

APPENDIX 3

Protocol for the consideration of ‘Exceptional Treatment’ (Interventions Not Normally Funded)

INTRODUCTION

NHS Gloucestershire must ensure that it provides the community of Gloucestershire with the best health care from the funds available. This includes the responsibility to make decisions regarding individual funding requests that do not fall under existing contracts, and ensuring that decisions made are equitable and in the interest of the whole population (see NHS Gloucestershire’s *Clinical Priorities Policy for Commissioning Selected Services*). An Interventions Not Normally Funded (INNF) Panel has been established to consider these individual requests. The membership of this committee includes health professionals, NHS Gloucestershire Directors and is chaired by a Lay Member.

This protocol presents a three-staged approach to the process of considering these requests. A flow chart outlining the process is provided in Addendum 1.

STAGE ONE – Application to NHS Gloucestershire

The referrer (the GP, consultant, or person managing the clinical care of the patient) must first consult NHS Gloucestershire’s current commissioning policy statement(s), and/or Interventions Not Normally Funded list, to establish that the patient is ineligible for the treatment requested.

If the patient’s clinician assesses that funding will not normally be available, the next step in the process is for a standard funding application form (Addendum 3) to be completed. Completion of the form must be undertaken by the GP, consultant, or person managing the clinical care of the patient, in liaison with the patient. **To avoid misunderstandings, and losing time in the resolution, the form requires the signature of both the clinician and the patient (or their carer/guardian).**

Completed applications should be posted, faxed or e-mailed to the address specified on the form.

Requests for exceptional funding must be submitted on the standard application form; this is to ensure that NHS Gloucestershire and/or the INN F Panel receives all the information, and only that information, needed to reach a decision. The information required includes the following:

- Name of GP/consultant making application
- Patient's name, address and date of birth
- Brief and relevant health history
- Treatment/intervention requested
- Information on alternative treatment(s) available
- Proposed provider of treatment
- Costings (if available/known) and length of treatment (number of treatment episodes, length of in-patient stay, etc)
- Evidence that the proposed treatment is likely to result in improved health for the patient
- Implications for patient if treatment is not funded
- Reasons why the patient's case is 'exceptional'

If the information requested is not supplied, consideration of the application will be delayed whilst the information is collected from the clinician. It is not the responsibility of NHS Gloucestershire to complete sections of the form on behalf of applicants. Where appropriate, supporting letters from other clinicians (specialists, other experts or other health or social care professionals involved in the patient's care) should also be provided.

The same application form is to be used for requests for equipment, drugs, surgery or other treatments that fall outside of existing commissioning contracts.

It should be noted that NHS Gloucestershire does not fund interventions retrospectively.

STAGE TWO – Initial assessment of the application

When the application is received by NHS Gloucestershire, it will be reviewed to

1. Agree that the healthcare intervention or equipment request is not currently commissioned
2. Assess whether the application demonstrates sufficient exceptionality to warrant its consideration by the INN F Panel

The latter assessment is guided by NHS Gloucestershire's Policy Statement *Guidance for considering 'exceptionality' in individual cases*.

Where an application suggests that exceptional funding may be warranted, the case will be taken forward to the INNF Panel for a decision.

STAGE THREE - The decision-making process

The INNF Panel

The INNF Panel will meet ten times a year in order to make decisions on individual funding requests received. At each meeting the Panel will receive an anonymised application form and anonymised copies of any additional correspondence or reports which may be relevant to the patient's case. When relevant, the Panel will receive and consider a briefing of the evidence-base supporting the requested treatment or intervention, prepared by NHS Gloucestershire's New Technologies and Drug Therapies Manager. The Panel will normally only support treatments with at least **moderate level** evidence of effectiveness¹. The Panel will also consider any evidence pertaining to the level of cost-effectiveness of the treatment or intervention requested.

Purpose

The INNF Panel is responsible for considering requests for exceptions to the current commissioning policies of NHS Gloucestershire.

Requests may be referred to the Panel by the patient's managing clinician; requests received directly from patients without the endorsement of their managing clinician will not be considered and will be referred back to the patient's GP. However, patients may submit information to support their case alongside the application form that is completed by their managing clinician.

The decisions of the Panel will be communicated directly to the referring clinician and/or the patient's GP (if this is not the same person). Decisions are not communicated directly to the patient unless requested to do so by agreement between the patient and their managing clinician and indicated on the signed application form. The PCT exercises caution in communicating the Panel's decisions to patients because these may potentially cause distress or require interpretation that can best be addressed by their managing clinician.

¹ This is defined as good quality observational control or case control studies or better i.e. randomised or controlled trials. This is based on the levels of evidence recommended by NICE.

In fulfilling the primary purpose of the INNF Panel, the Panel will ensure it has adequate information upon which to base its decisions. This may be information over and above that provided by the patient's managing clinician (for example, a second opinion may be requested). In the absence of such information, decisions will be deferred until supplementary information is provided to the Panel.

Scheme of Delegation

The Panel acts as a formal sub-committee of the NHS Gloucestershire Board. It has the authority to make exceptions to the Commissioning Policies of NHS Gloucestershire and thus commit financial resources within the frameworks agreed. The Panel will report its decisions to a meeting of the NHS Gloucestershire Board on a quarterly basis in an anonymised form.

Membership

The INNF Panel will comprise the following members:

- Lay Representative (Chair)
- Lay Representative (Vice Chair)
- Chair of the Professional Executive Committee or their nominated representative (a medically qualified member of the Board or PEC)
- Director of Public Health or their nominated deputy
- Director of Strategy Development and Corporate Services or their nominated deputy
- Director of Business Development and Performance or their nominated deputy
- Medical Director (Commissioning) or their nominated deputy
- The New Technologies and Drug Therapies Manager will be co-opted as necessary to report on the evidence for the clinical and cost effectiveness of interventions requested, but will not have any role in the decision-making process.

The Panel will be quorate when three members are in attendance, of whom one must be a lay representative; one must be an Executive Director of the PCT; and one must be the Chair of the Professional Executive Committee, or his/her representative (a medically-qualified member of the PCT's Board or Professional Executive Committee).

Note that the Chief Executive of NHS Gloucestershire cannot be delegated as a member of the INNF Panel because of their role as Chair of Appeals Panels that consider contested decisions or processes.

In usual circumstances, it is not considered appropriate for patients, or their representatives, to attend the meeting of the INNF Panel where their case is discussed. However, as noted above, patients are invited to submit information in support of their application for consideration by the Panel.

Informing applicants of the process

Applicants will be sent an acknowledgement letter when their application is received by NHS Gloucestershire. Following initial assessment, the applicant will be informed in writing as to whether their request is to be taken to the INNF Panel and/or whether additional information is required.

The INNF Panel meets a minimum of 10 times a year, and cases will be considered at the earliest possible meeting. Applicants and, where agreed, patients, will be informed of the Panel's decision within 15 working days of the Panel meeting.

What decision will be made

The INNF Panel can make one of three different decisions regarding individual cases:

1. Agree to fund/support the request
2. Defer a decision pending further information/investigation
3. Refuse to support/fund the request

Requirement for Urgent Decisions

It is recognised that on occasions urgent decisions are required. In such instances, the INNF Panel will consider cases outside of scheduled meetings, using fax/e-mail/telephone conference facilities as necessary. However, despite urgent circumstances, no members of the INNF Panel can make decisions on their own, and urgent decisions should be delegated by the Chair of the INNF Panel to, as a minimum, an Executive Director of NHS Gloucestershire, the Chair of the Professional Executive Committee (or designated deputy) and a lay representative.

Re-presentation of the case

If the request for funding has been refused by the Panel, the applicant can re-present the case if there is additional information to suggest exceptionality. If this information is deemed 'new evidence' by the Director of Public Health and/or the Director of Strategy Development

and Corporate Services or their nominated deputies, it will be considered at the next available meeting of the Panel.

Appeals

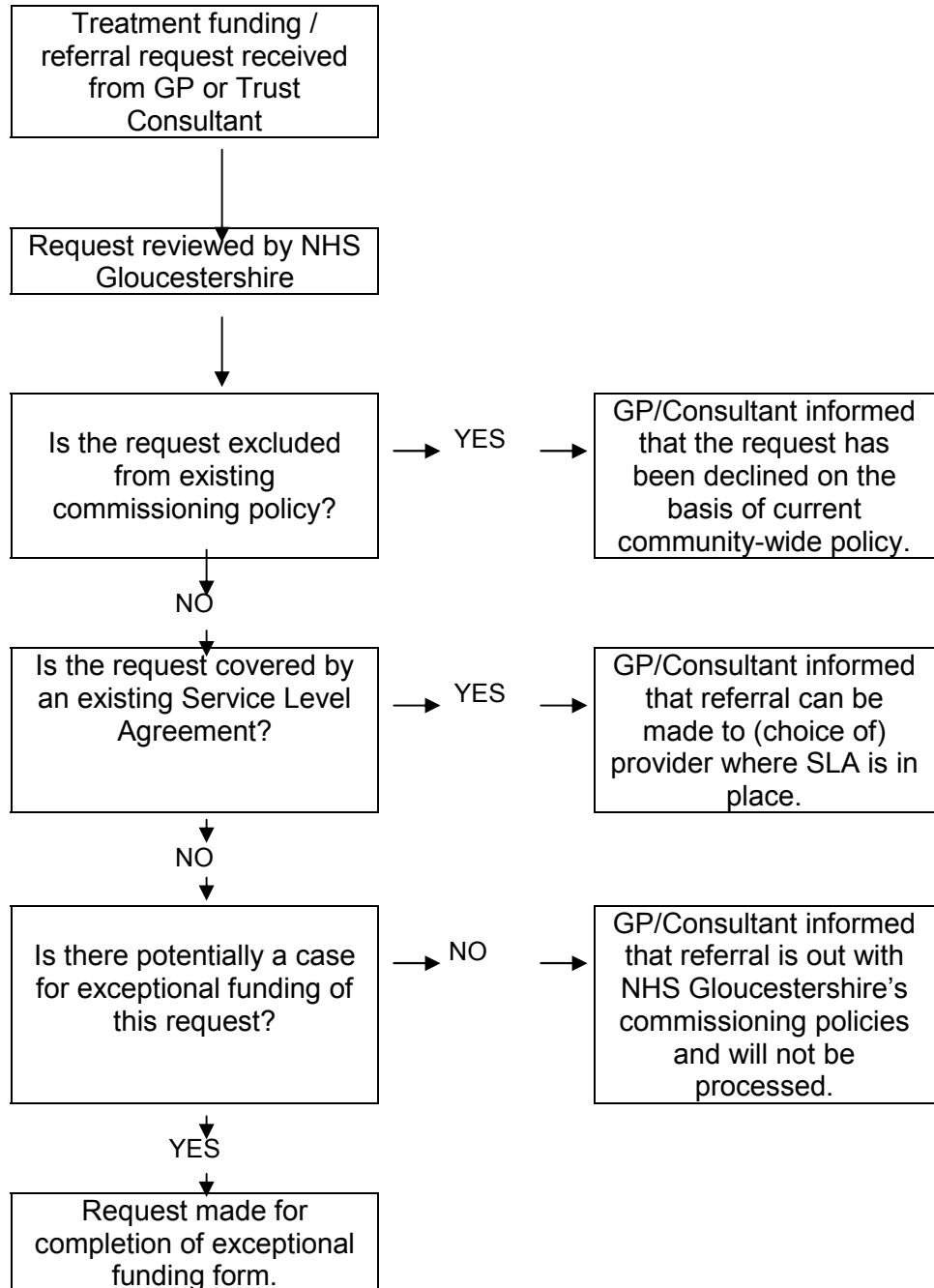
In the event that the applicant and/or patient wishes to appeal against a decision made by the INNF Panel, then the Appeals Procedure set out in Addendum 2 must be followed.

If the appeal is against the procedure followed by the INNF Panel when considering the case, then NHS Gloucestershire's usual Complaints Procedure is invoked.

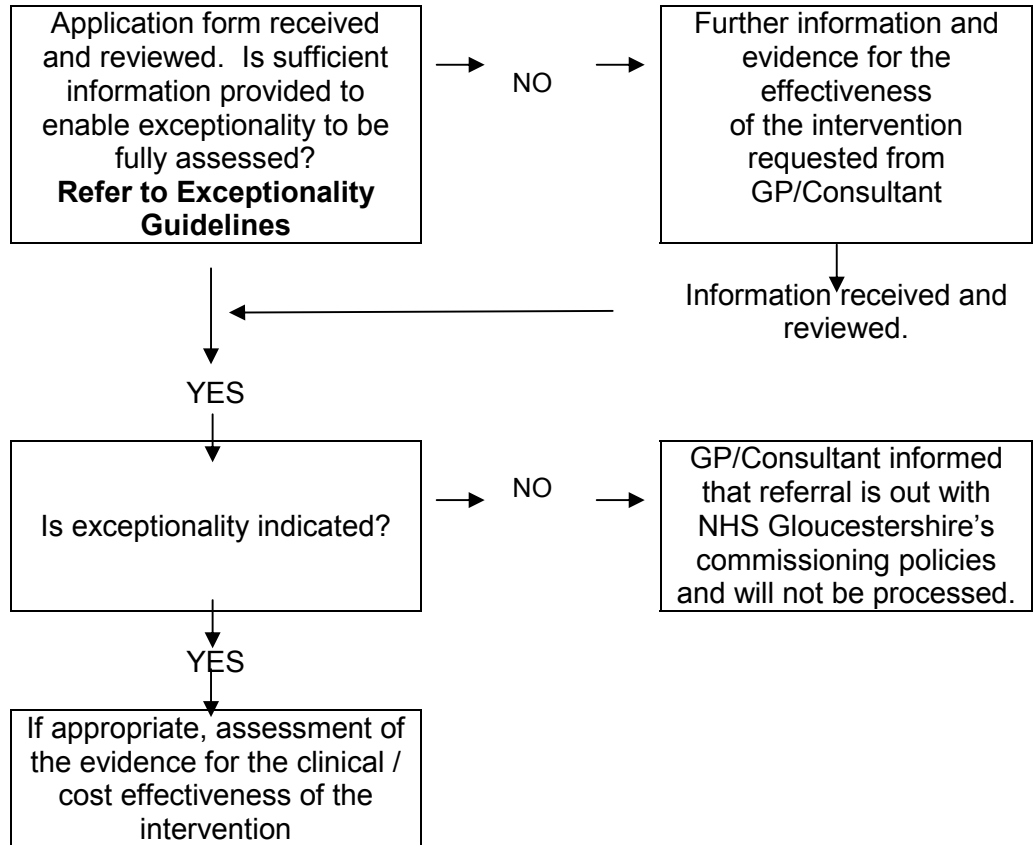
Addendum 1

INNF Panel - flow chart of the decision-making process

STAGE ONE



STAGE TWO



STAGE 3

