

NHS Dorset Clinical Commissioning Group

Policy for Individual Patient Treatment



Supporting people in Dorset to lead healthier lives

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NHS DORSET CLINICAL COMMISSIONING GROUP

POLICY FOR INDIVIDUAL PATIENT TREATMENT

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POLICY FOR INDIVIDUAL PATIENT TREATMENT

1. EXECUTIVE SUMMARY

- 1.1 Most NHS care and treatment is commissioned by Clinical Commissioning Groups (CCGs) on behalf of their whole population although specialised and some other specific care and treatments are commissioned by NHS England. This policy outlines the processes for considering individual patient requests for treatments where NHS Dorset Clinical Commissioning Group (the CCG) is the responsible commissioner.
- 1.2 An individual patient treatment request is defined as a request to fund healthcare for an individual which falls outside the range of services and treatments that the CCG has agreed to commission. This policy outlines the processes for considering such requests. A patient information leaflet which provides a summary of the process is available on the CCG's website: <http://www.dorsetccg.nhs.uk/Downloads/aboutus/Policies/Clinical/Policies%20from%20Sept%202014/IPT%20Leaflet.pdf>. This website also includes a copy of the individual patient treatment request form and a guide to its completion.
- 1.3 NHS England is the statutory body responsible for a range of commissioned specialised services and treatments, and these are detailed in its Manual for Prescribed Specialised Services, a technical document which outlines the relevant services and the rationale for commissioning these on a national basis. NHS England commissions these services in accordance with national service specifications and clinical policies. Where individual treatment requests for specialised services are received in respect of patients that fall outside of these clinical policies, responsibility to consider such requests sits with NHS England, who will consider these requests in line with its own individual patient treatment policy. Both the Manual and its individual treatment request policy can be accessed from the NHS England website: <https://www.england.nhs.uk/commissioning/spec-services/key-docs/>
- 1.4 These requests are outside the scope of this policy which relates solely to treatments which are the commissioning responsibility of the CCG.
- 1.5 A key principle of CCG commissioning plans is that the value of NHS services locally can be improved for individuals by ensuring that the CCG commissions evidence based services that meet identified healthcare needs. This means providing interventions where there is a high probability of benefit and a low probability of harm, and doing them in the right place and at the right time.
- 1.6 Commissioners need to balance the requirement to provide treatments for individuals against the need to improve value by commissioning services for populations for which they are responsible. This means that there is a focus on reducing or stopping the commissioning of procedures which are of limited or lower clinical value.
- 1.7 It should also be noted that the commissioning process is based on the CCG's local understanding of need, rather than historic demand for services. Where there is clear capacity for individuals and populations to benefit from interventions, this is a recognised health need. The fact that an individual

wants a particular procedure or intervention does not constitute a need. It is important that all commissioning decisions are based upon need (that is capacity to benefit from a treatment) and are planned in a systematic and clear way that will ensure:

- that evidence for the safety and clinical effectiveness of treatments influences decisions;
- that best value is gained from the money spent, this means it is cost effective;
- a fair and transparent processes for decision making in the overall use of healthcare resources for the whole population; and
- that the priorities identified as a need by the local population have been reflected .

1.8 It has always been the case that real or potential demand has outstripped the finite supply of resources available for meeting health and healthcare needs and as the local population changes and technology advances there is no evidence that this is changing. As a result, there are times when the CCG has to choose between providing one type of service or treatment over another. The CCG is committed to deploying resources where they are most needed and in such a way that the greatest benefit for its populations overall, is achieved.

1.9 In meeting this commitment the CCG will use all available data and information to assess the relative merits of particular treatments and may specify some treatments as 'services not routinely commissioned'. These are treatments which have been deemed to be of low clinical priority compared to other treatments on the basis of the available data and information and are sometimes referred to as low priority procedures.

1.10 It is inevitable that population based decision making will mean that sometimes an individual patient's needs cannot be met through existing care pathways or contracted services. This policy sets out how the CCG will consider individual funding requests outside of existing pathways and criteria based access protocols. This policy also covers the decision making process for criteria based access, prior approval and services not routinely commissioned.

1.11 This policy is intended to ensure consistency in decision making in Dorset and has taken account of policies in neighbouring areas. NHS England has its own national policy for individual treatment requests which applies to a specific range of specialised treatments where approval of treatments is required to ensure that referrals comply with best practice criteria that ensure the most health gain together with the most appropriate use of resources.

1.12 This policy covers requests for treatments for individual patients that are not met through existing care pathways or contracted services, these will include:

- Prior approval with criteria based access, where protocols exist. This will include interventions classified as services not routinely commissioned;

- Individual treatment requests submitted where Criteria Based Access Protocols exist but the patient is outside of the relevant access criteria and a request is submitted for support on the grounds of clinical exceptionality;
- Individual treatment requests for which there is no protocol or policy and the clinician feels there are exceptional individual circumstances. These will include requests for new, experimental, and unproven treatments and treatments for rare presentations where the CCG has not developed a commissioning position;
- Requests for referral to a healthcare provider where there is no relevant NHS contract in place;
- Cross border healthcare within the European Economic Area in accordance with relevant current legislation;
- Requests from individuals who wish to pay for additional private care;
- Requests for NHS funding for a treatment pathway commenced within the private sector;
- Patient Choice and second opinions;
- Requests to continue funding for patients coming off clinical trials;
- Requests for referral to a specialist provider;
- Decisions inherited from other Commissioners;
- Military veterans.

1.13 This policy does not cover requests for treatments that are not prioritised and therefore not commissioned, for which there are no exceptional individual circumstances. Requests for treatments which relate to a group of individuals should be considered as service developments through the CCG's prioritisation process on the basis of relative priority alongside current priorities.

1.14 Where an individual patient treatment request is supported, the funding arrangements for the treatment will be in accordance with the relevant contractual and collaborative agreements.

1.15 It should be noted that this policy does not apply to:

- the NHS Continuing Health Care processes and applications (this policy can be found on the CCG website);
- provision of community equipment;
- high, medium and low secure mental health placements;
- requests for cancer drugs made to the Cancer Drug Fund, which are the responsibility of NHS England;

- out of county in-patient children and adolescent mental health placements;
- services for prisoners and others detained in other prescribed accommodation, which are the commissioning responsibility of NHS England;
- prescribed specialised services commissioned, which are the responsibility of NHS England;
- secondary and community health services for members of the armed forces and for their families, where the latter are registered with Defence Medical Services;
- all dental services including hospital services, which are the commissioning responsibility of NHS England.

2. PRINCIPLES UNDERPINNING THE POLICY

- 2.1 Commissioners are responsible for making decisions about investing in new, existing and/or additional services. Care and treatment is commissioned on behalf of the whole population by the CCG, although specialised and some other specific services are commissioned by NHS England. Access is based on healthcare need, clinical evidence and national guidelines, where available. Appendix A gives details of the commissioning principles underpinning decision making by the CCG to ensure that resources are committed fairly and equitably.
- 2.2 The aim of commissioning is to achieve the greatest possible improvement in health outcomes for the local population, within the resources available. The commitment of resources for one person that is disproportionate to their need or capacity to benefit, means that those resources are then denied to others who might benefit more and this would be inequitable. In addition if a treatment is funded for one person then that treatment should be funded for all people with similar clinical circumstances; to do otherwise would be inequitable.
- 2.3 A key principle of CCG commissioning plans is that the value of NHS services locally can be improved for individuals and populations by ensuring that evidence based services are commissioned that meet the local populations identified health needs. This means providing interventions where there is a high probability of benefit and a low probability of harm, doing them in the right place and at the right time.
- 2.4 The CCG needs to balance the requirement to provide treatments for individuals against the need to improve value by commissioning services for the populations for which it is responsible. This means that there is a focus on reducing or stopping the commissioning of procedures of limited or lower clinical value.
- 2.5 It should also be noted that the commissioning process is based on the CCG's local understanding of need, rather than historic demand for services. Where there is clear capacity for individuals and populations to benefit from

interventions, this is a recognised health need. The fact that an individual wants a particular procedure or intervention does not constitute a need.

- 2.6 The decision on an individual request for treatment is not based on whether it is clinically appropriate for a patient to have the treatment recommended by the requesting clinician but whether it is appropriate for that treatment to be funded. This responsibility has been recognised in the courts, most notably in the ‘Child B’ case, where the judge said:

“I have no doubt that in a perfect world any treatment which a patient, or a patient’s family, sought would be provided if doctors were willing to give it, no matter how much the cost, particularly when life is potentially at stake.”

“It would however, in my view, be shutting one’s eyes to the real world if the court were to proceed on the basis that we do live in such a world. It is common knowledge that health authorities of all kinds are constantly pressed to make ends meet. Difficult and agonising judgements have to be made as to how a limited budget is best allocated to the maximum advantage of the maximum number of patients.”

- 2.7 This observation has been quoted with approval in a number of appeal judgements on individual patient treatment requests since and remains an accurate statement of law.

- 2.8 The NHS is in a period of lower financial growth than in recent years, and given these constraints the CCG may not be able to afford all interventions supported by evidence of clinical and cost effectiveness within available budgets. Where this is the case the CCG will prioritise treatments and interventions that provide the best value for its population.

- 2.9 Some CCG decisions are informed by the Department of Health, other decisions are guided by local priorities and needs. The CCG aims to commission high quality services underpinned by national and international best practice as well as clinical effectiveness and clinical outcomes. Local hospitals, community services, the public, patients, primary care, the independent and voluntary sector all have a role in influencing the CCG’s local priorities. The CCG will also ensure that services are commissioned in a way that is consistent with the approach taken by NHS England in commissioning specialised elements of the care pathway.

- 2.10 The NHS Constitution for England, published in January 2009 confirms that patients:

“..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”.

- 2.11 The ethics of commissioning and decision making involve concepts that are complex and difficult to describe in a few words, these concepts are detailed in Appendix A and are followed when considering individual funding requests.

Decisions about Funding Treatments at a National Level

- 2.12 The National Institute for Health and Clinical Excellence (NICE www.NICE.org.uk) provides a range of guidance on public health, health technologies and clinical practice at a national population level. The CCGs decisions to fund treatments take account of NICE assessments and recommendations. NICE Technology Appraisal Guidance needs to be implemented within three months of the appraisal being published. NICE Clinical Guidelines and Interventional Procedures Guidelines are not required to be implemented in the same way as Technology appraisals and the implications of Clinical Guidelines will be considered carefully and prioritised within the CCG's Commissioning Plan. As the demand for healthcare is greater than the resources available, prioritisation of competing needs is necessary. There may, therefore, be occasions where the CCG is unable to implement specific NICE Guidance as it has not been prioritised in the context of available resources and is not, therefore, affordable.

Decisions about Funding Treatments at a Local Level

- 2.13 The CCG's approach to assessing the relative impact of potential investments and disinvestments within defined programmes and pathways take into account:
- Priority pathways, based on strategic initiatives and the CCG's Joint Strategic Needs Assessments (JSNA) of major health needs; and
 - The opportunity costs for health gain that may be lost by not investing in a particular treatment.
- 2.14 This means that investments and disinvestments can be viewed within the broader strategic context and if the financial situation changes investments and disinvestments can be reprioritised. .
- 2.15 The CCG does not expect to introduce new drugs/technologies on an *ad hoc* basis through the mechanism of individual case funding. The CCG expects consideration of new drugs and/or technologies to take place within the established planning frameworks of the NHS.
- 2.16 The Dorset Medicines Advisory Group provides advice and guidance on the clinical efficacy, safety and cost effectiveness of drugs and treatments. This advice is considered in defining priorities for investment in the following financial year. The CCG Governing Body ultimately makes the decision on service priorities. The Terms of Reference for this Forum can be found on the CCG website.

- 2.17 There may be occasions when clinicians will wish to make requests for funding for new drugs or technologies that have not yet been referred to the National Institute for Health and Clinical Excellence (NICE) for approval. In such cases, clinicians will need to demonstrate that their request is supported by the hospitals' own internal committees that consider clinical effectiveness, such as Drug and Therapeutics Committees or clinical effectiveness/evidence based practice committees. In-year requests will require previous priorities to be revisited with providers, if a new development or drug is felt to be of a greater priority than previously agreed plans. Drugs and technologies that relate to services commissioned by NHS England will need to be considered by that organisation.
- 2.18 Interventions will only be considered for routine commissioning where they would offer equal or greater benefit than other forms of care routinely commissioned. Priority will not be conferred on an intervention solely on the basis that is the only one available. In addition any new treatment proposed must be made available to all patients within the patient group unless contra-indicated.
- 2.19 New interventions should not be introduced through the individual patient treatment process. It is not rational for the CCG to manage new interventions by considering one patient at a time. This would also be unfair because it breaches a common principle that no treatment should be offered to an individual that would not be offered to other patients with equal clinical need. Where a request relates to an experimental treatment specific to an individual patient and which would not be sought in respect of a group or sub-group of patients it may be appropriate to consider on an individual patient basis if it is considered that there is some element of clinical exceptionality. In considering the request evidence of clinical effectiveness must be provided in support of the request.

Decisions about Funding Treatments for Individual Patients

- 2.20 It is inevitable that population based decision making will mean that sometimes individual patient's health needs cannot be met through existing care pathways or contracted services. This policy sets out how the CCG will consider individual treatment requests outside of existing pathways and protocols.
- 2.21 This policy covers requests for treatments for individual patients that are not met through existing care pathways or contracted services, these will include:
- Prior approval with criteria based access, where protocols exist. This will include interventions classified as services not routinely commissioned;
 - Individual treatment requests where criteria based access protocols exist but the patient is outside of the clinical access criteria and a request is submitted for support on the grounds of clinical exceptionality;

- Individual treatment requests for which there is no protocol and the clinician feels there are exceptional individual circumstances. There may be no protocol or policy because the condition is so rare that a policy has not been developed or the treatment is relatively new or experimental. Such requests may be submitted because the condition is affecting the patient in an unusual way due to other clinical factors and the usual treatments may not therefore be suitable;
- Cross border healthcare within the European Economic Area in accordance with existing legislation;
- Requests from individuals who wish to pay for additional private care;
- Requests for NHS funding for a treatment pathway commenced within the private sector;
- Choice and second opinions;
- Requests to continue funding for patients coming off clinical trials;
- Requests for referral to a specialist provider;
- Decision inherited from other Commissioners; and
- Military veterans.

Decisions about Funding Specialised Treatments for Individual Patients

- 2.22 NHS England is the statutory body responsible for the consideration of individual patient treatment requests for specialised services. The specialised services and treatments commissioned by NHS England are detailed in its Manual for Prescribed Specialised Services which is a technical document that outlines the relevant services and the rationale for commissioning these on a national basis. NHS England will commission these services in accordance with national service specifications and clinical policies. Where individual treatment requests are received in respect of patients outside of clinical policies, NHS England will consider these requests in line with its policy for considering such requests. This policy along with The Manual can be accessed from the NHS England website: <https://www.england.nhs.uk/commissioning/spec-services/key-docs/>
- 2.23 The CCG works closely with NHS England to ensure that requests for treatment will be considered by the appropriate commissioner at the earliest opportunity and within the timescales stipulated in the respective policies or access protocols for considering individual treatment requests. Mechanisms are in place to ensure that requests erroneously referred to the incorrect commissioner will be identified and forwarded to the correct commissioner for consideration of the request.

Decisions about Funding Treatments for Individual Patients Where Authority has been Delegated to another Organisation

- 2.24 Some individual patient treatment requests that relate to treatments where the CCG is the statutory body responsible are considered on its behalf by other

organisations. These relate to treatment requests made by clinicians at hospitals in London, Southampton, Bristol, Portsmouth, and Oxford.

- 2.25 Individual Patient Treatment Requests originating from hospitals in these areas are considered on behalf of the CCG by Optum UK in relation to London providers and Commissioning Support South in respect of the hospitals in the other areas highlighted above. The CCG has delegated authority to the Individual Treatment Teams at these organisations to make decisions in respect of its patients.
- 2.26 The process for considering these requests is that outlined in the Individual Patient Treatment Requests policy of the respective commissioning support organisation. However, the decision is based on the CCG Policy for Individual Patient Treatment and the CCG access protocol relating to the specific treatment, where appropriate.
- 2.27 The CCG works closely with both commissioning support organisations to ensure that requests for treatment will be considered by the appropriate commissioner at the earliest opportunity and within the timescales stipulated in the respective policies for considering individual treatment requests. Mechanisms are in place to ensure that requests erroneously referred to the incorrect commissioner are identified and forwarded to the correct commissioner for consideration of the request.
- 2.28 The CCG receives outcome reports in respect of decisions delegated to these organisations to ensure that decisions are made in a timely manner and in a way that is consistent with CCG policy.

3. DECISION MAKING FRAMEWORK FOR INDIVIDUAL TREATMENT REQUESTS

- 3.1 The process for managing decisions in relation to the different types of treatment requests is detailed below. Regardless of the type of request there are defined stages any requests will go through:

Stage 1 – Making a Request

- The requesting clinician completes the appropriate request forms available for download from the CCG Website or from the email addresses below.
- Requests must include email contact details for the requesting clinician. Requests should be submitted electronically to improve legibility and they should be submitted to either:
 - DOCCG.IndividualRequest@nhs.net –patient identifiable information must be sent from an Nhs.net account to this account to ensure confidentiality
 - Individual.requests@dorsetccg.nhs.uk – this can be used within the NHS in Dorset where email encryption processes are in place

- * Email is the preferred method of submission as this reduces delays and improves legibility. Decisions letters will usually be conveyed by email; Requests can however also be received by the CCG through the post;
- * Requests will not be accepted where the paperwork is incomplete or has not been completed correctly or is illegible. Clinicians are encouraged to submit requests using the standard Individual Patient Treatment request form. This ensures that all relevant information is incorporated and allows the clinician to denote patient consent to the sharing of clinical information;
- * It is the clinician's responsibility to ensure that all the appropriate information is provided in respect of the request. Clinicians should be aware that incomplete submissions may result in delays in the consideration of a request;
- * For some interventions the form for completion is specific to the condition and must be used by the requesting clinician;
- * Patient confidentiality should be maintained with any method of submission.

Stage 2 – Request Logged

- The CCG logs each request and assigns a unique reference number. Each response however it arrives (email, letter) will be logged on the commissioning database that records key information (e.g. Name, GP, date received in the CCG, request, action).

Stage 3 – Review of Request

- The request is reviewed to ascertain:
 - * whether it has been submitted to the correct Commissioner. Requests received at the CCG that relate to treatments which are commissioned by NHS England will be forwarded accordingly and the requesting clinician notified;
 - * whether the request has come from, and is supported by, a clinician responsible for the individual's treatment. Requests from patients or their family/ advocate will not be accepted;
 - * what type of request it is and which decision-making pathway should be followed (Section 4);
 - * whether all of the necessary information has been provided to ensure that the Team/ Panel can make a full assessment of the request, including:

- the correct request form completed in full;
 - the clinical circumstances and history of the patient;
 - whether there are similar patients who might equally benefit from the requested treatment;
 - the planned treatment and the expected benefits and risks of treatment;
 - details as to why the standard treatment pathway is not applicable;
 - the evidence on which the clinical opinion is based, provided as full journal articles or weblinks to national guidance;
 - confirmation that the patient has consented to the access and sharing of necessary clinical information to enable consideration of the request;
 - the full costs of treatment;
- * if approval can be given outside of the Individual Patient Treatment Panel either by the Individual Patient Treatment Team or through the GP triage process;
 - * whether an individual patient treatment request is necessary, as the request may relate to an intervention where the CCG has developed clinical criteria which the patient meets;
 - * whether the request refers to retrospective funding. Notwithstanding any treatment commenced on an agreed urgent basis as outlined in paragraph 3.20 the CCG will not fund retrospectively the costs of any treatment commenced before the request is considered;
 - * if the referral should be declined as it either relates to a treatment that is not commissioned or is outside of access protocols, and no case has been made for clinical exceptionality or exceptionality is based solely on psychological and/or socio-economic factors;

Stage 3 of the decision making process will identify those treatment requests that need to be considered in either in Stage 4 (GP Triage) or in Stage 5 (Individual Patient Treatment Panel).

Where a decision is made at Stage 3 the Individual Patient Treatment Team will respond directly to the requesting clinician and will also forward a copy of the letter to the patient where consent to do so has been provided.

Stage 4 – GP Triage

Where clinical interpretation is required to ascertain whether the patient meets the relevant access criteria within a particular protocol or it is unclear whether there is a case for clinical exceptionalism that requires consideration by Panel (Stage 5) the request will be reviewed by a GP Triage Team comprising up to three GPs. A decision will be reached within seven days on the basis of consensus or alternatively a majority basis. In the event that there is no majority decision the request will be referred to the Panel for consideration. The GP Triage Team may upon review consider that there is a case made for clinical exceptionalism which warrants consideration by the Individual Patient Treatment Panel.

Where a decision is made at Stage 4 the Individual Patient Treatment Team will respond directly to the requesting clinician and will forward a copy of the letter to the patient

Stage 5 – Review by the Individual Patient Treatment Panel

- The Individual Patient Treatment Panel will consider a request within 28 working days of the request arriving with the Individual Patient Treatment Request Team, unless additional information is required. Requests where additional information has been requested and has not been provided will not be submitted to Panel.
- If additional information has not been submitted after six weeks the requesting clinician will be contacted to advise that if the information is not provided within one further month, the case will be closed and both the requesting clinician and patient informed of this outcome.
- The requesting clinician will be informed that the case is to be considered by a Panel.
- Each member of the Panel will be issued with copies of all documentation received. Cases may be supported by additional information covering the principles and ethical considerations detailed in Appendix A. Any photographs submitted as supporting evidence of clinical exceptionalism will only be viewed at the Panel meeting.
- The Panel will note the main points arising during consideration of the case and the reasons for the decision in a formal record of the meeting. In some circumstances the Panel will require further information to enable a decision. Such cases will return for a decision at the Panel meeting subsequent to receipt of the additional information;

Stage 6 – Panel Outcome

- The Panel decision will be notified in writing to the requesting clinician and patient, within seven working days of the Panel meeting. The correspondence will explain the basis for the decision and address the case made for exceptionality. If declined, this correspondence will inform the requesting clinician of the reconsideration, appeal and complaints process. The correspondence outlining the decision will be copied to the patient (or carer, or guardian where consent is provided) unless stipulated otherwise in the request. A copy will also be forwarded to the patient's GP if they are not the requesting clinician;

Stage 7 – Appeal Panel This is detailed in paragraph 3.24

Individual Patient Treatment Panel Membership and Frequency of Meetings

- 3.2 Membership of the Individual Patient Treatment Panel will not be fixed but will comprise representatives from appropriate disciplines, including:
- Up to three GPs who have agreed to represent the Dorset Clinical Commissioning Group. One GP will undertake the role of Clinical Vice-Chair;
 - Up to three Secondary Care consultants from local Trusts;
 - Up to two Patient and Public Involvement Representatives;
 - A representative from Public Health Dorset who has a role in providing public health advice to the CCG;
 - Medicines Management;
 - Commissioning Manager responsible for individual treatment requests;
- 3.3 The Panel will be chaired by an Executive Director of the CCG or their representative. A Register of Panel Members Interests will be reviewed and updated at the start of each meeting. Members will be expected to declare any potential conflicts of interest in respect of specific requests prior to their consideration and Panel members who have had any clinical involvement with a particular case will be excluded from the discussion of that case. Development needs for Panel members will be met by the CCG through an induction process.
- 3.4 The Panel will meet monthly, with quorum being attendance by six members, including at least one GP, one hospital consultant, a representative from Public Health Dorset (but only where no written advice relating to the specific requests to be considered by the Panel at that meeting has been provided prior to that meeting), one Patient and Public Involvement Representative and a commissioning pharmacist and a commissioning manager. The Panel will

endeavour to reach a consensus decision, and where this is not possible a simple majority decision will be sought. Voting will be restricted to GPs, Secondary Care Consultants, the Patient and Public Involvement Representatives, and the Public Health representative. In the event of a tied vote, the Clinical Vice-Chair will have a casting vote.

- 3.5 The Panel has been established by the CCG and has the delegated authority to make decisions in respect of the funding of individual cases. It is not, however, the role of the Panel to make commissioning decisions on behalf of the CCG. The Panel will take into consideration that the allocation of resources to support a request will reduce the availability of resources for previously agreed care and treatments for the CCG's population.
- 3.6 NHS England has its own processes and Panels for those treatments, interventions and conditions for which it is the responsible commissioner.
- 3.7 The Panel will not hear evidence in person either from clinical staff involved in a particular case, or patients or their representatives. The Panel will consider any information provided in writing.

Individual Patient Treatment Panel Consideration of Requests

- 3.8 The Panel will use the information provided by the requesting clinician to compare the patient to other patients with the same presenting clinical condition and the evidence provided to demonstrate the likely clinical and cost effectiveness of the treatment. The Panel will consider, based upon the information provided, whether the patient has demonstrated exceptional clinical circumstances which leads the Panel to believe that the patient would benefit significantly more from the treatment than would other patients for whom the treatment is not funded. The Panel must be assured therefore that there are justifiable grounds for funding the requested treatment when other patients with the same condition and at the same stage of progression will not receive such funded treatment.
- 3.9 In making the decision the Panel will restrict itself to considering only the patient's presenting clinical condition, the likely benefits which have been demonstrated by the clinical evidence as likely to accrue to the patient from the proposed treatment, and the likely cost-effectiveness of the treatment.
- 3.10 The Panel cannot base its decision purely on the views expressed by the patient or the requesting clinician concerning the likely benefits of the proposed treatment. The Panel will, rather, be chiefly concerned to examine and reach a conclusion on the quality of the evidence presented to support the request and/or the likelihood of and degree of benefit to the patient from the treatment.
- 3.11 It is recognised that due to the rarity of some clinical presentations there will often be limited published clinical evidence relating to the proposed treatment and that it may not be feasible to undertake robust trials. Rarity of the condition alone is not sufficient grounds to support a case and for accepting a lack of evidence. In such cases the requesting clinician may present evidence of clinical effectiveness in relation to another similar presentation. The Panel will consider the biological plausibility of the anticipated benefit based on this

evidence and supporting arguments for its extrapolation to the condition in question.

- 3.12 In such cases the Panel will consider the clinical evidence provided which might be limited to small and often heterogeneous case reports and/or report on short term outcomes. In doing so the Panel will also take into account the potential risks and benefits, costs and anticipated value for money, and the priority of the patient's needs compared to other unfunded treatments.
- 3.13 Where funding is approved in such circumstances ongoing support will be subject to review of outcome after an agreed time period. Support will also usually be dependent on contribution to any relevant clinical database or population registry.
- 3.14 The Panel is entitled but not obliged to obtain its own advice and reports from any appropriately qualified or experienced clinician concerning the likely clinical effectiveness of treatment and to consult any recognised published evidence or guidance. Any such reports and advice will be recorded with all other information provided in respect of the request. The onus, however, remains with the requesting clinician to provide evidence in respect of the clinical benefit, cost effectiveness and safety of the proposed treatment.
- 3.15 Where a request is approved the Panel may approve contingent on fulfilment of any reasonable condition as it considers fit. In the case of ongoing treatment, the Panel may approve a treatment for a specific initial period of time subject to receipt of an outcome report.

Urgent Requests

- 3.16 The CCG recognises that there may be occasions when an urgent decision may need to be made outside of normal timescales. Requesting clinicians can request urgent consideration of a case. The CCG will assess the request and determine whether it is justifiable to consider the case more urgently than other requests. Significant clinical risk must be evident in support of an urgent request.
- 3.17 In cases where urgent consideration can be justified, the Panel will be contacted via email. A response from at least four voting members of the Panel including one GP, one hospital consultant, a Patient and Public Representative, and a representative of Public Health Dorset will be required to enable a decision. The Individual Patient Treatment Team will review feedback from Panel members and inform decisions outside of the Panel.
- 3.18 An urgent consideration by the Panel may take between 48 hours and one week depending upon the availability of Panel members.
- 3.19 Urgency under this policy should not arise as the result of a failure by the Clinical Team to expeditiously seek funding through the appropriate route. All reasonable steps should be taken to minimise the need for requests to be made on an urgent basis. Requesting clinicians should not raise patient expectations that criteria based access to treatment will not apply in an urgent situation.

- 3.20 In the unlikely event that the request is so urgent that it requires a decision on treatment before the Panel next meets, the requesting clinician may be asked to consider the commencement of treatment before the decision is made. If a treatment is started in these circumstances and where the Panel is satisfied that the request was urgent and submitted in a timely manner it will consider the request on a retrospective basis and, where supported, treatment will be funded on that basis.
- 3.21 Decisions that are made urgently outside of the formal Panel meeting will be noted at the next Panel meeting.

Reconsideration of Individual Cases at a Panel

- 3.22 Clinicians can request reconsideration of an individual case. This has to take place within four weeks of receipt of the Panel decision, and is required to be submitted in writing. Reconsideration can only be made if the requesting clinician disagrees with the decision and considers that there is new information that should be considered or that the Panel has misunderstood the evidence presented. New information should be information that was not available at the time of making the original Panel decision. The Panel will not reconsider cases with no new supporting information. It is the responsibility of the requesting clinician, not the individual patient, to ensure that all necessary information is provided at the time that the request is made.
- 3.23 When a request for reconsideration is made, the case will be considered at the next available Panel.

Appeal Panel

- 3.24 If the referring clinician disagrees with the decision and feels that the CCG has been unfair in its decision making process they must clearly document what elements of the process have been unfair and how this has affected the Panel decision.
- 3.25 Appeals can only be lodged against the process used in reaching the decision. This means that appeals cannot be submitted on the grounds of the decision alone and cannot include new information. A request for an appeal must be made within four weeks of receipt of the CCGs decision, and is required to be submitted in writing. In these circumstances an Appeal Panel will be convened.
- 3.26 The CCG will acknowledge receipt of an appeal within 7 working days and will confirm on what ground the appeal is to be considered. Appeals that do not meet the above criteria will not be accepted and will be returned to the requesting clinician.
- 3.27 An Appeal Panel will have access to all relevant documentation on the case including correspondence, a synthesis of the evidence base and minutes of relevant meetings. Copies of the documentation will be available to the requesting clinician. The Appeal Panel will not hear evidence in person from the individual but the requesting clinician will be given the opportunity to attend the Appeal Panel at the discretion of the Chair.

- 3.28 The requesting clinician will not be able to present clinical information as the Appeal Panel are required to focus upon the process involved in arriving at the individual's treatment decision. If new information is presented by the requesting clinician the Appeal Panel will be closed and the case referred back for reconsideration at the Individual Patient Treatment Panel. The requesting clinician will be able to explain why they consider that the Individual Patient Treatment Panel did not follow due process in reaching its decision.
- 3.29 An Appeal Panel will consider whether the decisions were made in line with the principles in Appendix A and whether the process detailed within this Section 3 have been followed. An Appeal Panel may be adjourned to seek clarification on the clinical information supplied. An Appeal Panel will review whether a decision is consistent with any previous similar requests and if the decision was reasonable and fair and in line with the evidence and all material factors.
- 3.30 An Appeal Panel will not consider new evidence emerging after the initial Individual Patient Treatment Panel decision. If new information becomes available prior to, or during, an Appeal Panel, the Individual Patient Treatment Panel will be asked to reconsider the case.
- 3.31 An Appeal Panel will comprise people who have not previously been involved in the case:
- GP member of the CCG Governing Body (Chair);
 - Director of Public Health or representative from the local authority;
 - Director of Service Delivery or representative;
- 3.32 The Chair of the Appeal Panel may invite a GP who sits on the CCG Governing Body to help in understanding the clinical information supplied and whether the decision was reasonable and in line with the evidence. They would not be expected to bring new information to the Panel.
- 3.33 The Appeal will also be attended by an appropriate representative who attended the relevant Individual Patient Treatment Panel. This attendance is to ensure continuity and the provision of information to the Appeal Panel members. This is not a voting member of the Appeal Panel.
- 3.34 The Appeal Panel will endeavour to reach a unanimous decision. Where this is not the case a majority decision will be sought and, in the event of a tied vote the Chair will have an additional casting vote.
- 3.35 If the Appeal Panel considers the Individual Patient Treatment Panel has:
- failed in a material way to follow its own procedures; and/or
 - failed in a material way to properly consider the evidence presented to it (eg: by taking account of an immaterial fact or by failing to take account of a material fact); and/or
 - come to a decision that no reasonable Panel could have reached on the evidence before the panel;
- the Appeal Panel shall uphold the patient's appeal and shall refer the case for reconsideration by the Individual Patient Treatment Panel.

- 3.36 The Appeal Panel shall not have power to authorise funding for the requested treatment but shall have the right to make recommendations to the Individual Patient Treatment Panel and to request one of the Officers authorised to take an urgent decision. The Appeal Panel will be informed by the Chair of the Individual Patient Treatment Panel of the decision made following re-review of the case.
- 3.37 A failure in the process of handling a request for treatment does not, however, necessarily mean that the decision made was incorrect. Under these circumstances, the Chair of the Individual Patient Treatment Panel should be notified of the outcome. The Chair of the Appeal Panel will write to the requesting clinician and the individual patient within seven working days of the Appeal Panel decision. The individual case will be considered at the subsequent Individual Patient Treatment Panel. If an urgent review of the decision is indicated by the Appeal Panel the Individual Patient Treatment Panel will review the request through the process outlined in 3.17 .
- 3.38 There will be no further right of appeal to the CCG once the Appeal Panel has reached its decision. All Appeal Panel decisions will be final and binding.
- 3.39 Appeals will not be accepted from individuals or their representatives. The individual can complain about the CCG policy and how this has been applied, or about the outcome of an Appeal Panel through the established NHS complaints process which is detailed on the CCG website. A complaint which includes new information will be referred back to an Individual Patient Treatment Panel. The Complaints Process will not recommend individual treatments but may recommend review of a commissioned pathway of care or protocol.
- 3.40 The CCG Governing Body receives reports on the number of individual cases and the number of requests for appeals. A separate process exists in line with national requirements for complaints.

4. CRITERIA BASED ACCESS WITH OR WITHOUT PRIOR APPROVAL, WHERE PROTOCOLS EXIST

- 4.1 The CCG is entitled to require approval of individual cases prior to proceeding with treatment, with arrangements for how this will be incorporated into contracts with providers. Criteria Based Access protocols in respect of interventions which the CCG does not routinely commission are available on the CCG's website: <http://www.dorsetccg.nhs.uk/aboutus/clinical-policies.htm>. These protocols outline the clinical circumstances where the intervention would be made routinely available to the patient. The individual protocol will state whether or not prior approval is required before the patient is treated. Where the criteria are not met consideration of treatment can only be given through submission of an individual patient treatment request. The list of services for which prior approval is required may change over time as the evidence base for the application of treatments and technologies is clarified and as other aspects of commissioning policy advance.

- 4.2 The CCG may also require prior approval for any treatment where the risks to the CCG of supporting the treatment without prior approval are judged to be too high. High risk situations would include (but are not limited to):
- Where the epidemiology or the expected uptake of the treatment is unknown;
 - Where the financial commitment is high;
 - Where there is potential for the clinical criteria to be interpreted widely or where there is a risk of expansion of access beyond that intended by the existing protocol.
- 4.3 During stage three (described in Section 3) for individual patient treatments, it will be determined whether the request is for prior approval against the CCG's predefined access criteria and treatment will be supported if the patient meets these criteria. The type of treatments covered by such protocols includes breast surgery.
- 4.4 The Criteria Based Access Protocols identify groups of individuals for whom approval is not required if the individual has specific clinical symptoms and circumstances. These protocols relate to a range of interventions that are either:
- Classified as services not routinely commissioned (see definition below);
 - Part of a care pathway where other interventions must have been considered and tried first; or
 - Are clinically effective for specific clinical sub-groups.
- 4.5 The list of services not routinely commissioned currently defined is not exhaustive; rather it is indicative of the types of treatments that are considered to be of lower priority for funding than others and that therefore the CCG will not normally fund. Interventions are not routinely commissioned for a variety of reasons. Commonly, such interventions have some of the following characteristics:
- uncertain outcomes in the medium/longer term;
 - paucity of research evidence to support their use;
 - the problem for which treatment is sought causes 'unhappiness' rather than ill health or functional impairment.
- 4.6 Requests for individual treatments outside of protocols should only be made for people that meet the exceptionality criteria as defined in Section 5.
- 4.7 Requests that are for treatments for groups of patients will not be considered as exceptional and as such these treatment interventions will not be considered on an individual patient treatment basis. An individual funding request that will ultimately affect a group of patients, outside of the CCG's protocols, will not be considered by the CCG until the relevant intervention has been prioritised for investment through the CCG's prioritisation process.

4.8 Requests for authorisation outside of protocols for exceptional circumstances will be considered on the basis of clinical exceptionality as defined in Section 5 below. Often requests for individuals to be considered as an exception to these protocols are based upon the psychological or social/functional implications for that individual. The rationale why psychological and social factors are not considered as exceptionality criteria is given in Section 5 and also in Appendix C.

4.9 Appendix B presents a flow chart of the decision making process for individual requests within this definition.

5. INDIVIDUAL FUNDING REQUESTS FOR WHICH THERE ARE NO CRITERIA BASED ACCESS PROTOCOLS OR WHERE THE CLINICIAN FEELS THERE ARE EXCEPTIONAL INDIVIDUAL CIRCUMSTANCES

5.1 It is inevitable that there will sometimes be individual patient needs that cannot be met through existing care pathways or contracted services. Requests for these individual treatments will be considered following the principles detailed in Section 2. There are several reasons why the CCG may not be commissioning the treatment for which funding is sought. These include:

- The CCG might not have been aware of the need for this service so it has not been incorporated into service specifications and contracts;
- The CCG may have decided to prioritise the intervention for a specific population group for which the intervention is most effective;
- The treatment is for a very rare condition for which the CCG has not previously needed to make provision;
- It is a treatment that has not been considered by the CCG before, because it is a new way of treating a more common condition. This should be considered as a service development rather than considering the individual request unless there is grave clinical urgency;
- The CCG may have decided not to prioritise the treatment because it does not provide sufficient clinical benefit and/or does not provide value for money; and
- The CCG has accepted the value of the intervention but has decided not to prioritise it relative to other population priorities.

5.2 Individual funding requests should not be confused with decisions that are related to health care packages for patients with complex health needs.

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

- when the clinician requests funding for a treatment which is outside existing generic or treatment-specific protocols on the basis of an exceptional circumstance which applies specifically to that patient;

- when there is no protocol in place and the requests are likely to be rare.
- 5.4 Requests that are **not** considered to be an individual funding request include
- requests that represent a service development (e.g. a newly licensed drug);
 - requests where no information is submitted in support of the individual's exceptionality;
 - requests affecting more than 3-4 individuals per year within the CCG population.
- 5.5 Appendix B presents a flow chart of the decision making process for individual requests within this definition.

What Are Exceptional Circumstances?

- 5.6 The CCG will use an Individual Patient Treatment Panel to consider individuals whose circumstances might make them an exception to existing local protocols or the CCG's commissioning position. It is for the requesting clinician to clearly make the case for exceptional status. In such cases the requesting clinician must provide information to support the case for the individual concerned and reasons supporting exceptionality. The differences between the majority of patients for whom the treatment is not available and the patient in question must be abundantly clear and documented by the requesting clinician.
- 5.7 Whilst each patient's individual circumstances are, by definition, unique, this does not define exceptionality. Exceptionality instead refers to characteristics of the condition or response to treatments which are highly unusual or unexpected in that patient population. This may include patients who are affected by the treatment in an unusual way due to other clinical factors which mean that the usual treatments for the condition are not suitable.
- 5.8 If a patient's clinical condition matches the 'accepted indications' for a treatment that is not funded, their circumstances are NOT, by definition exceptional. When considering funding for individual patients the CCG has to consider whether it can justify approval when other similar patients will not be receiving funded treatment.
- 5.9 It is important to distinguish between an exceptional case and an individual funding request. In an exceptional case, a clinician seeks to show that the individual is an 'exception to the rule or protocol' and so may have access to an intervention that is not routinely commissioned for that condition. In contrast, an individual funding request arises when a treatment is requested for which the CCG does not commission.
- 5.10 It should be noted that the fact that a treatment is likely to be efficacious, or has been deemed to be efficacious, for a patient is not, in itself a basis for exceptional circumstances. In order for funding to be agreed, there must be

some unusual or unique **clinical** factor about the patient that suggests that they are:

- significantly different from the general population of patients with the condition in question and at the same stage of progression;
- likely to gain significantly more benefit from the intervention than might be expected from the average patient with the condition and at the same stage of progression.

- 5.11 The fact that the patient has exhausted all NHS treatment options for a particular condition does not, in itself, mean that they are clinically exceptional. In addition the fact that a patient is refractory to the standard commissioned treatments where it is evident that a cohort of patients will also be refractory to these treatments does not in itself make them clinically exceptional.
- 5.12 The fact that a patient has failed to respond to or is unable to be provided with one or more of the treatments usually provided to a patient with the condition (either because of another clinical condition or because of intolerance of side-effects) may be a basis for exceptionality. However, when considering the case for clinical exceptionality, the Panel will need to consider the expected frequency of treatment failure, adverse effects and complicating co-morbidities within this patient population.
- 5.13 Where it is stated that the patient has a severe form of the condition, the requesting clinician should clarify how the patient differs from others who would also be categorised as having the severe manifestation of the condition as described.
- 5.14 Where it is argued that a patient is exceptional due to having a specific genotype, evidence will need to be provided as to how this makes the patient different to others in the patient group and why they would be expected to benefit to a greater extent than others without or with a different phenotype.
- 5.15 It may be possible to demonstrate clinical exceptionality where the patient has a clinical condition or circumstances which are so rare that the CCG prioritisation process has not established and commissioned a care pathway for the relevant treatment. This is usually defined as 1 or 2 cases per annum within the NHS Dorset CCG population.
- 5.16 If approval based on exceptionality is sought the clinician must detail why they believe that the patient will derive greater benefit from the intervention than others in the patient group who cannot access the treatment.
- 5.17 There may be individuals for whom the requesting clinician outlines multiple grounds to demonstrate exceptionality. In such cases the Panel will review each factor individually to determine whether it constitutes clinical exceptionality.
- 5.18 If the Panel considers that none of the individual factors on their own constitute clinical exceptionality they will review the combined effect of these factors to determine clinical exceptionality.

- 5.19 Neither the CCG nor the Panel has an obligation to undertake its own investigations about the patient's circumstances in order to establish grounds for exceptionality nor to make assumptions in favour of the patient if one or more matters are not made clear in the application. The onus is therefore on the requesting clinician to provide a full and balanced case for exceptionality.
- 5.20 The CCG must justify the grounds upon which it is choosing to fund a patient when the treatment is unavailable to others with the condition. If an Individual Patient Treatment Panel is persuaded that a treatment is likely to be clinically and cost effective in a patient, where the requesting clinician is making an exceptional case request, then in the interests of equity consideration should be given to whether this patient may, in fact, represent a small sub-group in whom the intervention may meet clinical and cost effective criteria. If this is the case, the relevant access protocol will be amended to include a provision for treatment of this subgroup.
- 5.21 If social and psychological factors are included in decision making, it becomes more difficult to prevent inequity. Agreeing to fund a case based on social or psychological factors almost inevitably sets a precedent for funding a sub group and so, would prompt a review of access protocols. Therefore the CCG has defined exceptionality in relation to unique clinical factors. Case examples in Appendix C outline the rationale for decisions not to have social and psychological circumstances as the basis for consideration of exceptionality.
- 5.22 The CCG has not identified a group of patients whose social worth overrides the usual considerations of cost and clinical effectiveness, not only for the intervention in question but arguably for all their health care needs. If it did do this it would mean that others with a different social contribution or whose non-clinical circumstances are unknown would be subjected to inequity.
- 5.23 The CCG has not identified a group of patients with psychological factors that would override the usual considerations of cost and clinical effectiveness. The CCG takes the view that because of the difficulties associated with obtaining normative values for the majority of patients for whom an intervention is not available and in the interests of equity, psychological distress alone will not be considered as reason for exceptionality. The CCG recognises that psychological factors can impact on a patient's wellbeing and would expect them to be treated following referral to the mental health services commissioned by the CCG.
- 5.24 Exceptionality has been defined solely in clinical terms; to consider social and other non clinical factors automatically introduces subjectivity and inequality, implying that some patients have a higher intrinsic social worth than others with the same condition. It runs contrary to a basic tenet of the NHS namely, that people with equal need should be treated equally and introduces discrimination into the provision of clinical treatment. Therefore social and psychological circumstances are not factors that would make an individual exceptional.

6. CASES THAT DO NOT CONSTITUTE INDIVIDUAL TREATMENT REQUESTS

- 6.1 Requests cannot be considered on an individual patient basis where:

- there is a group of similar patients and where there is an existing criteria based access protocol and consideration should instead be given to a change in the access protocol.
 - The patient is part of a clinical trial;
 - there is a group of similar patients and where there is no existing criteria based access protocol.
- 6.2 The Individual Patient Treatment Panel **cannot** make a decision to fund a treatment that would set a precedent and establish a new criteria based access protocol. For example, in a situation whereby a patient is not in fact exceptional but instead is a representative of a particular group of patients even if the patient may be the first for whom a request is made.
- 6.3 In such circumstances the request will be deemed to represent a service development and in such circumstances this should be considered through the CCG's prioritisation process by:
- Inviting the provider to submit a business case for consideration as part of the annual commissioning process: or
 - Initiating an assessment of the clinical importance of the service development with a view to developing an access protocol or a statement of commissioning position having determined its priority for funding.
- 6.4 In these cases consideration of a request on an individual patient treatment basis will only be given if it is evident that the patient is clinically exceptional to that cohort of patients. Otherwise the request will be declined.
- 6.5 Requests which essentially relate to alteration of an existing access protocol cannot be considered as an individual patient treatment request. Instead consideration should be given to review of the protocol. Examples would include expansion of access to a new and distinct sub-group of patients, lowering threshold for access to treatment, or the addition of a new clinical indication for treatment.
- 6.6 The requesting clinician may seek reconsideration of a request which has been declined on the basis that the patient is part of a cohort of similar patients. However the request may only be reconsidered on the basis of clinical exceptionality and upon submission of new clinical information which indicates that the patient is significantly different from other patients in the relevant cohort.

7. CROSS BORDER HEALTHCARE WITHIN THE EUROPEAN ECONOMIC AREA

- 7.1 Under existing arrangements, patients can exercise their right to access treatment within the European Economic Area, under the terms of Directive 2011/24 European Union on the application of patient's rights in cross-border healthcare and the accompanying regulations. Patients choosing to exercise this right will receive reimbursement for eligible costs, according to their entitlement and the terms of the Directive. NHS England will be responsible for

administering the application and reimbursement processes for all requests. The approved reimbursement will be funded by the commissioner responsible for commissioning the specific treatment.

- 7.2 For services commissioned by NHS England that organisation will reimburse patients directly. For services commissioned by the CCG, NHS England will reimburse patients on behalf of the CCG, who will in turn be required to repay NHS England for the patients' eligible costs.
- 7.3 Where a patients' application relates to treatment that is normally commissioned by the CCG , NHS England will require information from the CCG on local entitlement to that treatment, to aid the decision making process. The CCG will therefore make local access based protocols available to NHS England and respond to ad-hoc enquiries from NHS England on patient entitlement. Where the treatment would not have been made available locally, reimbursement will only be made where an individual patient treatment request has been submitted and has been supported on the basis of clinical exceptionality.

8. REQUESTS FROM INDIVIDUALS WHO WISH TO PAY FOR ADDITIONAL PRIVATE CARE

- 8.1 This policy does not cover the arrangements and processes in Trusts for people who wish to pay for additional private care. However the CCG is sometimes approached by patients to top-up treatments covered by access protocols. These individuals may have sought to have their treatment supported on the basis of exceptionality. Individual requests to top-up the difference between the costs to the NHS of the recommended pathway of care for individuals and the requested treatment are not supported. This is deemed as co-funding which involves both private and NHS funding for a single episode of care and is in breach of national policy. The CCG will not consider any funding requests of this nature.
- 8.2 Frequent requests relate to breast augmentation previously performed privately. The specific CCG protocol allows for removal of implants when clinically necessary but not simultaneous replacement of both implants. Individuals often request to top up the NHS cost of surgery for new implants in both breasts. This is deemed as co-funding and is not supported by the CCG.
- 8.3 When an individual wishes to pay privately for a treatment not normally funded by the CCG, the individual will be required to pay all associated costs which would not otherwise have been incurred by the NHS had the patient not chosen to seek private treatment.
- 8.4 Appendix B presents a flow chart of the decision making process for individual requests within this definition.

9. REQUESTS FOR NHS FUNDING FOR A TREATMENT PATHWAY COMMENCED WITHIN THE PRIVATE SECTOR

- 9.1 Individuals who choose to access private healthcare, for whatever reason, retain the right to access NHS healthcare which is normally funded within the individual's CCG on the same basis as any other individual. The CCG will expect any transfer of care to follow locally agreed pathways of care and

access protocols. Requests to transfer to care outside of normally commissioned pathways will be considered as an individual patient treatment request and will only be supported if evidence of exceptionality is provided. This will ensure that patients who are unable to pay for treatment themselves have equal access to healthcare.

- 9.2 Patients have a right to revert to NHS healthcare at different points of their care pathway unless this is clinically contraindicated. There may be times when an NHS clinician declines to provide NHS treatment when they consider that the private treatment will undermine the effectiveness of NHS treatment. An individual who reverts to NHS care should be reassessed by the NHS clinician, they should not be given any preferential treatment by virtue of having gone privately and they should be subject to the national waiting times from the point of assessment in the NHS.
- 9.3 An individual whose private consultant has recommended treatment with a medication normally available on the NHS can ask the individual's GP to prescribe the treatment as long as the GP considers it to be clinically necessary and the drug is listed on the CCGs drug formulary or the drug is normally funded by the CCG. The exception to this would be if the medication is specialised in nature. In these cases, it is for the individual GP to decide whether to accept clinical responsibility for the prescribing decision recommended by another doctor. If the GP will not accept clinical responsibility, the only way the individual can access NHS prescribing is through referral to an NHS consultant.
- 9.4 Medications recommended by a private consultant that are more expensive than that locally prescribed for the same clinical situation within the NHS may not be available on the NHS. The NHS GP may follow the CCG prescribing advice. The Individual will retain the option of purchasing the more expensive drug through the private consultant.
- 9.5 Instances in which an individual can no longer afford ongoing private treatment costs or whose private healthcare insurance does not cover the full treatment costs, should not expect the CCG to pick up the funding for any treatment which is not commissioned for the local population. The fact that the individual has benefited from treatment is not sufficient grounds of itself to agree to fund a patient as an exception.
- 9.6 If the treatment requested has referral criteria for access and the individual falls outside of these the on-going cost of treatment will not be met unless evidence of exceptionality is submitted by the private clinician and this is accepted by the Individual Patient Treatment Panel. There will be no retrospective payments if approval is given for a transfer of care on the basis of exceptionality.
- 9.7 Individuals who have chosen to seek private treatment are entitled to request a second consultant opinion, but this will only be supported within the NHS.

10. CHOICE AND SECOND OPINIONS

- 10.1 From April 2008, patients have had the right to choose the organisation that provides their NHS funded care when they are referred for their first outpatient appointment with a service that is led by a consultant. This right to choose

from any healthcare provider offering treatment that meets NHS standards and costs means that the hospital must enable their service to be booked through the national Choose and Book system.

- 10.2 Individuals cannot be referred to services not advertised on the national system. Individuals who wish to choose a service not commissioned locally and not listed on the national system will need CCG agreement to be referred. Such cases will be considered under exceptionality.
- 10.3 Direct referrals to services commissioned by NHS England are not routinely supported unless specific criteria defined by NHS England are met.
- 10.4 A choice of hospital is available for most patients and in most circumstances any required treatment will be provided by the chosen hospital. Sometimes a clinician may ask a colleague for a second opinion if they are not fully certain of their diagnosis or suggested course of treatment. More information on NHS Choice is available on the NHS Choices website
- 10.5
- 10.6 Sometimes individuals are not happy with the chosen hospital after seeing a specialist. Individuals may ask for a second (or further) opinion. Although individuals do not have a legal right to a second opinion, people have the right to ask for one. A healthcare professional rarely refuses to refer for a second opinion unless there is sufficient reason. Clinicians will be supported to make referrals for second opinions within locally commissioned pathways of care. In Dorset there are a number of providers from which a second opinion can be sought or referrals can be made to the specialist hospital in Southampton or Bristol. Well established pathways of care will be used to ensure that any delay in treatment is minimised and to enable the sharing of relevant test results/investigations (such as x-ray) so as to minimise repeat investigations that would represent poor use of NHS money. It would be expected that a second opinion is shared with the requesting clinician to enable any ongoing care to be as close to home as possible.
- 10.7 The circumstances in which a second opinion would not be supported are:
- Individuals seeking a second opinion for an intervention linked to specific access criteria which they do not meet and the initial consultant has informed them that they do not meet the exceptionality criteria;
 - Individuals seeking a third/fourth opinion outside normally commissioned pathways of care;
 - Individuals seeking an opinion from the private sector.
- 10.8 If individuals request a second opinion, they should be aware that this will not take priority over other patient referrals, and they will not be seen on an urgent basis. A second opinion with a different consultant may be at a different hospital, which may involve some travelling.

11. REQUESTS TO CONTINUE FUNDING FOR PATIENTS COMING OFF CLINICAL TRIALS

- 11.1 The CCG does not expect to provide funding for patients to continue medication/treatment commenced as part of a clinical trial. In line with the Medicines Act 2004 and the Declaration of Helsinki, the responsibility for ensuring a clear exit strategy from a trial lies with those conducting the trial. This must ensure that patients who have benefited from treatments as part of a clinical trial must have ongoing access to that treatment. The initiators of the trial (provider Trusts and drug companies) are expected to continue funding patients benefiting from treatment.
- 11.2 Patients exiting a trial will invariably be representative of a cohort of patients with broadly the same clinical circumstances and funding of the treatment should therefore only be considered as a service development. The fact that a patient has received clinically beneficial effect from the trial does not in itself constitute clinical exceptionality as there will be other patients similarly identified from the trial outcome who would also benefit from the treatment. The CCG will consider any ongoing funding requirements through its annual prioritisation processes. Where treatments are not prioritised within the annual prioritisation process, the responsibility for continuing the treatment remains with the trial initiators.

12. REQUESTS FOR REFERRAL TO A SPECIALIST PROVIDER (TERTIARY, REGIONAL OR SUPRA-REGIONAL CENTRE OR SPECIALIST PRIVATE PROVIDER)

- 12.1 Most referrals to specialist centres are made by secondary care consultants and the treatments provided are commissioned by NHS England. The CCG, however, expects consultants to refer patients for tertiary/specialist care using established pathways and in accordance with national specifications, where relevant. Accordingly, requests for referrals to specialist providers outside existing pathways are usually only considered after assessment by appropriate specialists within the existing pathway.

13. DECISIONS INHERITED FROM OTHER COMMISSIONERS

- 13.1 Occasionally, patients move in to the area and become the responsibility of the CCG with a package of care or treatment option that has already been approved by a different commissioner (the one that was previously responsible for commissioning that individual's treatment). The CCG will normally honour such decisions, providing the care pathway has already been initiated - that is, an appropriate referral has previously been made and approved. The CCG may require information from the previous commissioner regarding the decision. Wherever possible, the CCG will work to ensure that such patients receive their treatment and/or packages of care locally.

14. MILITARY VETERANS

- 14.1 Individual patient treatment requests in relation to military veterans and reservists will be treated in the same way as other requests for treatments. Military veterans will not automatically receive access to services not routinely

commissioned or procedures covered by access based criteria for example, Bariatric surgery. NHS England is responsible for the commissioning of prosthetic limbs for veterans and for commissioning health services for reservists when mobilised.

- 14.2 Military veterans do receive priority access to NHS secondary care for conditions which are likely to be related to their service, subject to the clinical needs of all patients. Where the patient is content for their veteran status to be included, requesting clinicians are asked to clearly state this when drafting referral letters and include a clinical opinion if the condition may be related to military service.

15. AUDIT AND MONITORING

- 15.1 The process of approving treatments as described will be open and transparent, in accordance with this policy. All correspondence in connection with individual patients will be carried out in accordance with Caldicott principles, so as to maintain patient confidentiality at all times.

- 15.2 The database of treatment requests will provide a means of regularly tracking and auditing how requests are handled through the system. The Individual Patient Treatment Panel will receive three reports on a monthly basis. These are:

- A report of cases submitted in the previous month that have been considered outside of Panel and either approved, declined or closed;
- A report of cases which were not considered and resolved within 28 days;
- A GP audit of four cases chosen at random to ascertain if the Team has:
 - * interpreted clinical information correctly and responded having applied the appropriate protocol correctly; and
 - * responded within the time intervals required of this policy.

- 15.3 The Clinical Commissioning Committee will receive regular reports from the Director of Service Delivery summarising the commissioning decisions. The CCG Governing Body will receive reports on an annual basis outlining the volume of individual cases, developments in the process for considering individual patient treatment requests and number of requests for appeals. A separate process exists in line with national requirements for complaints.

16. THIS POLICY WILL BE PUBLISHED ON THE CCG WEBSITE.PATIENT AND PUBLIC INVOLVEMENT

- 16.1 This is version 4 of this policy. Changes made to the policy provide further clarification on the process for considering individual patient treatment requests.

16.2 Dorset residents have been separately consulted with by the CCG on the strategic aims of the organisation and investment and service redesign priorities. Patients and the public are routinely invited by the CCG to participate in strategic planning, designation and other commissioning process to inform individual policies. The Individual Patient Treatment Panel's membership includes two Patient and Public Involvement Representatives who provide their specific perspective and input to the process.

17. HOW THIS WILL IMPACT ON INEQUALITIES

17.1 This Policy will assist in establishing a consistent, transparent, and equitable approach to commissioning services, securing the best possible health benefit within available resources.

18. COMMUNICATION OF POLICY

18.1 This policy will be shared directly with key stakeholders and will be posted on the CCG website.

18.2 The principles and processes outlined in this policy are incorporated in a patient information leaflet which can be accessed from the CCG's website: <http://www.dorsetccg.nhs.uk/Downloads/aboutus/Policies/Clinical/Policies%20from%20Sept%202014/IPT%20Leaflet.pdf>

18.3

19. DATE OF REVIEW

19.1 This policy should be reviewed by the end of September 2019.

GLOSSARY

Services Not Routinely Commissioned	<p>Those where the evidence of clinical and/or cost effectiveness is limited (or they are only clinically effective in a specific groups of people or in certain clinical circumstances, when they might be funded), and/or where not funding such treatment is unlikely to have a significantly adverse effect on the patients physical or mental health or ability to undertake everyday living activities with reasonable independence</p>
Clinical Effectiveness	<p>Has been defined as the extent to which specific clinical interventions, when deployed in the field for a particular patient or population, do what they are intended to do – that is, maintain or improve health and secure the greatest possible health gain from available resources</p>
Prior Approval	<p>The process where commissioners of a service prior approves individual referrals for specified treatments or interventions</p>
Commissioners	<p>This word used in the policy applies to the CCG or NHS England, dependent upon the treatment or care provided and the organisation responsible for its commissioning</p>
Service Development	<p>This relates to any aspect of healthcare which the CCG has not historically agreed to fund and which will require the commitment of additional and predictable recurrent funding in order to provide the treatment to a defined cohort of patients with a particular condition.</p>
NHS England	<p>NHS England refers to a national NHS organisation and, in the context of this document, to its role as a commissioner of services that are defined as specialised and which can only be provided effectively and efficiently where commissioned at a national or regional level</p>
Requesting Clinician	<p>A healthcare professional, usually a GP or hospital doctor, who is treating the individual patient and will be aware of the patient’s clinical circumstances, the pathway of care and the treatment options and who will have an understanding of the patient’s needs in relation to others with the same condition and at the same stage of progression.</p>

POLICY FOR INDIVIDUAL PATIENT TREATMENT

APPENDIX A

**Commissioning Principles and
Ethical Considerations**

NHS DORSET CLINICAL COMMISSIONING GROUP

COMMISSIONING PRINCIPLES AND ETHICAL CONSIDERATIONS

1. INTRODUCTION

1.1 Commissioning is the means by which commissioners secure best value for patients and taxpayers when purchasing healthcare. Best value is defined as:

- the best possible health outcomes including reduced health inequalities;
- the best possible healthcare;
- within the resources made available by the taxpayer.¹

1.2 Commissioners work within a cash limited system, receiving a fixed allocation from NHS England each year with which to commission the health care for which it is the responsible commissioner and that is required by its population. Given that demand and expectations are constantly increasing, the Commissioners will not be able to meet all the requests for funding that might be received within any one year. It is therefore inevitable that the Commissioner must prioritise and make choices as to which types of healthcare to commission.

1.3 This appendix sets out the principles the CCG will use to make these decisions so as to ensure that the process is consistent, transparent and fair. These principles have been developed in consultation with partners across the local health community, local authorities and local people.

1.4 The CCG recognises the following framework from the national Public Health Commissioning Network that identifies what is meant by low value procedures in the NHS:

- interventions where there is proof of ineffectiveness or harm, for example prostate cancer screening;
- interventions where there is no evidence of effectiveness, except when these interventions are being offered in the context of high quality research;
- interventions which the patient would not have accepted had they been given clear and unbiased information about the probabilities of benefit and harm, for example cataract operations for people with minimal visual loss, or knee replacement surgery for people with loss of function and levels of pain which are not severe, or over-prescribing for very elderly people with Alzheimer's disease.

¹ Department of Health, London, 2006. *Health reform in England: update and commissioning framework.*

- interventions that produce less value than another intervention which could be offered to a patient with the same condition, for example the inappropriate prescription of domiciliary oxygen for patients compared with the use of the same amount of resources to provide rehabilitation therapy for people with chronic obstructive pulmonary disease;
- interventions which produce less value than the same amount of resources would produce if used to provide a service to patients with another disease, for example cataract operations for people with minimal visual impairment when the same resources could be used to treat people with diabetic retinopathy or macular degeneration.

1.5 Where there are high value interventions identified based on sound evidence, the CCG recognises that these should be prioritised for rapid implementation. The main way in which higher value interventions are likely to be funded is by releasing resources from lower value interventions

2. COMMISSIONING PRINCIPLES

2.1 Commissioning decisions will be based on the following principles:

- **Health Outcome** - the aim of commissioning is to achieve the greatest possible improvement in health outcome for the local population, within the resources available. In deciding which interventions to commission, the CCG will prioritise those which produce the greatest benefits for patients and population in terms of both clinical improvement and improvement in quality of life;
- **Clinical Effectiveness** – the CCG will ensure that the care it commissions is based on sound evidence of effectiveness. This will usually come from sources such as the National Institute for Health and Clinical Excellence (NICE) well designed systematic reviews and meta-analyses or randomised controlled trials. Clinical effectiveness is defined as the extent to which specific clinical interventions, when deployed in the field for a particular patient or population, do what they are intended to do – that is, maintain or improve health and secure the greatest possible health gain from available resources. The CCG identifies a distinction between ‘evidence of lack of effectiveness’ and ‘lack of evidence of effectiveness’. The CCG will seek to avoid supporting the use of interventions for which evidence of clinical effectiveness is either absent, or too weak for reasonable conclusions to be reached. In addition to the strength of evidence for a particular interventions account is also taken of the likely magnitude of benefit and safety for patients as well as the number of people who can reasonably be expected to benefit from that intervention;

- **Cost Effectiveness and Affordability** – the CCG will, where available, take into account cost-effectiveness analyses (and other economic analyses where appropriate) of healthcare interventions to assess which yield the greatest benefits relative to the cost of providing them. Cost effectiveness measures the health benefits of a treatment or intervention in relation to the cost of that treatment and that comparison provides an expression of value for money. The cost of treatment is relevant because every activity has ‘opportunity costs’ which means that if resources are used in one way, they cannot be used again in another, so the CCG must seek to use all resources in the most appropriate way in order to do the most good;
- **Equity** – the CCG considers each individual within the local population to be of equal value, and as such, will commission and provide health care services based solely on clinical need, within the resources available. The CCG will not discriminate between individuals or groups on the basis of age, sex, sexuality, race, religion, lifestyle, occupation, social position, financial status, family status (including responsibility for dependants), intellectual/cognitive functioning or physical functioning;

It should be noted that the CCG have a responsibility to address health inequalities across the population, and in doing so, must acknowledge the proven links between social inequalities and inequalities in health, access to health care and health needs. Greater focus/higher priority may therefore be allocated to interventions addressing health needs in sub-groups of the population who currently have poorer than average health experience (e.g. higher morbidity or poorer rates of access to healthcare);

- **Access** - the CCG will ensure that the care it commissions is delivered as close to where patients live as possible, within quality standards. However, it is noted that some specialist services cannot be provided within a local setting and as such, the Commissioners may need to commission some services from distant providers in order to ensure quality.
- **Patient Choice** - the CCG respect the right of individuals to determine the course of their own lives, including the right to be fully involved in decisions concerning their health care. However, this has to be balanced against the CCG’s responsibility to ensure equitable and consistent access to appropriate quality healthcare for all the population. In commissioning healthcare, the CCG will:
 - * ensure that in assessing the effectiveness of health care, account is taken of the outcomes that are important to patients and the patient’s experience of the care;
 - * ensure, wherever possible, that within the care commissioned or provided there are a range of alternative options available, and that patients are given the necessary support to make an informed choice;

- * recognise that evidence of effectiveness usually relates to groups rather than individuals. The CCGs have therefore established an “individual case” mechanism to allow individuals to be considered as an exception to commissioning policy where evidence suggests that an intervention not routinely funded may be of particular benefit to them;
 - * the CCGs will not provide individual funding for care that is not routinely commissioned or provided solely on the basis that an individual, or a clinician involved in their care, desires it. This is in line with the CCGs responsibility to ensure consistent and equitable access to care for the whole population. It also reflects the commitment of the CCGs not to fund care for one individual which could not be openly offered to everyone within the local population, with equal clinical need;
 - * the CCG reserves the right to direct the patient for treatment at a designated service provider where a contract is placed.
- **Affordability** - the CCG may not be able to afford all interventions supported by evidence of clinical and cost-effectiveness within its available budgets. Where this is the case, further prioritisation will be undertaken based on criteria including national and local policies, clinical protocols, and strategies and local assessment of the health needs of the population, to ensure that available resources are not exceeded;
 - **Disinvestment** - as well as commissioning new services on the basis of the criteria above, the CCG will keep existing services under review to ensure that they continue to deliver clinical and cost effective services at affordable cost meet the principles in this policy. Where possible, the CCG will seek to divert resources from less effective services to more effective ones.
 - **Quality** - the CCG aims to commission high quality services as evidenced against national and international best practice. The quality of services will be measured where possible not only in terms of quality of outcomes and clinical effectiveness, but also in terms of:
 - * process and organisational efficiency;
 - * reducing dependency on health care;
 - * the quality of patient care; and
 - * the quality of the patient experience.

3. PROCESS FOR PRIORITISING INVESTMENT

- 3.1 The mechanism through which investment and disinvestment decisions are taken is the Annual Commissioning Plan. The CCG will not expect to make decisions outside this process and in particular will not expect to commit new resources in year to the introduction of new healthcare technologies (including new drugs and surgical procedures) since to do so risks ad hoc decision making and can destabilise previously identified priorities and agreed investment plans.
- 3.2 The Annual Commissioning Plan process will be the final mechanism used to determine those interventions that the CCG prioritises for future investment. The diagram below shows how benchmarking, needs and strategic priorities are linked to the efficiency and effectiveness of major pathways.
- 3.3 Where an individual patient treatment request is supported, the funding arrangements for the treatment will be in accordance with the relevant contractual and/or collaborative agreements.

4. ETHICAL CONSIDERATIONS

Autonomy

- 4.1 A patient's capacity to think and decide what they want for themselves should be respected, and the CCG recognises an obligation to help people to make such decisions by providing any and all information that they need. It is also recognised that their final decision should be respected, even if it is not what the CCG thinks is best for them. It is assumed that most patients will wish to try the proposed treatments that the CCG is being asked to fund (although this is not always the case). However, of itself, this does not mean that the CCG should fund such requests.
- 4.2 The CCG also needs to consider another aspect of autonomy, albeit not strictly the ethical aspect of this: that some treatments may enable a patient to maintain their independence and/or dignity (e.g. prolonging the time that they can continue to perform everyday living activities with relative independence) and it is considered that this is a desirable objective, although it will not necessarily take precedence over other considerations. The CCG would need to see good quality evidence that a proposed treatment might reasonably be expected to benefit the patient in this way and this must be balanced against the other principles or elements of this policy.

Beneficence

- 4.3 The CCG recognises an obligation of beneficence, which emphasises the moral importance of 'doing good' to others, entailing doing what is 'best' for the patient or group of people, and it is recognised that many treatments might be considered to do so, albeit sometimes only to a very limited extent or in special or poorly predictable circumstances (for example, it is not always possible to know that a patient is likely to respond to a treatment in the way that those in a research trial did, especially if there are aspects of their circumstances that might have led them to have been excluded from the trial

or trials put forward as evidence for the effectiveness of the proposed treatment).

- 4.4 The CCG also has an obligation to do good to others and its responsibility is for all people registered with CCG GP practices not just for an individual person. The CCG therefore has to balance the impact of doing good for one person with the effect that that would have on its ability to do good for others. In considering this, it has to be recognised that all decisions set precedents: if it is agreed to fund this request for one person then there is an obligation to fund all requests where the circumstances are similar and this would increase the cost and thus the opportunity cost which could impact on the ability to do good for others. Therefore, even where there may be some evidence that a particular treatment or clinical intervention might 'do good' for an individual, this must be balanced against the other components of the principles framework.

Non-maleficance

- 4.5 It is recognised that the CCG has a duty of non-maleficance, which requires that it should seek not to harm people. However, it is important to recognise a distinction between a duty not to harm someone (which implies actively doing something that may harm them) – which is recognised as something that the CCG should not do – and not acting to prevent possible harm. It is considered that there is an important difference here because it is not possible for the CCG to prevent harm coming to everybody, and therefore there is not considered to be an obligation to fund an intervention just because it might reduce the risk of some sort of harm coming to an individual.
- 4.6 The CCG also needs to consider whether the likely risks of a proposed treatment are balanced by its likely benefits. It is also recognised that few, if any, treatments are likely to be without side effects or adverse reactions in all patients in all circumstances. Further, account needs to be taken of whether not funding a treatment might do the patient harm. However, there is also a duty not to harm others and funding a treatment inappropriately could do this, albeit indirectly, by denying them access to treatment that could otherwise do them greater good.

Distributive Justice

- 4.7 The principle of distributive justice emphasises two points: patients in similar situations should normally have access to similar health care; and when determining what level of health care should be available for one set of patients, account must also be taken of the effect of such a use of resources on other patients. In other words, the CCG should try to distribute limited resources (such as time, money, intensive care beds) fairly, and based on need.
- 4.8 Need usually exceeds the resources available. The CCG therefore cannot always enable every patient to have what some might think of as the 'best possible' care. This concept conflicts with the principles of some clinicians who, understandably, take the view that every patient should be given the 'best possible' care and that every therapeutic option should be tried irrespective of cost. However, if the 'best possible' care is provided for everyone then at some time during the year there will be nothing left for others: some patients will be given 'everything' and others 'nothing'. It is considered that such an approach would be inappropriate and resources should be shared resources 'fairly', this usually meaning (i) giving resources preferentially to those who are in greatest need and who can benefit the most from them, and (ii) settling for what is adequate and not necessarily what may be the 'absolute best'. The CCG believes that this approach is consistent with the opinion expressed by Sir Thomas Bingham in his judgment in the 'Child B' case.
- 4.9 The table below summarises the range of information that is requested and how this helps inform decision making based on the above principles and ethical considerations.

Item of information	How it helps the decision maker/ making
The treatment	
Information about the disease, its course of development and its management	This provides important background information and indicates the potential impact of the treatment
Information about the new treatment/existing treatment for a new condition and how it is thought to work	This helps inform the validity and value of the outcome measures used in trials. This is particularly important when proxy measures, such as biological changes, have been used, as they may not translate into actual benefit for the patient.
The number of people in the local population who are likely to have been treated now and in the future.	This is needed to estimate the benefit and cost impact.
Information about key aspects of delivering the new treatment/existing treatment for a new condition	This provides information related to prioritisation (for example related service costs that have to be taken into account), feasibility of introducing the new service (for example, manpower requirements and potential shortages), policy making (for example, the need to impose controls on a treatment's use) and planning implementation.
The evidence	
The health outcomes found in trials	This indicates the health gain that might be associated with the treatment
The quality and nature of the evidence	<p>This indicates the level of confidence with which the treatment will provide the outcomes stated.</p> <p>See also the table below showing the grading of evidence and how this will be weighted when considering evidence</p>
Identification of sub-groups of patients that might gain more or less	Provides some policy options

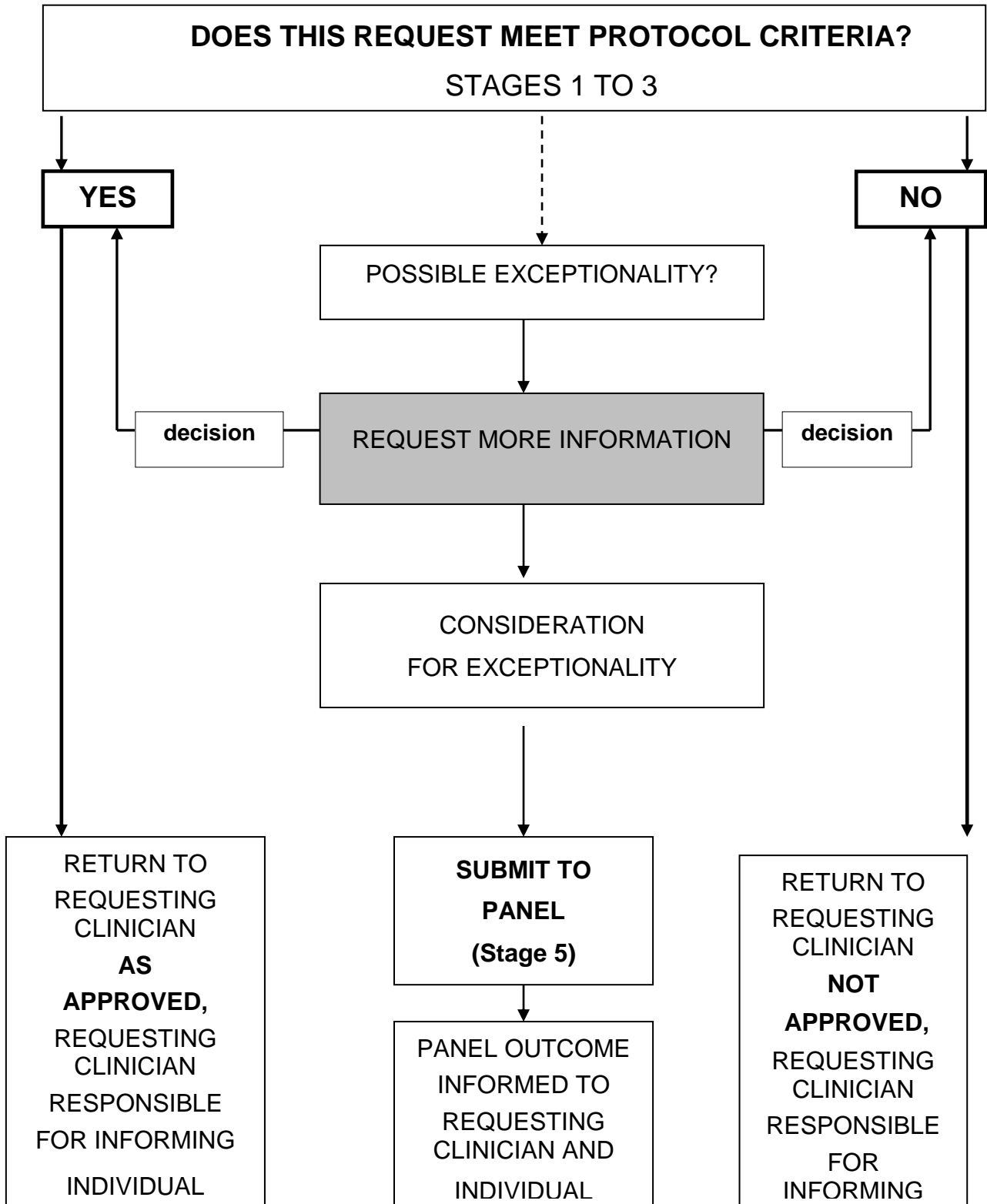
Item of information	How it helps the decision maker/ making
benefit than other patients	
<p>The NNT (number needed to treat) For example, if the NNT is 20 then 20 patients will need to be treated before one patient will gain benefit. Included in the evidence will be the results from specific well conducted cost analyses where available or comparative costs and benefits can be compared to current practice.</p>	<p>When combined with other information, this gives an indication of value for money</p>
The costs	
<p>The total cost of providing the new treatment</p>	<p>This is needed to assess affordability and the size of opportunity costs</p>
<p>The cost of different policy options</p>	<p>This provides the opportunity cost and affordability of policy options. This is particularly useful if it is not possible to provide access to all patients</p>
Other	
<p>Identification of new ethical or policy principles</p>	<p>This indicates whether the Commissioner needs to initiate a piece of work to address wider policy issues</p>
<p>How does this treatment support the delivery of agreed priorities for specialised commissioning or the service area specifically</p>	<p>This, together with other information, helps shape the priority of the treatment within a programme area, and in the context of commissioned health services generally.</p>

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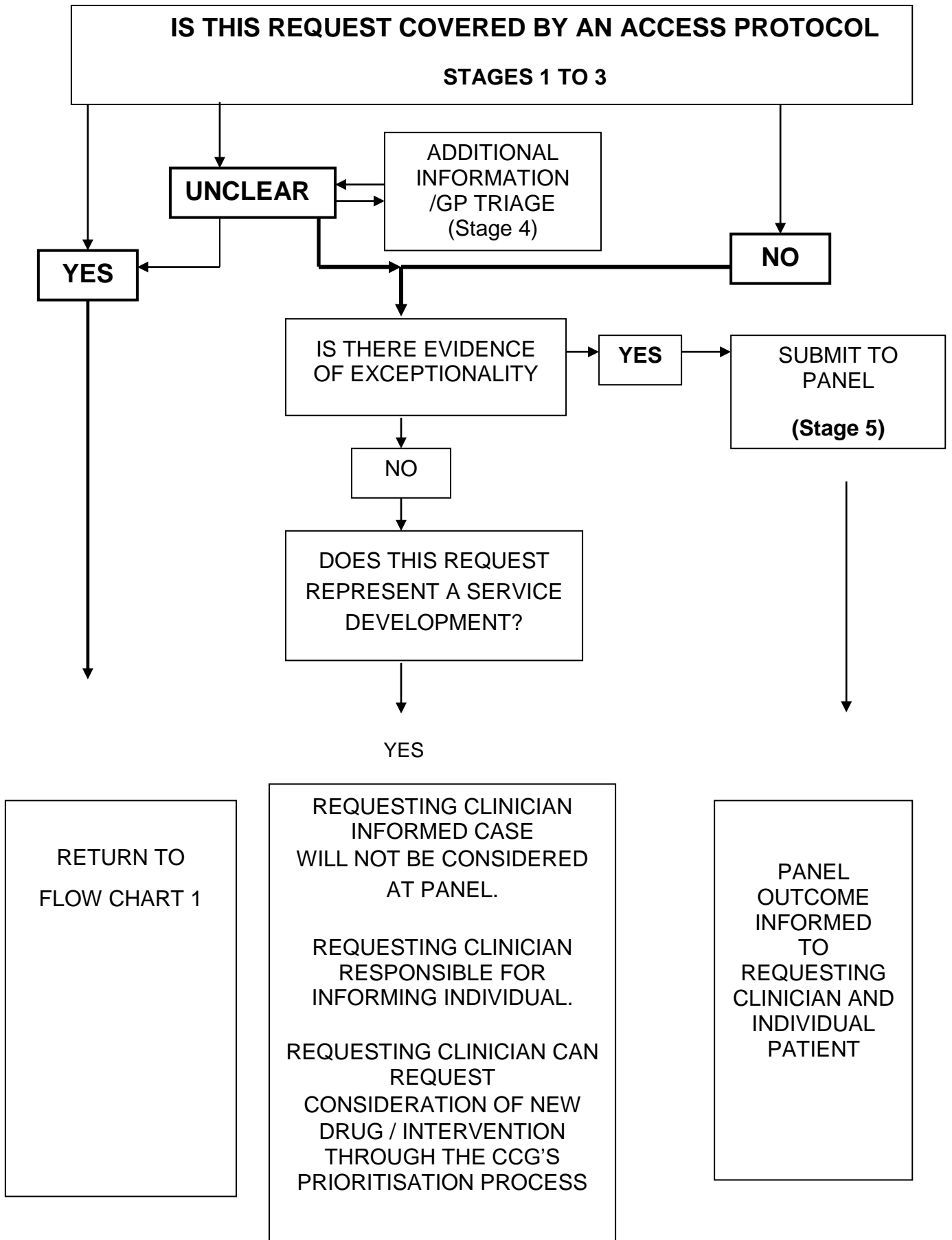
APPENDIX B

**Flow Charts of the Decision Making Process
for Individual Treatment Requests**

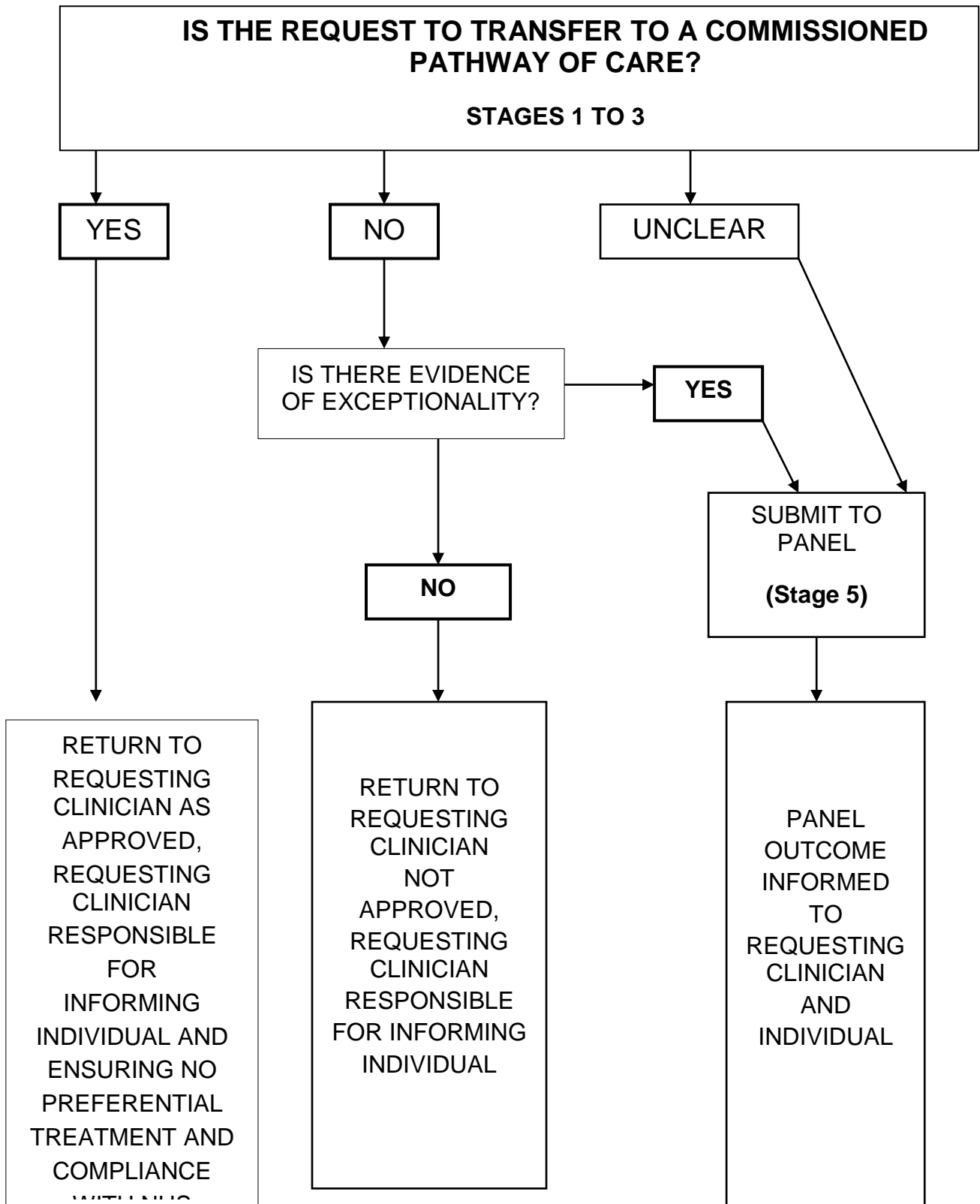
Flow Chart 1: Decision Making Process for Prior Approval with Criteria Based Access, Where Protocols Exist (Including Services Not Routinely Commissioned)



Flow Chart 2: Individual Funding Request for which there are No Access Protocols or Where the Clinician Feels there are Exceptional Individual Circumstances



Flow Chart 3: Individual Funding Requests for NHS Funding For a Treatment Pathway Commenced Within the Private Sector



POLICY FOR INDIVIDUAL PATIENT TREATMENT

APPENDIX C

**Exceptionality:
Social and Psychological Circumstances**

EXCEPTIONALITY: SOCIAL AND PSYCHOLOGICAL CIRCUMSTANCES

The case examples in the boxes below give the rationale for decisions not to have social and psychological circumstances as a basis for consideration of exceptionality.

Case 1

Implications Of Including Social Circumstances In Decision Making

The Commissioner (in this example, NHS England) has decided to not fund treatment X, a newly licensed treatment for recurrent cancer. In reaching its decision, the Commissioner considered that the 10 week median survival advantage of treatment X over the standard treatment was not cost effective. This was based on quality of life measures during that 10 week period and the cost of the drug.

The individual is 67 and has had recurrence of cancer. He is the main carer for his disabled son aged 39. He points out that although the median survival is 10 weeks, survival of 45 weeks has been recorded in a very small number of patients. He argues that because it is impossible to predict which patients will attain this longer survival he should have access to treatment X because the costs to society of providing care for his son outweigh the costs of the drug. He also believes that even if he was only able to attain an additional 10 week survival, which would enable him to make better arrangements for his son after his death.

If agreement were given to fund treatment X for the individual the Commissioner acknowledges the value of the care he provides for his son. It would then be difficult to argue that this care is of more worth than the care given to an elderly relative enabling that person to continue to live at home or the pivotal role played by the parent of a young family. Thus, the Commissioner would need to adopt a protocol to fund treatment X in all those with a caring responsibility for a vulnerable adult or children. This would then need to be reflected in the other prioritisation policy documents of the commissioner.

If a decision to support treatment X were made it would imply that the usual considerations of clinical and cost effectiveness do not apply to those with such a caring role and so access to medicines and treatments should be judged on a different basis for this group.

Case 2 illustrates the implications of funding a service not routinely commissioned because of psychological distress

Case 2

Implications of Including Psychological Factors in Decision Making

Mrs X has lost approximately 11 stone in weight. She is very conscious of the large pendulous folds of excess skin especially on her upper arms and finds it impossible to expose them in public. She is the lone parent of young children and is anxious that they adopt a healthy lifestyle, however, she is so embarrassed by her arms that she cannot accompany the children in exercise such as swimming, parks, playgrounds and other leisure activities. She is also limited in the exercise she can take to maintain her new weight because she is aware of the movement of the skin folds. She is depressed because of the restrictions this places on her choice of clothes and regularly cries before getting ready to go out. She points out that she has saved the health service significant amounts of money by not accessing the bariatric surgery services and asks that the money that could have been spent on this should be used to help her now.

If the commissioner chooses to fund this lady when others seeking cosmetic surgery are not funded, it would need to be sure that the functional impairment described is greater than that found in both a general population but also that the level of distress is significantly different to the distress of others for whom cosmetic surgery is not available.

If the commissioner feels that the level of distress is proven then the cosmetic surgery protocol should be amended to allow for the treatment of people who exhibit this level of functional disturbance on an objective scoring system. This criterion should then apply to all cosmetic procedures that have restricted access. The commissioner would need to consider whether other protocols should be amended to enable treatment of people who are distressed by lack of access to services.

Case 3 illustrates the implications of funding a service not routinely commissioned based on social factors

Case 3

Implications of Funding a Service Not Routinely Commissioned Based on Social Factors

Mr X is a 40 year old man who is asking the commissioner to fund reversal of his vasectomy. Eighteen months ago his children aged 11 and 8 were killed in a car accident. He and his wife, aged 36 would like to try to have another child or children. He cannot recall being told that NHS funding would not be available for reversal at the time of the original procedure simply that it was technically possible but that results were variable. There is no documentation available from the original procedure

Choosing to fund Mr X should prompt the commissioner to amend its protocol on reversal of vasectomy to include a provision for funding the procedure in the case of death of children. The commissioner would need to be clear on whether it would fund reversal only when all living children had died or in circumstance in which a child/children survived. It would also be appropriate to consider the position of a family in which a child is diagnosed with a terminal disease.

POLICY FOR INDIVIDUAL PATIENT TREATMENT

APPENDIX D
REFERENCE MATERIAL

This guidance has been developed with the assistance of the following:

North West PCT Alliance Medicines and Treatments Group – Principles and Exceptionality

North Central London Policy for 'low priority' treatments written by Dr Andrew Burnett February 2010

Department of Health 2004 Code of Conduct for Private Practice

Department of Health 2009 NHS Constitution

Department of Health 2009. Guidance on NHS patients who wish to pay for additional private care

Promoting Clinical Effectiveness: a framework for action throughout the NHS. Department of Health 1996

Sir Thomas Bingham MR in R v Cambridge Health Authority ex p B (1995)

Priority setting: managing new treatments. Institute for Innovation and Improvement 2008

Professor C Newdick: Who Should We Treat? Rights, Rationing and Resources in the NHS

Imperial College London, Business School: The doctor-patient relationship under general conditions of uncertainty

BMA: Guidance for consultants prepared by the Central Consultants and Specialists Committee in conjunction with Ethics department of the General Practitioners Committee, November 2006

NHS England. Service Specifications and Clinical Policies for Specialised Services

NHS England: Who pays? Determining responsibility for payments to providers, August 2013.

NHS England: Manual of services 2016/2017;

NHS England: Interim Standard Operating Procedure: The Management of Individual Funding Requests, February 2016;

NHS England: Commissioning Policy: Interim Policy. Individual Funding Requests, April 2013.

NHS South Commissioning Support Unit: Policy and Procedure for Restricted Treatments and Procedures concerning Clinical Commissioning Groups. September 2016

POLICY HISTORY AND VERSION CONTROL SHEET:

Policy Reference: 01 POLICY FOR INDIVIDUAL PATIENT TREATMENTS

Version: 4

Approval		Distribution		
	Clinical Commissioning Committee	Intranet	Website	other
Date	16 August 2017	Yes	Yes	

Document History				
Date of Issue	Version No.	Next Review Date	Date Approved	Nature of Change
July 2013	1	July 2014	25 September 2013	New Policy. Adopts principles and approaches outlined within the NHS Bournemouth and Poole and NHS Dorset Policy for Individual Patient Treatment. Updated to reflect arrangements post April 2013 including transfer of commissioning responsibility to NHS England, where appropriate.
September 2014	2	September 2016	15 October 2014 (By Clinical Commissioning Committee)	Policy revised to provide further clarification on clinical exceptionalism, the Individual Patient Treatment Panel process and on dealing with requests which relate to service developments for groups of patients with similar clinical circumstances.

August 2016	3	September 2017	October 2016 (By Clinical Commissioning Committee)	Policy revised to reflect changes to the composition of the IPT Panel and the quorate requirement. Minor amendments made to reflect agreed operational changes.
August 2017	4	September 2019	August 2017 (By Clinical Commissioning Committee)	Policy revised following review of content and operational robustness by the Individual Patient Treatment Panel