NHS
Bath and North East Somerset, Swindon and Wiltshire
Integrated Care Board

Exceptional Funding Requests, Prior Approval & Criteria Based Access Policy

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Implementation Plan:	
Development and Consultation	BSW Medical Director BSW Director of Nursing & Quality Consultant Public health
Dissemination	The policy is available to all ICB staff, independent contractors, and members of the public via the main ICB website and ICB clinical policies website. Information about the policy is provided by email notification to GP Practices and secondary care commissioners and is also available as documentation associated with the main provider contracts.
Training	In-house training provided to all members of the team
Monitoring	Key data to be reported twice yearly to executive team. Internal and external audit.
Review	Six monthly as part of twice-yearly review. Rolling programme of review every 2 years.
Equality, Diversity & Privacy	Equality Impact Assessment - Privacy Impact Assessment
Associated Documents	The Exceptional Funding Request form Standard Operating Procedure – Exceptional Funding Request Standard Operating Procedure – Prior Approvals Terms Of Reference – Exceptional Funding Request Appeal End of year report
Documents Informing Papers	• NHS Constitution 2012 • NHS Commissioning Board (2013) *Commissioning Policy (ref: NHSCB/CP/06) Experimental and unproven treatments.* • NHS Commissioning Board (2013) *Interim Commissioning Policy (ref: NHSCB/cp/03): Exceptional Funding Requests* • Soest, Tilmann M. von; Kvalem, I. Lundin; W ichstrøm, L. (2012) *Predictors of cosmetic surgery and its effects on psychological factors and mental health: a population-based follow-up study among Norwegian females*. Psychological Medicine, 42(3):617-626

Table of Contents

1.0 Introduction

1.1 This policy attempts to define the collective responsibilities of BSW ICB and the activities of the Exceptional Funding Request (EFR) and Prior Approval (PA) teams.

1.2 Integrated Care Boards (ICBs) commission local NHS health services, excluding primary care services and NHS England.

NHS England commissions highly specialised health services and core General Practitioner services, both organisations use national and local policies to prioritise treatments based on available resources and competing demands. This policy relates solely to services commissioned by (BSW ICB). Local policies are available on our website.

1.3 The NHS exists to serve the needs of all its patients, but it also has a statutory duty to financially remain within its allocated budget. The BSW ICB has a responsibility to provide health benefits for the whole of its population, whilst commissioning appropriate care to meet the clinical needs of each individual patient.

1.4 There will always need to be a process for considering NHS funding for a patient based on either individual clinical circumstances or exceptional clinical circumstances.

BSW ICB has an Exceptional funding request team to perform this function. Clinicians are entitled to make a request to the ICB for treatment to be funded on the grounds of individuality where a patient requires healthcare which falls outside of the range of services and treatments the ICB has agreed to commission.

The EFR team also considers requests to fund patients with more common conditions for which the ICB has commissioned care pathways with access to treatment via threshold criteria, these are commonly known as Prior Approvals (PA).

1.5 The NHS Constitution (March 2012) informs patients they have the right to expect local decisions on funding of drug and non-drug related treatments to be made rationally, following appropriate consideration of the evidence provided within the application. It states: “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.”

1.6 To ensure that good quality services are available to those patients with the greatest need, it is necessary to restrict the funding of procedures which have limited or no clinical benefit. These procedures may also be referred to as low priority treatments. Therefore, BSW ICB; has Prior Approval systems in place which ensure that access to certain elective procedures is subject to threshold criteria. This will mean that some procedures will only be available for patients who meet a defined set of criteria.

1.7 The prior approvals process is in place to assess applications for such procedures against set threshold criteria. This ensures optimal clinical effectiveness and an appropriate clinical pathway for the patient.

1.8 BSW ICB will not make payments retrospectively. Funding must be sought prior to treatment provision; any treatments conducted without prior funding approval will not be funded by (BSW ICB).

2.0 Equality and Health Inequalities

2.1 Promoting equality and addressing health inequalities are at the heart of NHS values.

The ICB aims to design and implement services, policies and measures that meet the diverse needs of our service, population, and workforce, ensuring that none are placed at a disadvantage over others. It considers the Human Rights Act 1998 and promotes equal opportunities for all. This policy has been assessed to ensure that no-one receives less favourable treatment on grounds of their gender, sexual orientation, marital status, race, religion, age, ethnic origin, nationality, or disability.

3.0 The National Institute for Health and Clinical Excellence (NICE)

NICE is an independent organization responsible for producing evidence-based guidance and advice for health, public health, and social care practitioners. They develop quality standards and performance metrics for those providing and commissioning health, public health, and social care services. NICE also provide a range of information services for commissioners, practitioners, and managers across the spectrum of health and social care.

4.0 Purpose

4.1 Requests for non-commissioned care usually come under Exceptional Funding Requests and this policy is designed to provide assurance that the ICB process is compatible with the requirements referred to in the NHS Constitution.

4.2 This policy will ensure a clear and transparent process is in place for decision making and provide reassurance to patients and clinicians that decisions are made in a:

- Fair
- Open
- Equitable
- Consistent manner

4.3 Clinical policies are subject to change at any time. New patient cases will be assessed against current policy without exception. Those patients who may have been assessed against a historical policy but declined or deferred the supported treatment, procedure, or management plan at that time, will be assessed against the new policy on re-application.

5.0 Definitions

5.1 Criteria Based Access (CBA)

CBA applies to treatments that are considered appropriate for patients in certain circumstances provided that specific pre-determined and evidence-based access criteria have been met. Unlike PA procedures, for CBA procedures a reviewing clinician should demonstrate that a patient meets CBA criteria, the patient can then proceed for treatment without any requirement for BSW ICB funding to be secured. Secondary care providers must ensure that the patient meets criteria and must evidence this within the patient’s medical records for future audit purposes.

5.2 Prior Approval (PA)

PA Is a process in which clinicians demonstrate how a patient meets a set of threshold criteria prior to referral to secondary care for treatment? If a patient has already been seen by a Secondary care consultant and a restricted procedure is deemed necessary, prior to listing any patient for treatment the consultant must apply for prior approval funding and ensure funding is in place before treatment is conducted

Prior Approval means that a General Practitioner and/or provider must seek the agreement of the responsible commissioner to fund a treatment for an individual for an intervention before that treatment is conducted. Policies to this effect may be found on the BSW ICB website.

The Prior Approval process then compares requests for elective procedures against a set of threshold criteria. There may be times when an individual patient may fall outside of the PA threshold criteria, clinicians may ask for a reconsideration of the decision or by demonstrating how despite this the patient is clinically exceptional. In these cases, the request will then be considered via the Exceptional Funding Request process.

5.3 Exceptional Funding Request (EFR)

There can be no exhaustive description of the situations which are likely to fall within the definition of *exceptional clinical circumstances*. The onus is on the clinician making the request to set out the grounds for clinical exceptionality clearly for the EFR Team.

Exceptional" in EFR terms means that a person to whom the general rule should not apply. This implies that there is likely to be something about their clinical situation which was not considered when formulating the general rule or established care pathway. Very few patients have clinical circumstances which are genuinely exceptional, clinical reasons must be provided to demonstrate and justify how one patient is likely to derive significantly more benefit than any other patient with the same condition. The EFR Monthly Panel must be satisfied that the clinician has demonstrated clinical exceptionality and therefore general policies should not be applied. To clarify, EFR Committee members must consider whether it is fair to fund one individual's treatment where the same treatment is not available to others with the same condition.

The fact that a patient has failed to respond to or is unable to be provided with, all treatment options available for a particular condition (either because of a co-morbidity or because the patient cannot tolerate the side effects of the usual treatment) is unlikely, on its own, to be sufficient to demonstrate exceptional clinical circumstances.

Many conditions are progressive and thus inevitably there will be more severe form of the condition – severity of a patient's condition does not in itself usually indicate exceptionality.

To support an Exceptional Funding Request based on failure to respond to standard care, the EFR Monthly Panel would normally need to be satisfied that the patient's inability to respond to or be provided with, the usual treatment was a genuinely exceptional circumstance, which lies outside the natural history of the condition.

5.4 NHS ENGLAND COMMISSIONING POLICY

Exceptionality status (what makes the individual sufficiently different from the usual cohort of patients) Exceptionality is central to consideration of individual requests for funding.

For funding to be agreed there must be unusual or unique clinical factors about the patient that suggest that they are:

- Significantly different to the general population of patients with the condition in question

And are

- Likely to gain significantly more benefit from the intervention than might be expected from the average patient with the condition.

However:

- The fact that a treatment is likely to be efficacious for a patient is not a basis for an exception.
- If a patient's clinical condition matches the 'accepted indications' for a treatment that is not funded, their circumstances are not, by definition, exceptional.
- Social value judgements (the 'worth' of patients) are not relevant to the consideration of exceptional status but there may rarely be exceptional circumstances where benefits may go beyond the patient (e.g., as a caregiver) in respect of social or health related benefits for others.

BSW ICB adopted this definition, and it has been incorporated within response letters to clearly explain how a request has not been considered as exceptional.

5.5 Cohort definition

A cohort of similar individuals for the purposes of this policy has been defined as the number of requests received or likely to be received per year which will require consideration of a commissioning policy. In these circumstances the EFR process to fund may only be considered if the individual is clinically exceptional to the cohort.

The number of individuals for whom the treatment will be requested is five or more individuals per year from the population served by BSW ICB.

Should a cohort be identified by the EFR Team this will be treated as a service development and will require consideration as to whether a commissioning policy should be initiated? Any emerging cohorts will be raised and discussed at the BSW Clinical Policy Working Group (CPWG) and highlighted to the ICB directors via quarterly reports for consideration.

6.0 Scope

6.1 This Policy covers the following:

All Exceptional Funding Requests (EFR) and Prior Approval (PA) requests for adults and children which the BSW Integrated Care board have responsibility. This excludes all treatments that fall under the responsibility of NHS England.

NHS England sets out the services it commissions and the services: https://www.england.nhs.uk/publication/manual-for-prescribed-specialised-services/

- The arrangements to consider funding requests that do not fall within existing contracts or are considered low priority.
- The processes in place to respond to these requests and appeals.
- The structure and function of the Exceptional Funding Team

6.2 This policy applies to any patient for whom BSW ICB are the Responsible Commissioners and patients who are registered with a BSW ICB General Practice. The BSW ICB is responsible for commissioning services to meet the health needs of its population and is required to commission services which are evidence based, clinically and cost effective, improve health outcomes, and reduce health inequalities whilst representing value for money.

7.0 Roles and Responsibilities

7.1 BSW Quality, and Performance Assurance Committee (QPAC) – Is responsible for approving this policy.

7.2 Chief Executive – Accountable Officer - Has overriding accountability for the actions of the EFR team and any related Committees.

7.3 Executive Team & QPAC - Have oversight of the EFR twice-yearly report and will escalate any serious risks and/or concerns to the Governing Body.

7.4 Head of Medicines Optimisation, Exceptions and Prior approvals has delegated responsibility to ensure this policy is applied and adhered to and will aim to produce a twice-yearly report on activity and adherence.

7.5 The EFR Committee - The EFR committee has delegated authority from BSW ICB to make decisions in respect of funding for individual cases. Accountability for those decisions rests with the representatives of the committee. Decisions will usually be made based on consensus.

The EFR committee will report any significant issues and risks arising to QPAC via the twice-yearly report. The EFR Committee will highlight any cohorts to the relevant commissioner to ensure services are reviewed in line with BSW ICB priorities.

7.6 Public Health Consultant – Supply support and advice to the EFR committee. Their role is to give public health advice in relation to clinical appropriateness, clinical effectiveness, and cost effectiveness of a treatment. However, a Public Health Consultant does not need to be present for a meeting to be quorate.

7.7 The PA/EFR team will be responsible for logging and monitoring all PA & EFR applications. Team-members will co-ordinate all responses within set time frames and communicate with clinicians regarding processes and decisions. The PA/EFR team will co-ordinate and prepare cases for pre-screening meetings, the monthly EFR Committee meeting and to prepare cases for PA decisions.

8.0 THE EFR PROCESS

8.1 The EFR process only considers clinical information. Although initially it may seem reasonable to fund treatments based on a moral or compassionate

view, or considering an individual's situation, background, occupation, or current family circumstances. However, this reasoning would then be based on a judgement of 'worthiness' for treatment. As a central principle, the NHS does not make judgements about the worth of any individual and seeks to treat everyone fairly and equitably. Consideration of these non-clinical factors would introduce the concept of 'worth' into clinical decision making. It is a core value that NHS care is available – or unavailable – equally to all. Whilst everyone's individual circumstances are unique, it is likely that the same or similar arguments could be made for all or many patients who cannot routinely access the care requests.

8.2 EFR does not fund equipment or on-going maintenance or placements in long term care. Personal Health Budget's and voucher schemes are available through the Continuing Health Care Team (CHC team). Any requests for funding of Neurology related treatments are discussed with CHC prior to processing as an EFR.

8.3 The BSW ICB wants the best care available for our patients. It is important that when a patient reaches a stage in their treatment pathway that requires a specialist intervention, it is expected that they will be referred to officially designated, accredited Centre to ensure a high quality of care. The ICB will not support specialised treatment at un-designated, non-accredited Centre's.

8.4 The EFR Monthly Committee shall have a broad discretion to determine whether the proposed treatment is a justifiable expenditure of ICB resources. The EFR Monthly Committee is however required to bear in mind that the resources requested to support the individual will reduce the availability of resources for other investments. The EFR Monthly Committee may make such approval contingent on the fulfilment of such conditions as it considers fit.

8.5 Very occasionally an EFR presents a new issue which needs a substantial piece of work before the ICB can reach a conclusion upon its position. This may include a wider consultation with other ICBs/GPs/Consultants. When this occurs the EFR Monthly Committee may defer a decision on an individual case until that work has been completed.

8.6 The EFR Monthly Committee shall take care to avoid adopting the approach described as the "the rule of rescue." The fact that an individual has exhausted all NHS treatment options available for a particular condition is unlikely to be sufficient to demonstrate exceptional circumstances. Should severity be cited by the requesting clinician as part of the argument for exceptionality, the application should make clear:

- Whether there is evidence that the individual's presentation lies outside the normal spectrum for that condition. Preferably a recognised scoring or classification system should be used to describe the individual's condition.
- Whether there is evidence that the individual has progressed to a severe form of the condition more rapidly than the range of progression that is documented and usually observed within the natural history of the condition.
- How the individual is expected to benefit from the treatment sought and in what quantifiable way.
- Whether a second opinion has been sought

8.7 The EFR process is clinician-led, and applications must be made by a clinician. Deliberations at the EFR Monthly Committee will be based on evidence of individual clinical exceptionality and will not consider issues relating to social or personal circumstances. It is therefore not appropriate for individuals to attend the EFR Monthly Committee meeting and Commissioners are not legally bound to invite them. However, individuals may submit a supporting statement that is limited to clinical issues i.e., what effect the condition has on the individual's activities of daily living.

8.8 The EFR team/monthly Committee shall routinely screen EFR to see whether there is a need for a service development. The key question used to screen out service development will be: are there more likely to be other similar individuals in the area? If there is evidence that this individual is representative of other similar people and forms a cohort, the request will be considered on an individual basis as per the clinical evidence, but the provider will be requested to follow normal procedures for introducing new services by the submitting a fully costed business case.

8.9 On occasions the EFR team may receive rare requests for treatments, drugs, or services where the responsible commissioner is unclear, or where there is no existing commissioned service. Such requests will be considered on an individual basis until commissioning responsibility can be ascertained. Should a cohort be identified the Exceptional Funding Committee will treat this as a service development requiring consideration of a commissioning policy. Any emerging cohorts will be highlighted to the ICB Executive team. The EFR Committee will consider the people who are part of the cohort on their individual clinical circumstances in the interim or until a commissioning decision and/or policy has been developed. Should the person have an individual clinical circumstance which prevents them from utilising other existing commissioned services and the intervention is clinically appropriate, funding may be approved by the EFR team or on behalf of the ICB.

8.10 Exceptional requests cannot be used as a means of 'creeping implementation'
for recent technologies, services, or policies. Consideration therefore needs to be given as to the likelihood of other patients having the same clinical need who
could also benefit from the proposed treatment. If there are or are likely to be other patients then, consideration must be given as to if the request is for a service development and not an individual application.

8.11 Where a decision may affect other patients, the application should be considered as a service development and should not be considered through the EFR process. The Committee shall routinely screen Exceptional Funding Requests to see whether they represent a service development. The key question used to screen out as a service development will be 'are there likely to be other similar patients in the ICB?' If there is evidence that this patient is representative of other similar patients and forms a cohort, the request will be considered on an individual basis as per the clinical evidence, but the provider will be requested to follow normal procedures for introducing new services by the submission of a fully costed business case.

8.12 If a medication/drug request meets routine commissioning criteria this will be sent to the Medicines Optimisation Team for processing. Medication/drug

requests will be considered in line with this policy on the grounds of clinical exceptionality and the same principles will be applied. The EFR Lead will work collaboratively with the senior pharmaceutical leads in responding to requests and draw upon their knowledge and expertise.

8.13 Psychological issues are not considered as grounds for exceptionality. This is line with BSW guidance based on reviews of evidence.

8.14 Information that is immaterial to the decision, including information about the social, economic, or personal circumstances of the patient which does not have a direct connection to the patient's clinical circumstances, shall not be considered.

9.0 EFRs for 'experimental treatments'

9.1 A treatment may be considered experimental where any of these points apply:

- The treatment is still undergoing clinical trials and/or is a drug yet to undergo a phase III clinical trial for the indication in question.
- The treatment does not have marketing approval from the relevant government body for the indication in question.
- The treatment does not conform to a usual clinical practice in the relevant field.
- The treatment is being used in a way other than that previously studied or that for which it has been granted approval by the relevant government body.
- The treatment is rarely used, novel or unknown and there is a lack of authoritative evidence of safety and efficacy.
- The treatment has a NICE guidance which states the procedure should only be used with special arrangements for audit/research.

9.2 The experimental basis of the treatment will become relevant when the EFR Monthly Committee assesses the effectiveness of the treatment for the individual and then primarily when the EFR Monthly Committee considers the degree of confidence it has on the safety and efficacy of the treatment for the person and whether it would be an effective use of the ICB resources.

9.3 Where evidence about the treatment is not yet available for public scrutiny or there is limited evidence for one of the reasons set out above, the EFR Monthly Committee may have limited confidence in the evidence that has been presented.

9.4 The EFR Monthly Committee will not fund treatment in response to an EFR if it considers that it would be more appropriate for the treatment to be the subject of research trials. Primary research into novel treatments should be progressed through the usual research funding routes and will not be funded through this EFR policy.

9.5 EFR funding for cases following Clinical Trials

A few individuals are provided with treatments or devices through clinical trials which are not routinely commissioned by the BSW ICB. This includes drugs, devices and treatments which are either still in development or are established as a treatment, however, BSW ICB has been unable to secure resources to fund the treatments.

There are three types of Trials:

- **Commercially Funded** - To assess the efficacy of treatments they are developing; commercial companies will often sponsor trials on individuals offering free access to treatment for a limited period. Responsibility for providing on-going access to these treatments lie with those individuals or parties that have initiated and sponsored either the clinical trial or drug company sponsored treatment.
- **Non-commercially funded** - Similarly to commercially funded trials, organisations such as charities will on occasion fund clinical trials to assess the efficacy of treatments by offering free access to the treatment for a limited time.
- **Self-funded individuals**, or their family and friends, will on occasion fund trials with treatments or devices to assess whether they will benefit from the treatment. This is often for treatments which are established and have been previously considered by the Commissioner, however, they have been unable to identify resources to routinely commission treatment for a cohort of people.

9.6 Informed Consent Prior to Commencing a Trial

It is the responsibility of the organization participating in the trial and the individual's clinician to ensure that people are fully informed about the circumstances in which funding for a trial is being provided. That is:

- Treatment will not be continued routinely by BSW ICB following the end of the trial.
- How long the funding will be provided?
- What will happen when the trial treatment is withdrawn?

The individual should agree to their management plan on cessation of treatment. Individuals should be made aware of this commissioning policy in advance of treatment starting and their consent should be documented.

It is also the responsibility of the organization participating in the trial and the individual's clinician to ensure that such arrangements are explicitly approved by the relevant governance body of the provider trust (QPAC).

It is the responsibility of the pharmaceutical/medical device company, the organization conducting the trial (usually a provider trust), and the individual's clinician, to ensure that people are fully informed that funding for the continuation of treatment delivered as part of a clinical trial, that has been sponsored by a pharmaceutical or medical devices company, will not be provided unless it is agreed in writing by BSW ICB and the sponsoring pharmaceutical/medical devices company at the outset of the trial.

This includes drugs, devices and treatments which are either still in development or are established as a treatment, but BSW ICB has been unable to secure resources to fund the treatments.

9.7 Requests for "pick-up funding"

Commonly the timing of requests for funding for individuals who have been in clinical trials is around the time that a license for the drug/indication is granted. There is an assumption by some clinicians conducting clinical trials that once the drug is licensed then BSW ICB should assume responsibility for funding the drug. **This is incorrect and will not be funded.**

The BSW ICB have a responsibility to consider and prioritise new treatments being made available but this in no way places any obligation on the commissioner to fund individuals already on treatment funded by industry by whatever route.

BSW ICB will not routinely make funding available to enable continuing access to treatments provided under clinical trials. This includes areas where it can be shown that the individual has benefitted from the treatment provided during a trial. Responsibility for providing on-going access to a treatment lies with those individuals or parties that have initiated and sponsored either the clinical trial or sponsored treatment.

The BSW ICB will not expect to provide funding for individuals to continue medication/treatment commenced as part of a clinical trial. In line with the Medicines for Human Use (Clinical Trials) Regulations 2004 and the Declaration of Helsinki, the responsibility lies with those conducting the trial to ensure a clear exit strategy from a trial AND that those benefiting from treatments provided within the trial setting will have ongoing access to those treatments. The initiators of the trial (provider trusts and drug companies) have a moral obligation to continue funding individuals benefiting from treatment until such time as BSW ICB agree to fund through the annual commissioning round. Where the treatment is not prioritised through the annual commissioning round, the responsibility remains with the trial initiators. The Research Ethics Committee should require this assurance as part of the approval for the trial.
Requests for the routine pick-up of funding will therefore be rejected.

9.8 Commissioning of Treatments or Devices

The appropriate time for a commissioner to assume responsibility for on-going funding is if/when, a decision has been made to fund the service development, and access to the treatment is opened to all individuals meeting treatment criteria under the policy. This includes treatments mandated by NICE under a NICE Technology Appraisal or where services/treatments are explicitly commissioned by BSW ICB.

10.0 Urgent Treatment Decisions

10.1 BSW ICB recognises that there will be occasions when an urgent decision needs to be made to consider approving funding for treatment for an individual outside the ICB policies. In such circumstances the ICB recognizes that urgent decisions may have to be made before the monthly committee can be convened.

The following provisions apply to such a situation:

- An urgent request is one which requires urgent consideration and a decision because the individual faces a substantial risk of significant harm (the individual's life may be in danger) if a decision is not made before the next scheduled meeting of the EFR Monthly committee.

The EFR Lead and ICB Clinical Lead are responsible for agreeing whether a case requires an urgent decision after considering the nature and severity of the individual's clinical condition. Urgency under this policy cannot arise as the result of a failure by the clinical team expeditiously to seek funding through the proper route and/or where the individual's legitimate expectations have been raised by a commitment given by the provider trust to supply a specific treatment to the individual. In such circumstances the CCG/ICB expects the provider trust to go ahead with treatment; however, funding will not be guaranteed and may be at their financial risk.

10.2 Provider trusts must take all reasonable steps to minimise the need for urgent requests to be made through the EFR Monthly Committee process. If clinicians from any provider trust are considered by the ICB not to be taking all reasonable steps to minimise urgent requests to the EFR Monthly Committee, the ICB may refer the matter to the provider trust Chief Executive.

10.3 When an urgent decision needs to be made to authorise treatment for an individual, it is the responsibility of the EFR Clinical Lead to request a virtual discussion on the case. The period within which the decision needs to be taken will be five working days of receiving the case request or earlier depending on the individual case.

10.4 The urgent decision will be made by "virtual discussion" via email or phone between the EFR Monthly Committee members.

- The "virtual discussion" will, as far as possible, be within the constraints of the urgent situation, follow the policy set out in making the decision. The EFR team shall collect as much information about the individual's illness and the treatment as is feasible in the time available.

10.5 The BSW ICB Monthly Committee members shall be entitled to reach the view that the decision is not of sufficient importance that a decision needs to be made outside of the usual process.

10.6 Decisions will be sent to the referring clinician and GP and the individual within five working days of receiving the case request for a virtual Committee meeting. If the committee decides not to fund a drug or treatment, the decision letter will include an appropriate explanation.

11.0 Drug Requests

11.1 The EFR team processes requests for Drugs which are not routinely commissioned this would include:

- High-cost drugs excluded from contracts.
- New treatments where no policies exist.
- Treatments that we as a ICB have decided we will not fund routinely, or only fund in certain circumstances. This may include primary care prescribing or requests from Trusts and other providers.

11.2 If a request meets routine commissioning criteria this will be sent to the Medicines Management Team for processing. Drug requests will be considered in line with this policy on the grounds of clinical exceptionality and the same principles will be applied. The EFR Lead will work collaboratively with senior pharmaceutical leads in responding to requests and draw upon their knowledge and expertise.

12.0 **Criteria Based Access Process -** The Assessment Process

12.1 The Clinical Commissioning Policies list identifies all procedures that have Criteria Based Access (CBA) and provides details of the criteria that the individual will need to meet to proceed for treatment. The list can be found on our webpage: bswICB.nhs.uk

12.2 Assessment of the individual against the relevant CBA criteria can be made at any point in the individual's pathway prior to treatment but should be undertaken at the earliest possible stage in the pathway once the need for CBA procedure has been identified. This means that an assessment against the CBA criteria will either be made by the referrer prior to the referral, or by the secondary care clinician following triage or initial assessment in secondary care.

12.3 Where the responsible clinician believes that an individual demonstrably meets the criteria set out in the ICB's Clinical Commissioning Policies list, the person can proceed for treatment. If the assessment is undertaken by a referring GP, that GP must ensure that details of this are included within their referral. Secondary care providers must ensure that evidence that the individual meets the CBA criteria is included within the individual's medical record for audit purposes.

12.4 All providers of NHS care have a responsibility for ensuring that CBA procedures, as identified on ICB Policy list, are only undertaken where the relevant clinical criteria are met.

12.5 On any occasion where a provider undertakes CBA activity where the individual does not meet the relevant criteria, that provider will not be paid for the associated activity.

12.6 The BSW ICB Process for Ensuring Compliance with CBA policy

12.7 The BSW ICB will undertake a regular audit process to review a representative sample of CBA procedures undertaken by providers to ensure relevant CBA criteria were met. The audit process will involve review of medical records, and an assessment of whether there is sufficient evidence to demonstrate that the CBA criteria were met.

12.8 If the audit process identifies cases where the relevant criteria were not met, or where there is insufficient evidence to provide assurance that the criteria were met, the provider will not be paid for the associated activity.

12.9 Providers will be given the opportunity to review any cases identified through the audit process, and if they are able to provide sufficient evidence within agreed timescales to demonstrate to BSW ICB satisfaction that the CBA criteria were met, then the provider will be paid for the activity.

13.0 Prior Approval Process

13.1 BSW ICB Primary and Secondary care clinicians are required to apply proforma
to demonstrate how the individual meets current threshold criteria. Relevant clinical letters and/or objective data to support the individual's application should be included and will be requested if not supplied with the initial application.

For example: x-ray reports, scan results, optician reports, medical evidence, clinical scores, clinic letters and images etc., **See section 15.0 for photographic evidence**.

13.2 Prior approval forms should be received typewritten only. Handwritten forms will be returned to the requester if they are illegible. This is to ensure that the

content & information is easy to read, avoiding any misunderstandings and enabling the best application is made on behalf of the patient.

13.3 Every section on the application form should be fully completed before submission to assist the Committee in making an informed decision. If necessary, where sections of the request form are incomplete, members of the team will contact the referrer for additional information, or in extreme circumstances will reject the application back to the referrer thereby delaying a decision for the patient.

13.4 Completed applications are sent electronically to the EFR & Prior Approvals Team. The case is recorded on an electronic IT system database.

The ICB aim to deal with all applications within a 30-working day turn around; this is within the contractually stated 30-day timeframe and is in line with Standard Operating Procedures. Members of the team determine whether the presenting condition requires prior approval and considers if any additional information is required before submission.

Requests which clearly do not meet criteria and where no additional information has been provided to support the application can be directly declined.

Decisions will be made with an aim to:

- Promote consistency, fairness, and equity.
- Ensure effective use of resources but also ensure that decisions are based on clinical evidence.
- Improve the processes ensuring decisions are rational, reasonable, and transparent.

13.5 Treatments and services referred to in this policy should not be undertaken or provided without Prior Approval being obtained as indicated. Where Prior Approval has not been appropriately obtained, treatments or services provided will not have been legitimately delivered and will not be funded by BSW ICB. Funding will not be paid retrospectively.

13.6 The responsibility for discussing the outcome of any funding request and answering any questions which the patient may have about the request, or their clinical options will lie with the requesting clinician. This is because the clinician will have the full details of the reasons for the decision and will need to share these. The clinician should contact the patient at their earliest convenience to discuss the outcome and any resulting implications for future care.

13.7 Where a Prior Approval application has been declined clinicians may ask for the decision to be reconsidered by submitting new or additional clinical evidence within 6 months of the date of the letter declining funding. Further submissions will be reviewed as reconsideration requests. If the second request is also declined and the case is submitted for a third time, this will be considered an exceptional funding request and will be submitted for a decision at the next available Exceptional Funding Meeting. Should this be refused again, the Panel or Committee will not consider the case again.

14.0 Exceptional Funding Request Process

14.1 All applications to the EFR team should be submitted on the approved request form (appendix 1 and as per points 13.2 and 13.3). The form should be referred to for further detailed instructions on completing it. Written support and evidence should be provided by the clinician treating the individual using the request form and include any relevant research findings. Where appropriate. A personal statement from the individual can be included to support the case.

14.2 On receipt of the funding request, the case is recorded on the IT electronic system. The application will be checked to verify sufficient information has been included in the request form, if this is not the case team members will ask the referring clinician for more information.

14.3 All EFR cases will be screened by the BSW EFR Manager and the Director of Medicines Optimisation and Clinical Policies (or a nominated deputy) on a weekly basis. Complex cases will automatically be sent to a pre-screen panel meeting for discussion; Drug cases will be discussed with the relevant Senior Medicines Management Team member.

14.4 Following the EFR Monthly Committee, decision responses will be emailed to the referring clinician within ten working days of the meeting, which is within the 30-day requirement stated within contracts and in line with the BSW ICB Standard Operating Procedures. If the EFR Monthly Committee decides not to fund a drug or treatment the decision letter will include an appropriate explanation as to how and why this decision was made.

14.5 NHS BSW ICB would expect all treatments to commence within a 12-month period from the date of the decision. If for any reason the approved treatment is not started within 12 months of the decision, the provider will be required to resubmit an application form for funding from BSW ICB

15.0 Storage of Photographic & EFR Applications

15.1 The clinician should send photographic evidence, with the individual's consent, or directly from the patient should they wish to do so. The clinician is responsible for informing the individual that the evidence may be viewed by the EFR monthly committee members. Photographs should be presented at the meetings by the administrator and should be available for meeting members to view when the case is being discussed. The EFR Senior Manager must be considered as the custodian of photographs and has responsibility to ensure the policy about data being shared in photographic form is followed.

15.2 Where photographs are submitted that are not medical photographs, the clinical referrer, if appropriate must ensure that the quality of photography is such that the Committee members can easily identify the relevant features necessary in making an informed decision.

15.3 The photograph is kept electronically with the application and will be held for an 8-year period in line with current NHS guidelines for corporate record retention. Guidelines advise that all elements of a request should be kept for the entire retention period in the event of a complaint or review being raised sometime in the future.

15.4 The EFR application will be stored on the EFR IT software as per NHS guidelines Corporate Records Retention & Disposal Schedule & Guidance.

16.0 EFR Monthly Committee

Refer to **Appendix 1** for Terms of Reference for the EFR Monthly Committee

16.1 The monthly Committee meeting will usually consider cases where there is either:

- Exceptional applications

OR

- Uncertainty about whether the treatment falls within existing policy

OR

- Evidence for exceptionality is unclear

OR

- Where complaints and appeals have been received regarding a Prior Approval policy and the EFR monthly Committee view is required

OR

- Where the referring clinician appeals against the decision made previously by the Committee and there is new clinical information to consider.

In considering the funding requests, the Committee will aim to:

- Promote consistency, fairness, and equity.
- Ensure effective use of resources but also ensure that the decisions are based on clinical evidence.
- Improve the rigor of the processes ensuring decisions are rational, reasonable, and transparent.
- Explore the grounds for any relevant clinical exceptionality presented and apply the EFR policy.

16.2 Decisions will be reached by consensus where possible but if a consensus cannot be achieved, this will be decided by a vote of the Committee members. If the Committee is equally split following extensive discussion, then the chair of the Committee will have the casting vote.

16.3 The EFR Monthly Committee shall be entitled to approve/decline or defer Exceptional Funding Requests. The following will be considered:

The EFR Monthly Committee is not authorised to approve funding for cases which are considered to form part of a service development. Providers are expected to seek funding for new treatments and services through commissioning managers by submitting a business case and not through the EFR system.

However, the committee can consider approving funding for individual cases where the individual is clinically exceptional to the cohort in question and the requested intervention has evidence of safety, efficacy, and cost effectiveness.

In addition, in rare circumstances if a new (first time) request for an un-commissioned service is received for an individual, consideration for funding may be appropriate whilst a business case is being developed for consideration of funding for the cohort. In these circumstances it must be demonstrated that the treatment for this individual would be safe, effective, and cost effective, as demonstrated by critical review of the literature. In addition, the ICB may decide that funding for a rare condition will only be

considered individually rather than commissioning a service for a cohort. In these circumstances it would be expected that a commissioning policy is developed to support decisions.

The EFR Monthly Committee is not required to accept the views expressed by the individual or the requesting clinicians concerning the clinical outcomes for the individual of the proposed treatment.

The Committee is entitled to reach its own views on the likely clinical outcomes for the individual of the proposed treatment; and the quality of the evidence to support that decision and/or the degree of confidence that the Committee has about the likelihood of the proposed treatment delivering the proposed clinical outcomes for the individual.

The EFR Monthly Committee shall be entitled, but not obliged to commission its own reports from any duly qualified or experienced clinician, medical scientist or other person that has relevant skills concerning the case that is being made that the treatment is likely to be clinically effective in the case of the individual.

The EFR Monthly Committee shall be entitled to approve requests based on exceptionality, where the following condition is met:

- In determining whether an individual can demonstrate exceptional circumstances the EFR Monthly Committee shall compare the individual to other people with the same presenting medical condition at a similar stage of progression.
  Based upon the evidence provided to it the Committee shall determine whether the individual has demonstrated exceptional clinical circumstances. The evidence to show that, for the individual, the proposed treatment is likely to be clinically effective may be part of the case that the individual's clinical circumstances are exceptional.

16.4 The meeting notes will form the rationale and decision for each application

The EFR Monthly Committee will make one of the following decisions:

- Approve the funding request
- Decline the funding request
- Defer the request and ask for more information from the referring clinician.

Funding decisions made by the team and/or EFR Monthly Committee on behalf of the organization may impact on various healthcare budgets within the organisation.

16.5 Where the request is agreed the letter may request that a report is provided on the individual's progress to determine whether the treatment is effective. The ICB may use this information to consider the continuation of treatment.

16.6 Where the request is refused, a clear, accurate and comprehensive explanation must be given. The letter should state that the case could be reconsidered at the next available EFR Monthly Committee if new clinical evidence becomes available.

16.7 The refusal notification must include advice to the referring applicant about the terms on which they can make a reconsideration request. It is the duty of

the referring applicant to inform the individual about the reconsideration process.

17.0 EFR Reconsideration requests

17.1 The purpose of a reconsideration request is to revisit previous decisions made by the EFR monthly Committee where new or additional clinical information that was not previously submitted before will be considered before a further decision is made by the Committee.

17.2 Reconsideration requests must be made by a clinician on behalf of the individual. The ICB will not accept requests instigated by an individual, their family or other non-clinical representative (e.g., local MP).

17.3 Reconsideration requests must be submitted in writing to the EFR Administrative Team within 6 months of the date of the decision letter declining funding.

17.4 Applicants or individuals wishing to complain about the decision itself should contact the relevant Individual Advice Liaison Service (PALS) for advice or complaints team to make a formal complaint.

18.0 EFR Appeals Process – The EFR Appeal process enables applicants to appeal against the decision made by the EFR committee.

See appendix 3 for Terms of Reference.

18.1 The committee will reconsider a case once, on the understanding that new clinical information will be provided within the application. If the patient/clinician are still unhappy with the outcome, an appeal may be logged with the EFR/PA team.

18.2 Appeal requests must be submitted in writing to the EFR Administrative Team within thirty days of the date of the decision letter to decline funding.

18.3 The purpose of the Appeals Panel is to review previous decisions made by the EFR monthly Committee, where it was arguable that the decision was either not made in accordance with the ICB Clinical Policies or where it was made without taking account of relevant information.

18.4 The appeal request must indicate the applicant's grounds for appeal. There are three grounds for appeal that can be considered:

- Illegality: the refusal of the request was not an option that could lawfully have been taken by the EFR Monthly Committee.
- Procedural Impropriety: There were substantial and/or serious procedural errors in the way in which the EFR Process was conducted.
- Irrationality: Whether the decision was irrational considering the information available to the committee.

18.5 Supporting statements from the individual(s) and third parties can be submitted to accompany the request for consideration as part of the appeal, however, no new evidence can be provided for consideration following a reconsideration

request and the decision to decline funding has been made.

The correct procedure is to submit additional information as part of a request for reconsideration.

18.6 The BSW ICB may request an EFR Committee from a neighbouring ICB or a panel made from senior colleagues within the ICB who have not previously sat on the Exceptional funding meetings to revisit the case to ensure it has been independently reviewed and an impartial decision made.

18.7 The decision of the Appeals Panel is final

19.0 Complaints

19.1 Individuals have the right to raise a formal complaint with the ICB via the NHS Complaints Procedure should they be unhappy with the ICB's managing of their case (i.e., staff attitude, communication, or the way in which the policy or procedure has been followed, adherence to procedure).

The NHS Complaints Procedures is set out to address concerns over service provision and not funding decisions. It cannot be used to investigate or influence funding decisions and the appropriate process for reconsideration or appeal should be followed.

Appendix 1 - Exceptional Funding Request Committee - Terms of Reference

1.0 Introduction

1.1 The Exceptional Funding Request (EFR) Committee is the committee the ICB has authorised to take decisions on its behalf regarding Exceptional funding requests. The purpose of the EFR committee is to consider funding requests on behalf of the BSW ICB. The EFR committee will decide in each case whether funding should be approved or declined in line with the Exceptional Funding Requests policy for BSW.

1.2 The EFR committee meeting will consider cases where there is: uncertainty about whether the treatment falls within existing policy or where evidence for exceptionality is claimed. Or if the referring clinician appeals against the decision made by the committee and there is new clinical information to consider.

2.0 Membership

2.1 Membership of the EFR committee shall include:

- Director of Medicines Optimisation, EFR and Prior Approvals (Chair)
- Public Health Consultant/Specialist or nominated deputy (If unavailable, will not affect quoracy)
- 3 Practicing GP representatives (Deputy Chair)
- EFR Senior Manager or nominated deputy (non-voting member)

2.2 In the event of the Chair being unable to attend all or part of the meeting, the Deputy Chair (one of the attending GP's) will deputise for that meeting.

2.3 Additional members may be co-opted, and the EFR committee may decide whether they have decision making rights in the EFR committee discussions, e.g., Public Health Registrars and Commissioners

2.4 For particularly complex cases, other individuals with clinical expertise and skills may also be Included on the EFR committee, these colleagues can also contribute to the work of the EFR process as part of their training. They can attend EFR committee meetings as non-voting members

3.0 Quorum

3.1 The committee will be quorate if four of the members are present; this should include two of the GP representatives, the Head of EFR or nominated deputy and the EFR Senior Manager or nominated deputy. Any members unable to attend will be expected to leave their comments on each case for discussion at the EFR committee meeting. Comments will be tabled at the meeting from members who are not present. However, an EFR committee meeting with only four members present should be the exception.

3.2 No formal business shall be conducted where a quorum is not reached.

4.0 Frequency of meetings and attendance

4.1 EFR committee meetings are held monthly and will ensure a minimum of ten Meetings per year.

4.2 Members of the EFR committee should make every effort to attend every scheduled committee meeting.
The EFR Manager will monitor attendance and will report on this annually

5.0 Authority

5.1 The EFR committee has delegated authority from the ICB to make decisions in respect of funding for Exceptional cases. Accountability for those decisions rests with the committee. Decisions will be made based on consensus with the Chair holding the deciding vote.

5.2 The EFR committee is not obliged to allow patients to attend committee meetings.
The EFR process is clinician lead and all deliberations at the EFR committee meetings will be based on evidence of individual clinical exceptionality and will not consider issues relating to social or personal circumstances. It is therefore not appropriate for patients to attend the EFR committee meetings and Commissioners are not legally bound to invite them. Patients may submit a supporting statement; however, this needs to be limited to clinical issues i.e.: what effect the condition has on the patient's activities of daily living.

5.3 The EFR committee is authorised to make the following conclusions:

- Approve the funding request
- Decline the funding request.
- Defer the request and ask for more information from the referring clinician.

NHS BSW ICB expects treatment to commence within a 12-month period from the decision. If for any reason the approved treatment is not started within 12 months from the decision, the provider will be required to seek re-authorisation of funding from NHS BSW ICB.

6.0 Emergency powers

6.1 Should the case need EFR committee consideration the urgent decision will be made by virtual discussion, via email or phone between the committee members using the same quoracy principles set out in section 3 (See EFR policy regarding urgent requests; section 9. The exercise of such powers shall be reported and minuted at the next committee meeting.

7.0 Duties

7.1 **Decision making at EFR committee -** In considering the funding requests, the EFR committee will aim to promote consistency, fairness, and equity. Ensure effective use of resources, but also ensure that the decisions are based on clinical evidence. Improve the rigor of the processes ensuring decisions are rational, reasonable, and transparent. Explore the grounds for any relevant clinical exceptionality presented and apply the EFR policy. Consider rare cases where no commissioning policy/service exists on an individual basis.

7.2 The committee is not authorised to make case by case decision making for service developments where the patient represents a cohort of patients who may benefit from the same treatment, The EFR committee shall routinely screen Exceptional funding requests to see whether they represent a service

development. The key question used to screen out as a service development will be ‘are there likely to be other similar patients in the ICB?’ If there is evidence that this patient is representative of other similar patients and forms a cohort, the request will be considered on an individual basis (as per EFR policy), but the provider will be requested to follow normal procedures for introducing

7.3 The EFR committee shall be entitled, but not obliged to commission its own reports from any duly qualified or experienced clinician, medical scientist or other person that has relevant skills concerning the case that is being made that the treatment is likely to be clinically effective in the case of the individual patient.

7.4 The committee shall be entitled to approve requests based on exceptionality line with the most recent EFR policy.

8.0 Patient confidentiality and conflicts of interest

Any EFR committee members who believe they may have had any clinical involvement with a particular case will excuse themselves from the case. Confidentiality is the responsibility of all committee members and should be always maintained. Committee members must follow BSW ICB declarations of interest policy to be noted at every meeting.

9.0 Reporting arrangements to the Governing Body

10.0 Annual review of the EFR committee

The EFR committee will undertake a twice-yearly self-assessment to:

- Review that these Terms of Reference have been complied with and whether they remain fit for purpose.
- Determine whether its planned activities and responsibilities for the previous year have been sufficiently discharged; and,
- Recommend any changes and / or actions it considers necessary, in respect of the above.
- Provide the Governing Body with an annual report, which details the outcome of the annual review.

11.0 Committee servicing

11.1 The EFR committee shall be supported administratively by the EFR team (Or other nominated representative); whose duties in this respect will include:

- Prepare clinical cases for the meeting.
- Taking the minutes and keeping a record of matters arising and issues to be carried forward.
- producing a single document to track the Committees agreed actions and report progress to the committee.
- Producing draft notes with which to inform the decision letters for approval within five working days of the meeting.

THIS PAGE MUST BE COMPLETED FOR ALL REQUESTS STRICTLY PRIVATE AND CONFIDENTIAL APPLICATION FOR **EXCEPTIONAL** FUNDING:	**Nature of proposed treatment or intervention:**

A. Patient Information			**PATIENT HAS REQUESTED TREATMENT:**			
Name		Male	☒	Female	☒	
Address **Post Code**						
Date of Birth		**NHS Number**				
B. Referrer's Details (GP/Consultant/Clinician)						
Name						
Address **Post Code**						
Telephone		**Email**				
GP Details (if not referrer)						
Name		**Practice**				

By submitting this form, you confirm that the information provided is, to the best of your knowledge, true and complete and that you have:

- Discussed all alternatives to this intervention with the patient
- Had a conversation with the patient about the most significant benefits and risks of this intervention
- Informed the patient that this intervention is only funded where criteria are met, or exceptionality demonstrated
- Checked that the patient is happy to receive postal correspondence concerning their application where appropriate, or clarified alternative needs
- Checked that the patient understands spoken and written English, or clarified required needs

Understand that it is a legal requirement for fully informed consent to be obtained from the patient (or a legitimate representative of the patient) prior to disclosure of their personal details for the purpose of a Committee/EFR team to decide whether this application will be accepted, and treatment funded. By submitting this form, I confirm that the patient/representative has been informed of the details that will be shared for the purpose and consent has been given.

Signed Referrer: ..... **Please also print name: ……**

Date: ……

Submission

The completed form(s) should be sent electronically (from a nhs.net email address) in confidence with any other supporting documents to: BSW.EFR@nhs.net

To **comply with information governance standards, emails containing identifiable patient data should only be sent securely, i.e., from an nhs.net account.**

Exceptionality Status Statement

What makes the individual sufficiently different from the usual cohort of patients) Exceptionality is central to consideration of individual requests for funding.

For funding to be agreed there must be unusual or unique clinical factors about the patient that suggest that they are:

- Significantly different to the general population of patients with the condition in question

  AND ARE

- Likely to gain significantly more benefit from the intervention than might be expected from the average patient with the condition.

  HOWEVER:

- The fact that a treatment is likely to be efficacious for a patient is not a basis for an exception.
- If a patient's clinical condition matches the 'accepted indications' for a treatment that is not funded, their circumstances are not, by definition, exceptional.
- Social value judgements (the 'worth' of patients) are not relevant to the consideration of exceptional status but there may rarely be exceptional circumstances where benefits may go beyond the patient (e.g., as a carer) in respect of social or health related benefits for others.

Taking account of the Exceptional status statement above – Why do you consider this patient to have Exceptional Clinical circumstances? Please provide details and evidence to support your request.

D. Costs Cost of treatment requested: (For drug therapy – cycle and annual costs	

Appendix 3

EFR Appeal Panel: Terms of Reference

1.0 Governance Arrangements

1.1.1 The EFR Appeals Panel will be accountable to the Integrated Care Board (ICB) Governing body via its committee structure.

1.1.2 Members of the EFR Appeals Panel will be appointed by the ICB's Chief Officer or BSW ICB will request a neighbouring ICB and its EFR team to independently review the case.

1.1.3 The EFR Appeals Panel will be supported to discharge its responsibilities administratively by the EFR service.

2.0 Duties and Responsibilities

2.1.1 The EFR team will receive and acknowledge the letter of appeal. The EFR triage meeting will be responsible for undertaking the preliminary assessment of the appeal request to determine whether new evidence has been received and if the case should be sent back to Committee. If no new evidence has been received, the case should be passed to an EFR Appeal Panel.

2.1.2 Where it is decided to convene a Panel, members of the Appeals Panel should be provided with full details of the case including all correspondence, evidence of clinical and cost effectiveness, full documentation of the discussion and outcome.

2.1.3 The Appeals Panel will need to consider whether there are grounds for appeal:

- Illegality: the refusal of the request was not an option that could lawfully have been taken by the EFR Committee.
- Procedural impropriety: There were substantial and/or serious procedural errors in the way in which the EFR Process was conducted.
- Irrationality: Whether the decision was irrational considering the information available to the Committee.

2.1.4 An EFR Appeal Panel will not consider new evidence. New evidence must be considered as an EFR resubmission.

2.1.5 If the Appeal Panel upholds the original EFR Committee's decision, the appellant will be advised that if they wish to take the matter further this must be done through the NHS Complaints process.

2.1.6 If the Appeals Panel considers that the EFR Committee did not consider all the evidence provided the application can be directed back to the EFR Committee for re-consideration.

3.0 Constitution

3.1 Meetings

3.1.1 EFR Appeal Panel meetings will be held in private. Patients and their representatives will not be permitted to attend the panel discussions to put forward their case verbally. All appeal cases must be submitted in writing to the Panel.

3.1.2 The EFR Appeal Panel will adopt the consensus method of decision making where a unanimous view cannot be reached on an individual case. In the case of an equal vote, the Chair shall have a second and casting vote.

3.2 Membership

3.2.1 All EFR Appeal Panel members must be independent of any of the original decision-making processes and not have been a member of the EFR Committee involved in the original decision. The members must be familiar with all relevant policies and procedures.

3.2.2 EFR Appeal Panel members are required to declare their interests before serving on an EFR Appeal Panel. Any conflicts of interest must be declared as a standing item at the commencement of every meeting and the Chair will decide the appropriate action, including requesting that members withdraw from the meeting.

3.3 Chair

3.3.1 The Chair must be identified in advance of the meeting and must be available to approve the minutes and relevant correspondence and fulfil and any other obligations within the specified period**.**

3.4 Frequency of Appeals Panels

3.4.1 The numbers of appeals that may be received are difficult to predict and therefore arrangements for Appeal Panel meetings will be flexible and will be arranged to ensure that appeals are considered within forty working days of an appeal being received by the EFR Team.

3.4.2 If a matter is exceptionally urgent the Chair shall have the power to call an EFR Appeal Panel at any other time.

3.5 Quorum Arrangements

3.5.1 The EFR Appeal Panel may not proceed unless at least two members are present, including the Chair.

3.6 Reporting

3.6.1 The minutes of the meetings shall be recorded by the relevant EFR Manager/Officer and approved by the Chair of the Appeal Panel.

3.6.2 Copies of minutes will not be distributed to EFR Appeals panel members for their retention and will not be placed in the public domain to preserve patient confidentiality.

4.0 Confidentiality

4.1 Anonymity is essential for two reasons:

- To protect patient's identity, for this reason the requesting clinician is asked to not refer to the patient by name or initials within the rest of the application form.
- For equity of decision making, to ensure that the Committee decisions do not consider personal details such as age or sex.

4.2 Depending upon individual clinical circumstances it may be necessary to reintroduce information on the patient's age and/or sex for consideration. When cases are

considered which require access to confidential clinical information through triage, implied consent to disclose such information to all members of the EFR Appeal Panel will be assumed. This will be indicated to patients by the referring clinician and be confirmed in EFR publicity material.

5.0 Review

5.1 The EFR Appeal Panel's Terms of Reference will be reviewed annually or considering any changes in legislation, practice, or local/national guidance.

Appendix 4

Individuals Changing Responsible Commissioner

Where the commissioner has assumed responsibility for exercising the Secretary of State's function under the NHS Act of 2006 in respect of individuals where:

- The individual has been previously provided with one or more treatments by another NHS commissioning body and wishes the ICB to continue to commission those treatments for the individual
- An individual in the same clinical circumstances would not routinely have been provided with those treatments by the commissioner.

The policy of the commissioner is to operate in favor of continuing to provide the treatments to the individual. However, the Commissioner reserves the right not to continue funding for all or any of the treatments if, in the circumstances of the case, the commissioner has a good reason for refusing to commission a particular treatment for the individual, Commissioners could reason that:

- The treatment is likely not to be clinically effective.
  OR
- The treatment is likely not be cost effective for the individual.
  OR
- That the commissioner had a concern an individual had arranged or may have arranged to change their responsible commissioner wholly or partly to obtain the requested treatment.
  OR
- Where the continuation of the funding for this treatment may create a level of inequity with other local individuals so that the commissioner considers that the treatment should not be funded.

The commissioner reserves the right to seek a formal clinical review of the individual's future healthcare needs and to consider whether the decision to provide the individual with any further courses of treatment of the type previously provided, and of any other nature, are equitable and appropriate.

The individual's future healthcare needs, including consideration of whether to provide the individual with any further courses of treatment of the type previously provided, will be determined through the commissioner's usual local decision-making mechanisms.

Appendix 5

Standard Operating Procedure

Prior Approvals

July 2020

Contents

1.0 Introduction:

1.1 The Prior Approval (PA) procedure sets out BaNES, Swindon, and Wiltshire Integrated Care Board's (BSW ICB) approach to treatments identified on the ICB's Clinical Commissioning Policies list as requiring Prior Approval.

2.0 Prior Approval

2.1 BSW ICB's Prior Approval process applies to treatments that are considered appropriate in certain circumstances, but where funding is granted on a case-by-case basis when BSW ICB is assured that specific pre-determined and evidence-based criteria have been met.

The Prior Approval process should not be confused with BSW ICB's Exceptional Funding Request (EFR) process which deals with requests for individuals who are 'exceptional' (i.e., there is something about the patient's condition or circumstances that differentiate them based on need from other patients with a similar diagnosis or condition and would justify funding being provided in an Exceptional case when it is not routinely funded for others).

3.0 The Application Process

3.1 The Integrated Care Board Clinical Commissioning Policies identify all procedures that require BSW ICB approval prior to treatment and provides details of the criteria that the patient will need to meet for PA to be granted.

3.2 Where the reviewing clinician believes that a patient demonstrably meets the criteria set out in the policy, a Prior Approval application, along with supporting evidence such as a clinical letter, must be submitted by the clinician to BSW ICB and confirmation of funding received before the patient proceeds for treatment.

3.3 The reviewing clinician must inform the patient that the proposed treatment is subject to Prior Approval, and that patient details will be shared with BSW ICB to support the PA process.

3.4 A Prior Approval application can be made at any appropriate point in the patient pathway prior to treatment but should be made at the earliest possible stage in the pathway after the need for a Prior Approval procedure has been identified. This means that Prior Approval will either be sought by the referrer prior to referral, or by the secondary care clinician following triage or initial assessment in secondary care.

4.0 The Decision-Making Process

4.1 All Prior Approval applications will be reviewed by BSW's PA/Exceptions Team to ensure that the relevant criteria have been met. Following the BSW review process the outcome will be communicated to the clinician that submitted the application, confirming:

- That the application is supported, and funding approved

OR

- That the application is supported for an assessment only in the first instance. (Should surgical intervention and/or further treatment be required following an assessment a further application would need to be submitted from secondary care for consideration to the prior approval office.

OR

- That the application is rejected, and funding is not approved

4.2 If the application does not demonstrate how a patient meets the necessary criteria, the application will be rejected.

4.3 BSW ICB will aim to respond to all Prior Approval applications within 30 days of receipt of the application.

4.4 BSW ICB will record details of all approved and rejected Prior Approval applications on the Exceptions & Prior Approval database, to support assessment of compliance with BSW ICB policy.

4.5 If the Prior Approval application is submitted by a referring GP, that GP must ensure that evidence of Prior Approval being granted is included within their referral to secondary care. If such evidence is not included in the referral the provider may reject the referral. Secondary care providers must ensure that evidence of PA being granted (either prior to referral or following triage or assessment) is included within the patient's medical record for audit purposes.

5.0 Consequences of Undertaking Activity without Prior Approval funding.

5.1 All providers of NHS care have a responsibility for ensuring that Prior Approval procedures are only undertaken where the relevant clinical criteria are met, and funding has been agreed through BSW's PA process. If Prior Approval has not been granted the procedure should not be undertaken.

5.2 On any occasion where a provider undertakes Prior Approval activity where a Prior Approval application has not been submitted or where a Prior Approval application has been submitted but has been rejected, in accordance with Service Condition 29.22 of the NHS Standard Contract that provider will not be paid for the activity.

5.3 On any occasion where a provider undertakes a PA procedure having sought PA approval, but where BSW ICB failed to respond within 10 working days of receipt of the request, in accordance with Service Condition 29.26 of the NHS Standard Contract, Prior Approval will be assumed to have been granted and the provider will be paid for the activity.

6.0 BSW ICB Process for Assessing Compliance with PA Policy

6.1 BSW ICB will assess compliance with this policy through a data driven review that compares approved cases against actual activity undertaken by providers. If this process identifies any cases that have been undertaken without the necessary approval, in accordance with Service Condition 29.22 BSW ICB will withhold payment for that treatment.

6.2 Providers will be given an opportunity to review any cases identified through the above process, and if they are able to provide sufficient evidence within agreed timescales to demonstrate to BSW's satisfaction that either Prior Approval was granted, or that Prior Approval did not apply to the procedure in question, then the provider will be paid for the activity.

Appendix 6

Standard Operating Procedure

for the

Management of Exceptional Funding Requests

July 2020

Contents

1.0	**Introduction**
1.1	This document sets out the principles and process for Exceptional funding requests i.e., requests for treatments that fall outside the usual (ICB) commissioning contracts and service level agreements. BSW ICB's Exceptional Funding Request (EFR) Panel is established to consider these exceptional funding requests and to ensure that decisions made are equitable, represent value for money and are in the interest of the entire population.
1.2	An element of this will be the consideration of cases based on evidence of effectiveness, cost effectiveness, impact on health and affordability, ensuring that BSW CCG/ICB has a robust process in place to ensure compliance with the NHS Constitution, CQC Regulations Essential Standards of Quality and Safety and other statutory regulations.
1.3	The purpose of this procedure is to: • Set out the process for handling Exceptional funding requests. • Clarify the decision-making criteria against which requests are judged. • Set out the reconsideration process.
1.4	This procedure applies to all written Exceptional funding requests for treatments for the registered population of BSW ICB, provided through primary care (General Practitioner services), secondary care (hospital services), tertiary (specialist) care and community services
1.5	This document should be read in conjunction with the following policies and documents: • Ethical Framework Policy • Exceptional Funding Request Policy • Standard Operating Procedure for Prior Approval Funding Requests • BSW CCG/ICB Clinical Commissioning Policy • Reconsideration and Appeals Procedure
1.6	All relevant documents are available on the NHS BSW ICB website:
2.0	**Managing Exceptional Funding Requests: The EFR Process** This section sets out the procedure for managing EFR requests.
2.1	**Submitting an EFR**
2.1.1	The referring clinician must first consult the ICB's current commissioning policy statements to establish that the patient's treatment does not fall within current treatment policies and commissioning responsibilities. https://bswICB.nhs.uk/your-health/what-we-do-and-don-t-fund

2.1.2	If the treatment is not normally funded the clinician needs to submit an Exceptional funding request application to the Panel in liaison with the patient. Applications will only be accepted from clinicians or other health care professionals involved in the care of the patient.
2.1.3	Exceptional funding requests must be submitted on the standard application form to ensure that the Exceptional Funding Request Panel receive all the relevant information to make a decision. The application needs to be submitted electronically to ensure legibility. https://bswICB.nhs.uk/your-health/what-we-do-and-don-t-fund
2.1.4	The information required includes the following: • Brief history to include the patient's current health status and any other health care issues. • Treatment/intervention requested, expected benefits and risks of treatment • Reasons why the patient's clinical circumstances are 'exceptional' or should otherwise lead to the ICB agreeing to an intervention outside of normal commissioning arrangements. • What are the anticipated clinical benefits with this treatment requested over and above other options or available treatments? • Evidence on which the clinical opinion is based • The cost of treatment (if available/known) and length of treatment (number of treatment episodes, length of in-patient stay, for example). • How will the benefits of the procedure/treatment be measured? What are the intended outcomes and how will these be determined? What 'stopping' criteria will be in place if the treatment is ineffective? NHS BSW ICB will require regular feedback on the outcome if the treatment is approved to include details of any long- term cost implications. • Evidence of individual's functional impairment. • Any other relevant information that should be considered? i.e., clinical factors, co-morbidities, or relevant personal circumstances.
2.1.5	It is the responsibility of the referring clinician to provide sufficient clinical evidence in the form of electronic references of research papers or other documentary evidence to support the application. Where appropriate, supporting letters from the patient, clinical specialists or other health or social care professionals involved in the patients' care should also be included.
2.1.6	Completed applications should be e-mailed to the address specified on the application form.
2.2	**Administration**
2.2.1	On receipt of EFR applications, key information about the application, including the date of receipt, patient information, referring clinician and treatment requested, is entered onto the BSW ICB EFR database by the EFR administrator.
2.2.2	All decisions will be fully documented and all communications from the EFR team will be confirmed by email/letter.

2.2.3	Records will be retained and processed in accordance with appropriate NHS policies regarding confidentiality and retention and disposal or records.
2.3	**Timescales for managing an EFR**
2.3.1	The standard response time for dealing with an EFR request is 40 working days from the date of receipt of the completed EFR application form to the date of the email/letter from the ICB informing the requesting clinician of the funding decision. This will exclude any days where the EFR team is awaiting information sought from the referring clinician or other external source. If there is a delay for any other reasons the referring clinician will be notified.
2.4	**Initial assessment of an EFR application.**
2.4.1	All funding applications are considered at a pre-meet panel made up of the Head of Medicines Management along with the EFR Senior Manager (or nominated deputy). The Panel is authorised to make the following decisions: • Return the application if the CCG/ICB does not have a responsibility for commissioning the care requested for the individual patient. • Return the application if the treatment is covered by an existing contract with a provider or covered by a Criteria Based Access policy where the patient meets the criteria, with an explanation that funding approval is not required. • Reject the application if other standard treatments currently commissioned for the condition have not yet been tried. • Reject the application if there is a cohort of patients with explanation that a service development proposal should be submitted. • Request further information to give the referring clinician every opportunity to describe any circumstances that may indicate that the patient is an exception to the BSW CCG/ICB policy. • Reject the application if it does not demonstrate sufficient clinical information to be considered by the Panel as an EFR. • Refer the case to the EFR panel for a decision.
2.4.2	Where there is uncertainty or doubt about the application of the EFR policy, the case will be referred to the EFR Panel.
2.4.3	All decisions made by the Panel will be recorded on the EFR database.
2.4.4	If further information is requested from the referring clinician or other external source to support the case, the forty working day timeline for responding to the EFR is suspended until that information is received.
2.4.5	The decisions of the pre-meet Panel will be communicated directly to the referring clinician and/or the patient's GP (if this is not the same person). The patient/guardian/carer will be copied into the response letter, unless the clinician making the request has indicated that it is not clinically appropriate to do so.
2.4.6	If a request is declined by the pre-meet Panel the EFR policy does not provide a right of appeal to the EFR Panel. The pre-meet Panel will always review a case should more clinical information be made available by the referring clinician. If the patient disagrees with the commissioning policy, he/she has a right to make a complaint under the NHS Complaints Procedure.
2.5	**The EFR Panel**

2.5.1	The EFR Panel will meet a minimum of ten times a year. The Panel acts as a formal sub-committee of the Integrated Governance and Quality Committee. It has the authority to make exceptions to the Commissioning Policies of the ICB and thus commit financial resources within the frameworks agreed. The Panel will report its decisions to the Integrated Governance and Quality Committee on an annual basis or earlier if significant risk issues identified.
2.6	**Membership of the Panel**
2.6.1	Membership will comprise of the following members or delegates: • Director of Medicines Optimisation, EFR and Prior Approvals (Chair) • Public Health Consultant / Specialist or nominated deputy - If available • 3 x Practicing GP representatives from within BSW ICB (Deputy Chair) • EFR Manger or nominated deputy (non-voting member)
2.6.2	The Panel will be quorate if four members are in attendance, two of which should be General practitioners, the head of EFR & Prior Approvals (Chair) or nominated deputy and the EFR Senior lead or nominated deputy.
2.6.3	The Chair of the Panel is approved by the ICB Board. Expert advisors may be invited as necessary to advise the Panel but will not have a role in the decision making.
2.6.4	Decisions are made by consensus. If consensus cannot be reached, decisions are made by simple majority voting, with each Panel member having one vote and the Chair having the casting vote.
2.7	**Format of meetings**
2.7.1	Panel meetings will be scheduled on a rolling programme at least 3 months in advance. The EFR Administrators will add cases on to the next available meeting date.
2.7.2	The EFR Manager will ensure that case files are prepared for the Panel meeting, providing all the documentation that has been received regarding the request in an anonymised form to protect confidentiality.
2.7.3	When relevant, the Panel will receive and consider a briefing of the evidence-base supporting the requested treatment or intervention, prepared by the public health team.
2.8	**Urgent EFR decisions**
2.8.1	It is recognised that occasionally urgent decisions are required. In such instances, the EFR Panel will consider cases outside of scheduled meetings, using email to circulate anonymised cases to the EFR Panel as set out in the Exceptional Funding Request Policy. Despite urgent circumstances, no members of the Exceptional Funding Request Panel can normally make decisions on their own.
2.8.2	In exceptional circumstances an executive director of the ICB can decide on an urgent request as set out in the Exceptional Funding Request Policy.
2.9	**Decision making & Outcome of the EFR Panel** **Exceptional Requests** - Exceptional clinical circumstances refers to a patient who has clinical circumstances which, taken as a whole, are outside the range of clinical circumstances presented by a patient within the normal population of patients with the same medical condition and at the same stage of progression as the patient. The EFR Panel will consider exceptionality in the context of the relevant commissioning policy statements and policies. The EFR Panel will apply the guidance on exceptional clinical circumstances as defined in the Exceptional Funding Request Policy.

	Whenever possible the panel will seek to decide on the day the panel sits (unless there is a need to request supplementary information).
2.9.1	There are three different decision options possible for an Exceptional case when presented to the EFR Panel. 1. Agree to fund/support the request. 2. Defer decision pending further information/investigation. 3. Refuse to fund/support the request.
2.9.2	The referring clinician will be informed of the Panel's decision within ten working days.
2.9.3	The decisions of the Panel will be communicated directly to the referring clinician and/or the patient's GP (if this is not the same person). The patient/guardian/carer will be copied into the response letter, unless the clinician making the request has indicated that it is not clinically appropriate to do so.
2.9.4	In line with the NHS constitution, it is expected that agreed treatment will normally start within 18 weeks of the application being supported. There may be legitimate clinical or patient choice factors which may require that the planned treatment does not start within 18 weeks. For this reason, the Panel decision is valid for the treatment to commence within a 12-month period from the decision. If for any reason treatment does not start within 12 months from decision, the applicant will be required to seek re-authorisation of funding from the Panel.
2.10	**Reconsideration of an application**
2.10.1	If a request for funding has been refused by the Panel, the referring clinician can re-submit the case if additional clinical information is available to the panel. If this information is deemed 'new evidence' by the pre-meet Panel, it will be considered at the next available meeting of the EFR Committee. Re-submissions with additional new evidence will be accepted within six months of the original application. Otherwise, a new application for the panel will be required.
2.11	**Appeals** If the referring medical practitioner and /or patient wishes to appeal against the decision the appeals procedure needs to be followed. If the appeal is against the procedure, then NHS BSW ICB's normal complaints procedure is invoked. Please see the Standard operating procedure for the appeals process for further information.
3.0	**Availability**
3.1	All the documents related to the Exceptional Funding requests are available on the ICB website and G-Care. If a different format of this procedure is required, it can be requested from the EFR Panel secretary.
4.0	**Monitoring**
4.1	Performance against expected service standards will be monitored throughout the year and reported to the Integrated Governance and Quality Committee as part of the EFR annual report. The key standards for the EFR process are as follows: Time from receipt of an EFR application to date of letter confirming the ICBs funding decision should not exceed 40 working days (excluding any time when the clock is suspended pending further information that has been requested from the referring clinician or other source).
4.2	The Panel will provide evidence of its annual effectiveness review and audit at the end of each financial year.