that of Primary Care Trusts. The responsibilities are set out in 'Towards establishment' in the collaborative arrangements section (chapter 7). This states...

9.2 *'Clinical commissioning groups cannot establish a joint committee which in itself has delegated decision-making authority. However each group may, for example, grant in its constitution delegated authority to members or employees participating in those joint arrangements to make decisions on its behalf (the group retaining liability for the decision). It is therefore the individual member / employee who has the*

delegated authority to make a decision rather than any joint arrangement. Where a group requires an individual member / employee to make a delegated decision, this must be recorded in the group's scheme of reservation and delegation.'

9.3 With this in mind, the CCGs have agreed to establish a joint committee and grant authority to *nominated* GPs (as delegated clinical decisions makers) across the area to participate in the membership of the IFR Panel. Each of the *nominated* GPs will be listed in the Scheme of Reservation and Delegation and will be required to enter into an honorary contract to act on behalf of all four CCGs in decision making.

9.4 All Clinical Decision Makers will be appropriately trained in line with the required duties. The first training session is to be held on 14th March 2013. Advice from the Strategic Collaborative Commissioning Committee suggests that CCGs wish the panels to continue to be held collaboratively i.e. a case mix from all four North Yorkshire and York CCGs to be considered at each meeting. Depending on the rota, suitable days/times/venue(s) will be confirmed following the training day. Where appropriate, panels may be moved to different venues to accommodate the needs of the GPs on rota at the time.

9.5 The Panel arrangements will be reviewed every six months or sooner should the need arise.

10. Scheme of Delegation

10.1 In order to ensure the validity of decision-making for Individual Funding Requests, the Clinical Commissioning Group is requested to approve an amendment to the Scheme of Delegation.

"This Clinical Commissioning Group permits the specified persons, or a class of persons, to take decisions on its behalf. Such persons not part of a CCG Member Practice, or an employee of the CCG will enter into an honorary contract with the CCG. (list name(s)

10.2 Further discussion or clarification on the legal aspect of delegation may be obtained through the CSU Legal Adviser, who will be pleased to assist.

11. Recommendations

The Governing Body is recommended to:

11.1 Note and accept the Joint Committee arrangements for Panel membership.

11.2 Note and accept delegated authority for Individual Funding Requests.

11.3 Note and accept that the provision for IFRs is a statutory duty and an area of risk.

11.4 Approve the IFR Panel and Appeal Panel Terms of Reference, including the membership and GP Clinical Decision Maker role.

11.5 Approve the attached amendment to the Scheme of Reservation and Delegation which is in line with the CCG Constitution to secure appropriate delegated decision making in relation to the IFR process.

Appendix A

Individual Funding Request Panel - Terms of Reference

1. Purpose

The purpose of the Individual Funding Request Panel is to deal with requests for an individual to receive a health care intervention that is not routinely funded by the CCGs (see Treatment Advisory Group Policy, section 6). For this purpose, the term 'healthcare intervention' includes use of a medicine or medical device, diagnostic technique, surgical procedure or other therapeutic intervention.

2. Membership

The membership of the Panel is as follows:

- Senior Commissioner (Chair)
- Two medically-qualified Public Health Specialists / Medical Directors/Clinical Advisor/GPs
- Legal Services Manager
- Principal or Senior Pharmacist (as appropriate)
- NHS Clinical therapist(s) (as appropriate)
- Mental Health commissioner (as appropriate)
- Other commissioners (as appropriate)

The panel will be supported by Commissioning/Case Managers

3. Chair

The panel will be chaired by a Senior Commissioner.

4. Quoracy

Two medical directors/public health advisors/GPs and a commissioner will be present to ensure the meeting is quorate.

The Panel will usually meet on a weekly basis.

5. Accountability and Decision Making

Until 1 April 2013 the CSU Medical Director is the accountable officer for all clinical decisions made by the IFR Panel. The Panel is accountable to the CSU Board through the Governance and Quality Committee.

Accountability and delegation of authority will be as described in the appropriate schedule of delegation.

Funding decisions will be taken by the two clinicians on the Panel. Other members attend in an advisory (not decision making) capacity.

6. Confidentiality and Consent

Patient consent will be required by the CSU for all cases. The consent of patients is expected to be sought by the GP or referring clinician before submitting a request to the IFR panel. Therefore, once a request is made to the IFR panel, it is done so on the understanding that the patient has given consent.

Patient confidentiality will be maintained at all times by those considering cases in accordance with the CSU's Information Governance and Safe Haven policies.

7. Individual Funding Request (IFR) Process and Application Form

See Section 11 of the Treatment Advisory Group Policy.

8. Timescales

The IFR team is committed to ensuring that the referring clinician receives a response which will usually be within 5-10 working days. In the majority of cases, and where all of the requested and relevant information has been provided, this will be with a firm decision on funding with the panel's reasons for the decision explained.

9. Decision-making

Only the medically-qualified members of the IFR panel make decisions on individual funding requests. Advisory members and commissioning/ case managers and support staff do not make decisions. In the unusual event of failure to agree, the Chairman may defer consideration of the case to a later meeting, to allow for reflection, or s/he may use a casting vote.

Appendix B

Commissioning Support Unit Independent Funding Request Appeal Panel - Terms of Reference

1. Purpose and Definition

The CSU Appeals IFR Panel is a separate body to the Individual Funding Request Panel. The purpose of the IFR Appeals Panel is to review the decision of the Individual Funding Request Panel and to judge whether or not that decision was valid in terms of process, factors considered and criteria applied.

The purpose of an Appeal is primarily to:

- Consider procedural irregularities
- Where it is alleged that the IFR panel failed to take relevant information into consideration
- Where it is alleged that the IFR panel took irrelevant information into account

2. Membership

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The membership of the IFR Appeal Panel is as follows:

- Non-Executive Director (Chair)
- Two Medically Qualified staff **who were not involved in considering** the case at the Individual Funding Request Panel.
- Relevant Commissioning/ Case Manager(s) (to prepare all documentation and service the Appeal Panel)
- Legal Services Manager
- Expert advisors (e.g. pharmacists) as required.

The Commissioning/Case Manager responsible for the case will prepare all documentation, including a time line detailing each step of the process. The Commissioning/Case Manager will ensure receipt of the documentation by Panel members at least 3 working days in advance of the meeting.

3. Chair

The IFR Appeal Panel will be chaired by a Non-Executive Director.

4. Quoracy

A Non-Executive Director, two medical directors/public health advisors/GPs and a commissioner will be present at the meeting to ensure quoracy. IFR Appeal Panels will be arranged on a monthly basis or as required.

5. Accountability and decision-making

The Commissioning Support Unit Medical Director is the accountable officer for all clinical decisions made by the IFR Appeal Panel. The Appeal Panel is accountable to the CSU Board through the Governance and Quality Committee. A decision will be made by the Non-Executive Director and the two clinicians present (as above).

6. IFR Appeal Panel Process

Should a referring clinician or a patient (who is strongly advised to have the support of the referring clinician) wish to appeal against a decision made by the panel, this should be sent in writing (or electronically through a secure network) to:

NHS North Yorkshire and York IFR Appeal Panel
Sovereign House
Unit 5, Kettlestring Lane
Clifton Moor
YORK YO30 4GQ

Appeals will be supported by the Commissioning/Case Manager who previously managed the case.

The IFR Appeal Panel will consider the points outlined in section 12 of the Treatment Advisory Group Policy.

7. Timescales

The referring clinician and patient will be informed in writing of the date of the Appeal Panel which will be held, wherever possible, within 20 working days of the notification of intent to appeal having been received.

The Chair of the IFR Appeal Panel will ensure that the decision is communicated to the relevant parties, in writing, within 3 working days of the IFR Appeal Panel meeting.

8. The decision of the Appeal Panel

The decision of the Appeal Panel is **final**. If the patient or referring clinician wishes to pursue the matter the only option is through recourse to the CSU's Complaints Procedure.

North Yorkshire and Humber Commissioning Support Unit

Horizon Scanning Service Specification
Version 5
DRAFT

Table of Contents

1. Horizon Scanning Service

The Horizon Scanning Service will provide a comprehensive overview and summary of all relevant clinical and pharmaceutical guidance to ensure that customers are aware of the commissioning implications.

1.1 Service Description

The CSU has established links with all relevant agencies in order for the service to receive, collate, analyse and summarise implications of all clinical and medicines management guidance.

The agreed sources of information are:

Phase 1 (areas of potentially high clinical and/or commissioning risk)

- NICE Guidance/Technical Appraisals/Clinical Guidance/Interventional Procedure Guidance etc
- Medicines Management
- Cancer Drugs Fund
- Subject Matter Experts (pro-active for their area of work)
- National Specialist Commissioning sources (via SMEs)
- SIGN, Scottish Medicines Consortium
- All Wales Drugs Group
- London Drugs Group
- NETAG and similar regional group
- Clinical Frameworks
- Commissioning Policy recommendations and decisions

Phase 2

- Journals including pharmaceutical and specialist medical, pharmaceutical, biotechnology and medical engineering companies information and newsletters and bulletins from other national and regional health technology assessment agencies –King's Fund, Nuffield, Dr Foster and other organisations who comment on social and health policy
- Outcome of Randomised Controlled Trials (relevance and scope to be determined)
- Reports on Case Series etc
- Health Economics/modelling Public Health Observatory
- Public Health England
- Other sources, as appropriate

Upon receipt of new guidance, or a request to assess the implications of a proposed new clinical pathway, the CSU will receive, log and triage the information through the identified Clinical Triage Lead using an appropriate Tool/template. [NB: identified Projects are excluded from this process]. A brief initial impact and risk assessment will be carried out prior to dissemination to the relevant subject matter expert(s), quality lead, finance and contracting leads and other CSU managers as may be appropriate.

Following this initial assessment, any items deemed to require the urgent consideration of customers (red flags/urgent clinical need/imminent financial implication) will be brought to their immediate attention using an appropriate Alert Tool. This could be via CCG and CSU intranet pages, Map of Medicine web views , Senior Pharmacists, nurse lead etc depending on the appropriateness.

For non-medicines management guidance, including any red flags/urgents, the initial assessment will then be reviewed by the **Impact Assessment Group (IAG)** which will meet on a monthly basis to collate information and advise Customers on the potential commissioning implications of the guidance/new pathway/information. **This stage is known as the Initial Impact Assessment. [**The Impact Assessment Group comprises of a range of subject matter experts covering clinical networks, public health, clinical effectiveness, care pathway specialists and commissioning intelligence together with appropriate input from Business Intelligence, finance and contracting.] Refer to TOR in Appendix 1.

The initial impact assessment reports from the IAG will be summarised and sent to the CCG customers so that they are quickly alerted to upcoming changes and potential implications for the CCG and patients. Further detailed work by the IAG/CSU, including epidemiology, prevalence etc through Public Health input, will populate and identify the likely impact for each CCG's population, the likely resource implications around services, quality and cost and the action recommended to CCGs, if any. The outcome of this further work will result in a Formal Impact Assessment which will be considered by the Treatment Advisory Group on a bimonthly basis and circulated to each CCG in order to:

- Formally receive the TAG recommendation
- Assess the likely impact at CCG level
- Adopt/amend the recommendation
- Advise the CSU of the outcome of CCG deliberation, the date, and the relevant committee sign off

For medicines management guidance the initial assessment will be reviewed by the Treatment Advisory Group and/or Area Prescribing Committee in line with CCG arrangements so that they can clearly see the implications around services, quality, costs and priorities. The IAG will recommend a commissioning policy to the customer for them to consider. Once a commissioning policy has been adopted by the Customer, any individual funding requests received for a specific drug/treatment will be considered against the customer's adopted policy. Such policies may be agreed collaboratively between customers or be individually tailored to meet local clinical priorities.

It will provide this service through the CSU infrastructure which incorporates service delivery and assurance services, quality services, contracting services and financial services.

Through a series of process mapping sessions, the process has been defined and is appended to this service specification (Appendix 2).

1.2 **Features and Benefits**

The following are the key features, advantages and benefits this function will offer, however these will continue to be developed and further refined through ongoing communication.

Features	**Advantages**	**Benefits**
Timely horizon scanning for new guidance and evidence based practice	Minimise 'high risk' situations which may have significant commissioning implications	Safe services are commissioned for patients within customer communities
Effective matrix working to be able to manage interdependencies through access to skills, experience and expertise as required.	The right skills and expertise are deployed to maximise efficiency and effectiveness	Right skills in the right place at the right time
High level skills including subject matter expertise across a wide range of commissioning disciplines and specialty areas	Expert support, advice and guidance to customers in line with national guidance and evidence so that timely and appropriate action can be recommended and/or taken.	Customers are able to make more proactive and informed decisions based on current and evidence based practice
Pro-active alerts for any guidance which reflects on patient safety Flag into Quality and Performance Dashboard for CCGs	Allows timely support and discussion so that appropriate action can be undertaken to minimise risk/patient safety issues	Help to minimise patient safety/risk concerns and ensure a safe and seamless service for patients

1.3 **Service Outputs**

- Provide pro-active and timely identification of potential high risk (red flag) areas by alerting customers directly, and feeding into Quality and Governance Performance Dashboard via red flag system and/or into performance management/contracting teams to assist rapid stocktake.
- On a regular basis provide a timely, comprehensive, impact and risk assessment summary to the customer for all clinical and medicines management guidance which will include completed NICE Costing Templates which utilise demographic information to estimate the local cost of implementing guidance.
- On a regular basis provide appropriate draft medicines management commissioning policies to the customer for adoption or amendment.
- Report from meetings of IAG to be received by TAG, and shared with the relevant CCG groups/committees/ Boards as required. (see also Appendix 3, Terms of Reference, Treatment Advisory Group).
- Minutes and Action Notes from IAG to be received by the appropriate Governance committee of the CSU.

1.4 **Interdependencies**

The service offered has the following interdependencies:

Internal interdependencies

- CSU functions – business intelligence, finance, contracting, performance, quality, subject matter experts, communications, individual funding requests

External partners

- NHS Commissioning Board and Local Area Teams (NCB/LAT)
- Public Health Observatory
- Clinical networks
- Public Health via MOU's.

1.5 **Performance Management**

The performance of the service will be measured as follows:

- Formal Impact Assessment summaries will be provided to the customer post TAG
- Comprehensive Medicines Management Commissioning policies will be provided to the customer through agreed mechanisms.

1.6 **Notable Exclusions**

Outline sources that will not be reviewed: