1 Introduction

1.1 This document sets out the principles underpinning how decisions to approve or decline the funding of an individual funding request (IFR) or extra contractual referral (ECR) are taken. It also details the process by which submissions are considered. Specifically the document aims to provide clarity on the following:

- The eligibility criteria for an IFR/ECR
- The process by which IFRs/ECRs are considered
- The mechanism by which a review of the relevant panel’s determination can be requested.

1.2 The procedure for the consideration of a submission is not a clinical decision making process. Rather, its purpose is to determine whether a particular request should be funded. To enable the Board to consider any request for funding, a clinical recommendation needs to be made by the relevant hospital consultant and supported by the Trust’s internal scrutiny procedures.

1.3 There are three categories of funding submission:

1. Individual Funding Request (IFR)
2. Extra Contractual Referral (Acute ECR) falling within the Acute programme of care
3. Extra Contractual Referral (Non Acute ECR) falling within one of the non acute programmes of care.

In all three instances the same broad procedures will be followed, although the composition of the panels may differ and there will be some differences of emphasis.
2 **Individual Funding Requests (IFRs)**

2.1 An individual funding request is a request for an individual to have access to a specific treatment (the majority of which are for a specialist drug treatment) within the acute programme that is not normally commissioned or funded within Northern Ireland. This may mean the request falls into one of the following categories:

1. The patient’s clinical condition represents an unusual or rare circumstance and one likely to occur very infrequently.
2. The treatment requested is a new or developing treatment not normally commissioned or funded by the HSCB.
3. The treatment is commissioned or funded in N. Ireland in certain circumstances but not applicable to the circumstances that apply to the IFR (for example a drug commissioned or funded for one disease but not for the illness for which it is requested).
4. For a variety of reasons, the treatment may not be commissioned or funded in Northern Ireland, for example because national guidance, such as issued by NICE, indicates that it is not recommended.

2.2 For drugs on which NICE has issued a technology appraisal, which has not yet been endorsed within Northern Ireland with an agreed commissioning plan, a separate process is in place. The IFR procedures are not expected to apply in these circumstances.

2.3 Requests for funding in each of the categories set out in paragraph 2.1 can only be approved by the HSCB if exceptional clinical circumstances can be identified.

2.4 Confirmation of clinical exceptionality needs to provide an effective response to the question, “On what grounds can the HSC Board justify funding treatment for this patient when others from the same patient group are not receiving the same treatment”.

2.5 The Board will apply the following definition in considering whether an individual meets a definition of exceptionality:

- The patient is significantly different to the general population of patients with the condition in question. Consistent with
commissioners in other parts of the UK, the HSCB will accept as significantly different ‘an individual whose clinical circumstances are outside the range of clinical circumstances presented by at least 95% of patients with the same medical condition at the same stage of progression as the named patient’.

AND

- Is likely to gain significantly more benefit for the intervention than might normally be expected for patients with that condition.

2.6 It should be noted in considering exceptionality the HSCB can only take account of the clinical circumstances that apply to the individual case. It is not in a position to take account of any personal or social circumstances such as age, dependants, occupation etc.

2.7 IFR Procedures

The procedures for submitting an IFR to the HSCB and for the Board to make a decision and communicate the outcome is outlined below.

2.8 The HSCB IFR Panel meets on a weekly basis to consider all IFRs received from all Trusts within the preceding 7 days.

2.9 The Panel comprises:

- Assistant Director, Public Health (or nominee), Chair
- Specialist or Consultant in Public Health
- Assistant Director, Specialist Services Commissioning (or nominee)
- HSCB pharmacist
- Doctor in training public health.

2.10 Administrative support is provided by the Board’s commissioning staff, under the direction of the Assistant Director of Specialist Commissioning.
2.11 For confidentiality reasons only those individuals required to participate in the decision making process or record the proceedings should be in attendance.

2.12 Submission of IFRs

- IFRs will be submitted on a standard template, by email to ifrs@hscni.net
- All IFRs are to be anonymised.
- For IFR requests for specific drug therapies, the HSC Board will only consider a request if the drug holds a UK license;
- IFR requests for off-label use of a licensed drug therapy will be considered.
- Before an IFR can be initiated, the request for treatment should be subjected to internal scrutiny within the Trust and endorsed.
- IFRs should be endorsed by the relevant clinical director (or equivalent) and senior manager of the relevant service area within the Trust.
- It is the responsibility of the individual requesting an IFR to provide the necessary documentation in support of their request.
- On receipt of the request, a member of the IFR Panel may request additional information before the request is formally considered by the Panel.
- The Panel will be advised of all requests received in the preceding week, including those awaiting additional information before being formally included on the agenda for consideration.
- IFRs which are properly completed and contain the necessary information to facilitate decision-making will be considered by the IFR Panel at their next weekly meeting.
- If a patient requires immediate treatment the responsible clinician, using the agreed Trust process, may make a judgement to commence treatment. In these cases the request will be considered retrospectively. The commencement of treatment on an emergency basis will be without prejudice to the outcome of the IFR Panel’s deliberations.
- When the IFR Panel meets it may request further information from the Trust and reconsider the request when additional material is available.
At the IFR Panel a record of decisions and the rationale underpinning those decisions will be documented on a standard template.

Decisions of the IFR Panel will be communicated, by email, to the relevant Trust (and clinical director) within one week of the IFR Panel meeting.

2.13 Funding requests for treatment expected to cost less than £1,000 should not be submitted to the IFR Panel.

3 Extra-contractual Referrals (ECRs) within the Acute Programme

3.1 Extra-contractual referrals (ECRs) normally arise, and are eligible for approval, in the following circumstances:

1 The patient’s clinical condition requires specialised care that could only be sustained for a large catchment population and cannot be provided for a small geographic area such as Northern Ireland.

2 The patient’s clinician wishes to seek a second opinion from a provider outside Northern Ireland because of complexities of the patient’s condition or circumstances.

3 The treatment is available locally but the patient has some exceptional reason which renders their case different from the vast majority of other patients with the same condition and which therefore justifies a referral for care or treatment outside Northern Ireland.

4 The service being requested is not reflected in commissioning arrangements such as a service level agreement (SLA) with a provider outside N Ireland.

5 The service being requested is not commissioned for the population of Northern Ireland, but the patient’s clinical circumstances are such that exceptionality can be demonstrated and a case justified for an ECR to access care from a provider outside Northern Ireland.

3.2 In respect of 5 above, confirmation of clinical exceptionality needs to provide an effective response to the question, “On what grounds can the HSC Board justify funding treatment for this patient when others for the same patient group are not receiving the same treatment?”.
3.3 The Board will apply the following definition in considering whether an individual meets a definition of exceptionality:

- The patient is significantly different to the general population of patients with the condition in question. Consistent with commissioners in other parts of the UK, the HSCB will accept as significantly different 'an individual whose clinical circumstances are outside the range of clinical circumstances presented by at least 95% of patients with the same medical condition at the same stage of progression as the named patient'.

AND

- Is likely to gain significantly more benefit for the intervention than might normally be expected for patients with that condition.

3.4 It should be noted in considering exceptionality the HSCB can only take account of the clinical circumstances that apply to the individual case. It is not in a position to take account of any personal or social circumstances such as age, dependants, occupation etc.

3.5 Other than in the exceptional circumstances cited above Trusts should not submit ECRs for the following:

- Care or treatment arising out of a service development proposal which has not been supported by commissioners, is under scrutiny or has been deferred because of a lack of recurrent funding.
- Care or treatment which is potentially capable of being developed locally but which has not yet been the subject of a Trust submission or commissioner determination.
- Care or treatment which is provided or capable of being provided in Northern Ireland but is temporarily unavailable. In such circumstances bespoke arrangements will be put in place.
- Care or treatment which falls within the normal profile of local Trust provision, but which is being highlighted to the Board because of its exceptional cost.
3.6 ECRs will normally be to health service providers in other parts of the UK. Only in circumstances where a particular service cannot be accessed from a health service provider will referral to the independent sector be considered.

3.7 There may be particularly specialised services which cannot be provided or accessed within the UK. In such circumstances referral may be made to another EU country with which a reciprocal arrangement exists and to which E112 (S2) procedures apply.

3.8 There may also be rare circumstances where the necessary care or treatment is not available either within the UK or another EU country with which a reciprocal arrangement exists. It may then be appropriate for care or treatment to be accessed from a provider outside the EU.

3.9 **Procedures for ECRs falling within the acute programme**

The procedures for submitting an Acute ECR to the HSCB and for the Board to make a decision and communicate the outcome are as set out below.

3.10 The HSCB Acute ECR Panel meets on a weekly basis to consider all ECRs received within the preceding 7 days.

3.11 The Panel comprises:

- Assistant Director, Public Health (or nominee), Chair
- Specialist or Consultant in Public Health
- Assistant Director, Commissioning (or nominee)
- Doctor in training public health.

3.12 Administrative support is provided by the Board's commissioning staff, under the direction of the Assistant Director of Commissioning.

3.13 For confidentiality reasons only those individuals required to participate in the decision making process or record the proceedings should be in attendance.
3.14 Submission of ECRs

- ECRs will be submitted on a standard template, by email to ecrs@hscni.net
- All ECRs are to be anonymised.
- Before an ECR can be requested it should be endorsed by the Trust.
- It is the responsibility of the individual requesting an ECR to provide the necessary documentation in support of their request.
- On receipt of the request, a member of the ECR Panel may request additional information before the request is formally considered by the Panel.
- The Panel will be advised of all requests in the preceding week, including those awaiting additional information before being formally included on the agenda for consideration.
- ECRs which are properly completed and contain the required information to facilitate decision making will be considered by the ECR Panel at their next weekly meeting.
- The ECR Panel may request further information from the Trust and reconsider the request when additional material is available.
- If a patient requires immediate or urgent treatment the Trust may make appropriate arrangements to initiate and the request will be considered retrospectively. The commencement of treatment on an urgent basis will be without prejudice to the outcome of the ECR Panel’s deliberations.
- All ECRs for elective procedures must await the outcome of the ECR Panel’s deliberations.
- At the ECR Panel a record of decisions and the rationale underpinning those decisions will be documented on a standard template.
- Decisions of the ECR Panel will be communicated, by email, to the relevant Trust (and clinical director) within one week of the ECR Panel meeting.

3.15 Funding requests for treatment expected to cost less than £1,000 should not be submitted to the ECR Panel.
4 Extra-contractual Referral (ECR) within the Non Acute Programmes

4.1 Extra-contractual referrals (ECRs) within non acute programmes normally arise, and are eligible for approval, in the following circumstances:

1 The patient’s clinical condition requires specialised care that could only be sustained for a large catchment population and cannot be provided for a small geographic area such as Northern Ireland.
2 The patient’s clinician wishes to seek a second opinion from a provider outside Northern Ireland because of complexities of the patient’s condition or circumstances.
3 The treatment is available locally but the patient has some exceptional reason which renders their case different from the vast majority of other patients with the same condition and which therefore justifies a referral for care or treatment outside Northern Ireland.
4 The service being requested is not commissioned for the population of Northern Ireland, but the patient’s clinical circumstances are such that exceptionality can be demonstrated and a case justified for an ECR to access care from a provider outside Northern Ireland.

4.2 In respect of 4 above, confirmation of clinical exceptionality needs to provide an effective response to the question, “On what grounds can the HSC Board justify funding treatment for this patient when others for the same patient group are not receiving the same treatment”.

4.3 The Board will apply the following definition in considering whether an individual meets a definition of exceptionality:

- The patient is significantly different to the general population of patients with the condition in question. Consistent with commissioners in other parts of the UK, the HSCB will accept as significantly different ‘an individual whose clinical circumstances are outside the range of clinical circumstances presented by at least 95% of patients with the same medical condition at the same stage of progression as the named patient’. 
• Is likely to gain significantly more benefit for the intervention than might normally be expected for patients with that condition.

4.4 It should be noted in considering exceptionality the HSCB can only take account of the clinical circumstances that apply to the individual case. It is not in a position to take account of any personal or social circumstances such as age, dependants, occupation etc.

4.5 Other than in the exceptional circumstances cited above Trusts should not submit ECRs for the following:

• Care or treatment arising out of a service development proposal which has not been supported by commissioners, is under scrutiny or has been deferred because of a lack of recurrent funding.
• Care or treatment which is potentially capable of being developed locally but which has not yet been the subject of a Trust submission or commissioner determination.
• Care or treatment which is provided or capable of being provided in Northern Ireland but is temporarily unavailable. In such circumstances bespoke arrangements will be put in place.
• Care or treatment which falls within the normal profile of local Trust provision, but which is being highlighted to the Board because of its exceptional cost.

4.6 ECRs will normally be to health service providers in other parts of the UK. Only in circumstances where a particular service cannot be accessed from a health service provider will referral to the independent sector be considered.

4.7 There may be particularly specialised services which cannot be provided or accessed within the UK. In such circumstances referral may be made outside the UK.
4.8 Procedures for ECRs falling within the non acute programmes

The procedures for submitting an ECR emanating from one of the non acute programmes to the HSCB and for the Board to make a decision and communicate the outcome are as set out below.

4.9 The HSCB Non Acute ECR Panel meets on a fortnightly basis to consider all relevant ECRs received within the preceding 14 days.

4.10 The Panel comprises:

- Assistant Director, Mental Health and Learning Disability (or nominee) (Chair)
- Assistant Director, Social Care and Children (or nominee)
- Social Care Commissioning Lead, Older People and Adults (or nominee)
- Assistant Director, Nursing (or nominee)
- Specialist or Consultant in Public Health
- Assistant Director, Commissioning (or nominee).

4.11 Administrative support is provided by the Board’s commissioning staff, under the direction of the Assistant Director of Commissioning.

4.12 For confidentiality reasons only those individuals required to participate in the decision making process or record the proceedings should be in attendance.

4.13 Submission of Non Acute ECRs

- ECRs will be submitted on a standard template, by email to ecrs@hscni.net
- All ECRs are to be anonymised.
- Before an ECR can be requested it should be endorsed by the Trust.
- It is the responsibility of the individual requesting an ECR to provide the necessary documentation in support of their request.
• On receipt of the request, a member of the ECR Panel may request additional information before the request is formally considered by the Panel.

• The Panel will be advised of all requests received since the previous meeting, including those awaiting additional information before being formally included on the agenda for consideration.

• ECRs which are properly completed and contain the required information to facilitate decision making will be considered by the ECR Panel at the next meeting following receipt of a finalised and completed submission.

• The ECR Panel may request further information from the Trust and reconsider the request when additional material is available.

• If a patient requires immediate or urgent treatment the Trust will make appropriate arrangements to initiate and the request will be considered retrospectively. The commencement of treatment on an urgent basis will be without prejudice to the outcome of the ECR Panel’s deliberations.

• At the ECR Panel a record of decisions and the rationale underpinning those decisions will be documented on a standard template.

• Decisions of the ECR Panel will be communicated, by email, to the relevant Trust (and clinical director) within one week of the ECR Panel meeting.

4.14 Funding requests for treatment expected to cost less than £1,000 should not be submitted to the ECR Panel.

5 Arrangements for Patient Travel

5.1 When an ECR is approved the referring consultant will be asked to inform the Board of travel requirements. The following information should be provided:

• The most appropriate form of travel in terms of cost and the patient’s needs.

• Whether the patient requires an escort or escorts, setting out the reasons. Escorts should be named.
5.2 When a patient contacts the Board to request travel arrangements to be made the patient travel officer will establish if the ECR in respect of the patient has been approved and will check to ensure that the travel arrangements booked are in line with the referring consultant's advice. The patient may submit a travel expense claim in line with the Patient Travel Expenses Policy. Reimbursement will be made in line with that policy.

6 EU Directive on Cross Border Healthcare (Article 56)

6.1 This EU Directive was adopted in March 2011 and must be implemented by October 2013. Each UK region has been tasked with putting forward an agreed regional timeline for implementation.

6.2 The Department of Health will lead on the implementation process on the basis of guidelines to be released by European Commission and consultation on implementation is currently underway.

6.3 The key points of the Directive are:

1. EU residents can seek treatment across national boundaries but can only be compensated for healthcare that they would be entitled to receive under the NHS.
2. Prior authorisation is needed for healthcare which is subject to planning requirements and involves at least one night stay in hospital OR requires the use of highly specialised and cost intensive medical equipment.
3. Commissioners will be required to cover the cost of treatments which are available within their own healthcare system.
4. Patients will be reimbursed for the cost of cross-border healthcare up the level of cost of that treatment under the NHS.
5. There is no requirement that travel expenses are reimbursed for patients accessing care or treatment under this directive.
6. Treatment may be within either state or private sectors
7. Local systems will be required to recognise prescriptions filled out in other member states.
8. National Contact Points will have to be established to provide patients with information related to cross-border healthcare on request.
6.4 The Board will consider requests under Article 56 and in doing so will apply the criteria set out above and any further guidance issued by the DHSSPS. In addition, the Board will expect that the care or treatment being sought under Article 56 referrals is considered clinically necessary by the relevant clinician and that appropriate supporting documentation to this effect is received.

7 Review of Panel Decisions

7.1 If an HSCB IFR/ECR Panel declines a request for funding, the referring clinician may submit new or additional clinical information as part of a new IFR request.

7.2 Alternatively, they may request a review of the Panel’s decision. A request for review must be submitted to the HSCB within 20 working days of receiving communication of the IFR/ECR decision.

7.3 The request can be made by the patient’s clinician or clinical director of the relevant service area and must be supported by the Trust.

7.4 For requests received under Article 56 of the EU Cross Border Directive on Healthcare the request may be made by the individual or their representative.

Scope of a Review

7.5 The grounds on which a clinician may request a review of the IFR/ECR Panel decision are as follows:

1 The HSCB has failed to act fairly, in accordance with the policy on IFR/ECR submissions
2 The HSCB has made a decision which is irrational in light of the evidence submitted as part of the IFR/ECR
3 The HSCB has exceeded its powers.

7.6 It is the responsibility of the individual requesting a review to provide the necessary documentation in support of their request.
7.7 It should be noted that a review of the IFR/ECR Panel determination does not constitute a review of the decision. Rather it limits a review to consideration of the process through which a determination was reached, and assesses whether process and procedures were consistent with policy and with the powers and responsibilities of the HSCB as commissioner.

7.8 How to Request a review of the IFR or ECR Panels determination

A review request must be made to the Commissioning Directorate at the HSCB, within 20 working days of receipt of the IFR or ECR Panels’ determination.

The request must detail the
- aspect of the decision being challenged and
- the grounds of the review request

7.9 The chair of the Review Panel may request additional information and has the discretion to decline to review an IFR/ECR Panel determination unless relevant information is provided. The Review Panel will consider the review within 20 working days of the request being received.

Composition of the Review Panel

7.10 The Review Panel will consist of individuals who have not had involvement in the original IFR/ECR Panel process or determination. Specifically the panel will comprise:

- Head of Corporate Services (chair)
- Director of Integrated Care (where a GP has requested a decision be reviewed, the Director of Finance rather than the Director of integrated Care will sit on the Panel)
- Non-executive member of HSC Board or PHA Board

7.11 Material for consideration of the Review Panel will be prepared by the Commissioning Directorate.
7.12 In the case of the non-executive member of the panel it is proposed that at least two members are nominated, with the intention that one should always be in attendance.

**Attendance at Review Panel Hearing**

7.13 No new clinical information or data can be considered by the review panel. If circumstances have changed or new clinical information has become available clinicians may wish to forward to commissioners as part of a new IFR or ECR request.

7.14 The Chair and members of the IFR or ECR Panel may be asked to attend the Review Panel to provide the information on the procedures followed and the rationale of decision-making by the IFR/ECR Panel.

7.15 The review panel’s role is to consider the process followed by IFR/ECR panel, not to hear new or different evidence in support of an IFR/ECR. In this context it would not normally be appropriate for patients or their representatives to attend the Review Panel.

7.16 However, the Review Panel has discretion to ask relevant individuals to attend the Panel to present the grounds on which a review request has been made. This may include (but is not restricted to) the referring clinician or relevant clinical director or (in the case of Article 56 requests) the patient or their representative.

7.17 The Review Panel may:

- Uphold the grounds of the review and ask the IFR panel to reconsider its determination

  OR

- Allow the determination of the IFR Panel to stand

The Panel may also make a recommendation for action to the HSC Board
7.18 The Review Panel will notify the IFR/ECR Panel referring clinician (and clinical director) and the relevant Trust of its decision within 5 working days of the Review Panel decision.

7.19 Notwithstanding the IFR/ECR procedures and the ability to request a review of the IFR/ECR Panel’s decision, patients who are dissatisfied may make a complaint through the Board’s normal complaints process.