NHS England
Specialised Commissioning

Service Development Policy

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NHS England Specialised Commissioning - Service Development Policy

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Equality and Health Inequalities Statement

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the service specifications and processes cited in this document, NHS England has:

- given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and

- given due regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities.

Contents

1 Purpose and Scope

NHS England is responsible for directly commissioning specialised services for the whole population of England, and is committed to providing the most effective, fair and sustainable use of resources for specialised services.

Each year, NHS England makes decisions about which new specialised services to routinely commission in England and which existing specialised services need to be changed or updated. New services could include new drugs, medical devices or other sorts of interventions. Investment in these new services and interventions is in addition to the investment in technologies that have received a positive National Institute for Health and Care Excellence (NICE) appraisal.

This Service Development policy sets out NHS England's approach for making decisions about which new treatments and interventions to routinely commission, and its approach for updating existing service specifications or creating new ones. This policy is accompanied by two methods documents: *Methods: National Clinical Policies* and *Methods: Service Specification* which set out the processes in detail.

This Service Development policy applies to all prescribed specialised services for which NHS England has direct commissioning responsibility. Health and Justice, armed forces and primary care services are out of scope for this policy, as are services that are commissioned by Clinical Commissioning Groups. Products which have been approved through a NICE Technology Appraisal or Highly Specialised Technology appraisal are also out of the scope of this policy.

2 NHS England Specialised Commissioning: Service Development policy

2.1 Overview

NHS England is responsible for directly commissioning specialised services for the whole population of England, and is committed to providing the most effective, fair and sustainable use of resources for specialised services.

This service development policy sets out NHS England's approach for making decisions about which new treatments and interventions to routinely commission, and the approach used for updating existing service specifications, or creating new ones.

It is intended to ensure that funding is allocated fairly and appropriately, with due regard to the competing demands on NHS England's available funding.

A **clinical commissioning policy** is a document that defines access to a service, drug or technology for a particular group of patients and is developed to ensure consistency in access to treatments nationwide.

A **service specification** is a document that defines the core requirements for the delivery of a service, and the quality standards expected. It may contain aspirational requirements to support continuous quality improvement.

The service development process set out in this policy, and the supporting methods documents, allows NHS England to make decisions on whether to routinely commission or not routinely commission new services, and on whether to change existing clinical commissioning policies and service specifications, or whether new service specifications are required.

In carrying out the service development process, NHS England applies the following **'process principles**':

- *NHS England will follow its normal good practice in making prioritisation decisions in a transparent way, documenting the outcomes at all stages of the process;*
- *NHS England will involve the diversity of stakeholders including the public and patients in the development of proposals and take appropriate account of their view;*
- *NHS England will take into account all relevant guidance; and*
- *NHS England will ensure compliance with relevant legislation including the duties set out in Equality Act (2010) and the Health and Social Care Act*

(2012). An Equality and Health Inequalities Analysis (EHIA) will be undertaken for every proposition.

When a new clinical commissioning policy or change to an existing service is proposed NHS England's default position is that the service will not be routinely commissioned until it has been assessed through the service development process. However, there are circumstances where a policy statement can be put in place to provide an interim commissioning position, which are set out in this policy.

The service development process has three phases:

- The first phase is the '**Clinical Build'**. This phase is where new or amended clinical commissioning policies and new or amended service specifications are proposed and developed. Policy propositions will need to be underpinned by a clinical evidence review. NHS England's specialised services Clinical Panel challenges and confirms whether the proposition has a sound evidence base. Service specifications do not normally require an evidence review and therefore are not normally considered by the Clinical Panel.

- The second stage is the **'Impact Analysis'** phase. This stage identifies the financial and operational impacts of moving from current pathways of care to the pathways proposed in the draft policy proposition or service specification proposition. The proposed policy or service specifications then are also subject to stakeholder testing, and public consultation.

- The third and final stage is the **'Decision'** phase. For policy propositions and service specification propositions which are cost-neutral or cost-saving, the decision on whether to approve is based on an assessment of its clinical benefit. For propositions which require additional investment and where there is not sufficient funding available to cover all interventions being proposed, the policy propositions are assessed on their likely relative clinical benefit and relative value for money. Using this information, NHS England carry out twice a year a relative prioritisation process to determine which services will be routinely commissioned.

NHS England can rapidly assess policy propositions, for example where there is an urgent clinical case and it would not be appropriate to wait for a decision to be made through the full service development process. In these circumstances a policy statement can be put in place to provide a **commissioning position** which allows interim access to the service, or to make it clear that there is no access to the service until a full assessment has been carried out. The policy may then be considered in full through the normal service development process.

The work programme, and results of the service development process, will be published on the NHS England website, to keep clinicians, patients and the public informed about: new clinical commissioning policies; revision or removal of existing clinical commissioning policies; and new and revised service specifications.

Clinical commissioning policies, and service specifications, are made for the provision of services to a cohort of patients i.e. a group of patients with similar clinical circumstances who could reasonably expect to benefit to a similar degree.

However, there are circumstances where an NHS clinician can ask NHS England for and on behalf of an individual patient to fund a treatment that would not routinely be provided by NHS England. This request could be appropriate in circumstances where a clinician considers that their patient's clinical situation is different to other patients with the same condition, and that they have greater potential to benefit from a treatment which is not routinely commissioned. This type of request is called Individual Funding Request (IFR). It is outside the scope of this policy but is considered under a separate process. Please refer to the IFR policy for details on this process.

2.2 Clinical Build Phase

2.2.1 Overview

The **'clinical build'** phase is the first stage of the service development process. The process begins with a clinician, endorsed by the most relevant Clinical Reference Group, proposing that there is a need for specialised services to routinely commission a clinical policy or service specification for the use of a particular treatment or intervention for a particular condition or patient group.

2.2.2 Clinical Build Phase for policy propositions

For policy propositions, NHS England's specialised services **Clinical Panel** assesses the preliminary policy proposal, based on the questions specified in the Methods document to identify propositions that meet the following '**qualifying principles**':

- *NHS England will only give priority to treatments or interventions where the intervention is likely to offer equal or greater benefit than other forms of care routinely commissioned by the NHS for the same patient group;*

- *While considering the benefit of stimulating innovation, NHS England will not confer higher priority to a treatment or intervention solely on the basis it is the only one available; and*

- *The intervention must be available to all patients within the same patient group, other than for clinical contra-indication.*

If the Clinical Panel determines that the preliminary policy proposal meets these criteria, it will proceed to the next part of the clinical build phase which is the '**clinical evidence review'**.

2.2.3 Evidence review for policy propositions

NICE will conduct the evidence review, form the draft policy proposition and conduct the Impact Analysis on behalf of NHS England through the Commissioning Support Programme. This approach is used for any licenced and pre-licensed medicines that

are not already being assessed by NICE, whether through a Technology Assessment, or the Highly Specialised Technology programme.

For all other policy propositions the Clinical Panel will set out the type of evidence review that is required to obtain the information that is needed to carry out the remainder of the service development process. The majority undergo an independent evidence review.

During the evidence review phase, the patient benefit **summary report** about the clinical evidence is compiled for NHS England Clinical Priorities Advisory Group (CPAG). This report is used for consideration in the Decision Phase, together with the impact analysis and consultation report produced in the Impact Analysis phase. The summary reports covers:

- The patient benefit(s) offered by the drug, device or intervention, as described in the independent review of the clinical evidence; and

- The quality of the evidence of clinical effectiveness.

The description of patient benefit should not include non-clinical factors, such as societal benefit, financial cost, affordability; and potential financial savings.

The Clinical Panel then assesses the policy proposition by considering whether the population, and subpopulation, is adequately defined; and by considering whether the policy proposition is built on the evidence base, as defined in the evidence summary; and whether the evidence presented is supportive of the proposed commissioning position.

If the Clinical Panel if satisfied that the policy proposition meets this assessment, it will proceed to the 'impact analysis' phase of the policy development process. If any areas are not adequately addressed, the Clinical Lead will be informed and the policy proposition will not proceed, unless relevant changes can be made.

2.2.4 Clinical Build phase for service specification propositions

Service specifications are also identified and proposed to NHS England by Clinical Reference Groups or the relevant Programme of Care. The Clinical Build phase is coordinated and managed by the relevant Programme of Care team.

Service specification propositions do not require an evidence review, unless specified by the Programme of Care. In those circumstances where an evidence review is undertaken, the Clinical Panel will be asked to consider the service specification proposition and the evidence review, to determine whether the proposition appropriately reflects the available evidence. If the Clinical Panel is satisfied that the proposition does reflect the evidence, it can proceed to the 'impact analysis' phase. The process is set out in *Methods: National Service Specification*.

2.2.5 Commissioning through Evaluation

There may be circumstances where a policy proposition is not supported by sufficient evidence to provide clarity about the level of clinical and/or cost-effectiveness of the intervention. In these circumstances, the policy proposition may be considered for NHS England's Commissioning through Evaluation (CtE) scheme.

The CtE scheme enables a limited number of patients to access treatments for which NHS England already has a 'not for routine commissioning' policy, but which nonetheless show significant promise for the future, on the basis that new clinical and patient experience data will be collected about the use of the treatment within a formal evaluation programme.

The data which is collected from a CtE scheme can then be considered alongside published data from research trials (where available) by the Clinical Panel, as part of the evidence review.

2.3 Impact Analysis Phase

2.3.1 Overview

The second stage of the service development process is the **'impact analysis'** phase. During this phase, the draft proposition is subject to stakeholder testing, impact assessment, formal public consultation and an equality impact assessment. A **Commissioning Implementation Plan** is developed to consider, in advance, the timing and method of implementation if the proposition is approved during the decision phase.

The impact analysis phase is coordinated and managed by the Programme of Care and concludes through a 'Gateway' managed by the relevant Programme of Care Board. For those topics evaluated through the Commissioning Support Programme, NICE will conduct the impact analysis up to the point of public consultation where the work is handed over to NHS England to lead and complete.

2.3.2 Impact Assessment

The first stage of impact analysis is the creation of an impact assessment for the policy or service specification proposition. This explores key assumptions (such as level of patient benefit), and models the financial impact of introducing the policy proposition over a 5 year period.

As a result of the impact assessment, it is possible to identify those policy propositions and service specification propositions which are likely to be cost-saving or cost-neutral, and those which will require additional investment. There is a different decision-making process depending on which category of cost implication the proposition falls into; this is explained in the 'decision phase' section below.

2.3.3 Stakeholder Testing

In addition to the impact assessment, there is a stakeholder testing phase where relevant stakeholders are identified and invited to comment on the draft proposition, providing views on the appropriate level of public consultation which should be undertaken, based on the type of proposition. This phase also includes the evaluation of the impact of the proposed policy/ service specification on equalities and health inequalities for different population groups. The National Programme of Care then produces an Engagement Report to set out the results of the stakeholder testing.

When it is decided that the policy proposition and its supporting documentation is sufficiently detailed and clear, a public consultation is conducted, the length of which varies according to the complexity of the proposition. This will set out the proposed policy or service specification and ask consultees to comment on whether all the relevant evidence has been taken into account (where applicable); whether the impact assessment fairly reflects the likely activity, budget and service impact; and to comment on any potential impact on equality and health inequalities which might arise as a result of the proposition described.

After the consultation is complete, and the responses have been analysed, changes are made as appropriate to the policy or service specification proposition to reflect

the consultation feedback. A **Consultation Report** is then produced, to summarise the nature of the consultation responses and explain how NHS England has responded to the consultation.

Once the Programme of Care team is content that the proposition and the related suite of supporting documents are complete, that effective patient and public engagement has been undertaken, and the financial impact of the proposition is fully defined, then the policy or service specification proposition will proceed to the Decision Phase.

Sometimes policy or service specification propositions do not proceed to the Decision Phase. This may occur, for example, when the National Programme of Care Board decides that the evidence review undertaken did not evaluate the full evidence base, or when new evidence on the proposed development is published and therefore needs to be considered. In these circumstances the policy or service specification proposition may be re-routed to the Clinical Build phase or the Impact Analysis phase for further assessment.

2.4 Decision Phase

2.4.1 Overview

The final phase of the service development process is the '**Decision Phase'.** The approach used in the Decision Phase differs depending on whether the proposition is cost-neutral or cost-saving, or if it requires additional investment.

Where there is sufficient funding to cover all of the policy and service specification propositions which require investment, each proposition will be considered in the same way as for cost-neutral and cost-saving propositions. The process used in these circumstances is set out in 2.4.4.

Where there is not sufficient funding available to cover all of the policy and service specification propositions, there is a three-stage process for deciding which of the propositions that are not cost-neutral or cost-saving will be funded. This allows for the propositions to be assessed and prioritised in the context of NHS England's overall priorities and available funding.

Generally, policy and service specification propositions that require investment are considered as part of the relative prioritisation process which takes place twice a year. Cost-neutral propositions, cost-saving propositions, and urgent cases can be considered in between relative prioritisation rounds.

At the end of the decision phase clinical commissioning policies and service specification will be either "routinely commissioned" where propositions have been agreed for investment; or "not for routine commissioning" where they have not been agreed for investment.

2.4.2 Propositions that require investment: relative prioritisation process

In circumstances where there is not sufficient funding available to cover all of the policy and service specification propositions which require investment, a three-stage process is used for deciding which of the propositions which are not cost-neutral or cost-saving will be funded. This process is run twice a year, with the level of funding available at each relative prioritisation round set at the discretion of NHS England, having regard to the other demands on its resources.

The first stage of the process is the **relative prioritisation process.** Through this process, CPAG forms recommendations on the relative prioritisation of the policy proposals using the following **'prioritisation principles':**

- *NHS England will normally only accord priority to treatments or interventions where there is adequate and clinically reliable evidence to demonstrate clinical effectiveness;*

- *NHS England will normally only accord priority to treatments or interventions where there is measureable benefit to the relevant group of patients;*

- *NHS England may agree to fund interventions for rare conditions where there is limited published evidence on clinical effectiveness;*

- *The treatment or intervention should demonstrate value for money.*

CPAG assesses the relative clinical benefits of the policy and service specification propositions. Once the relative benefits are confirmed by CPAG, the relative cost is then considered: cost is defined as *the cost to NHS England over five years, divided by the number of patients treated in that five year period.* A cost/benefit matrix (see Figure 1, below) is used which leads to a ranking in five groups, from highest to lowest priority. Full detail of this process is described in the Methods document.

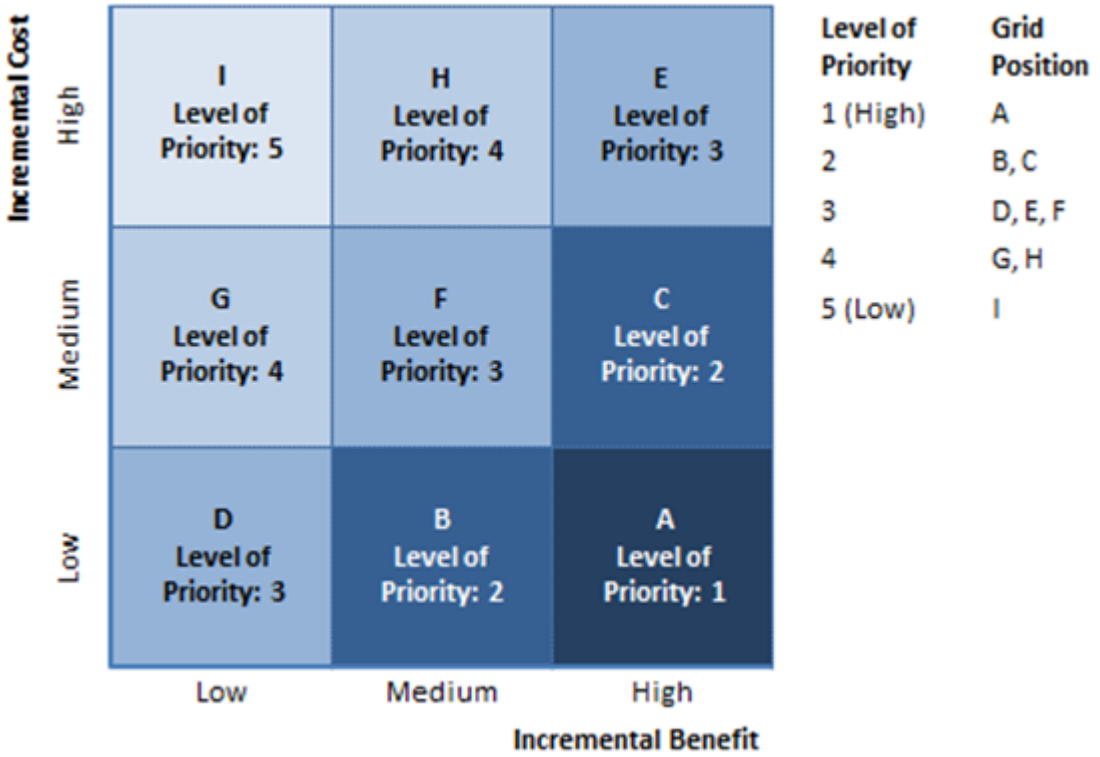

Figure 1: 9-box matrix

Before making its final recommendations, CPAG considers whether any adjustments should be made to the rankings, based on the extent to which the policy proposition may significantly support NHS England's '**strategic principles**', i.e. to what extent does the drug, device or intervention significantly:

- *Benefit the wider health and care system?*
- *Advance parity between mental and physical health?*
- *Offer the benefit of stimulating innovation?*
- *Reduce health inequalities and promote equality?*

SCOG receives CPAG's final ranked groupings, and information about the propositions' total budget impact year-on-year, over five years. Based on the level of available funding, SCOG establishes how many of the proposition groups can be recommended for routine commissioning.

Once this process is complete, SCOG makes a recommendation to the SSCC about the outcome of the prioritisation process, stating which prioritised policy and service specification propositions should be for routine commissioning, and those which should not be routinely commissioned.

The final stage of the process is that SSCC makes the final investment decision about the treatments or services.

Policy propositions and service specifications which are not agreed for investment may be re-entered into the Service Development process.

In total, a policy or service specification proposition may be considered in a relative prioritisation process on up to three occasions (including the original prioritisation round), thereby providing the opportunity to address any gaps in the supporting clinical evidence, and / or to revise a high financial or operational impact identified through the Clinical Build or the Impact Analysis phase.

If a proposition still has not been agreed for routine commissioning after three attempts, the final policy position must be to not routinely commission the service.

2.4.3 Propositions that require new investment: outside the relative prioritisation process

There may be occasions where NHS England considers funding a policy or service specification proposition outside the twice-yearly relative prioritisation process. This may occur when it is determined that, on the basis of the evidence review (where applicable) and impact assessment, that the proposition fits the following criteria:

- It is clinically effective, and demonstrates potential for such an exceptional degree of improved patient outcomes that it would be unreasonable for NHS England to delay a consideration of the proposition until the next prioritisation round; and

- It is affordable to fund outside of a planned prioritisation round; and

- It would have been highly likely to have been supported by NHS England in the last prioritisation round, with clear indication of how it would have been ranked relative to other service developments.

NHS England may also fund a new policy or service specification where it constitutes an investment that will allow NHS England to meet NHS Constitution delivery requirements.

In these circumstances, SCOG is provided with the summary of the proposition, and CPAG's recommendation. SCOG can then make a decision to approve the proposition for routine commissioning, or decide that the proposition should not be routinely commissioned as the proposition does not have sufficient clinical merit.

SCOG may wish to request more evidence of the benefit to the relevant patient group in order to make their decision. They may decide that, while there may be clinical merit in funding the proposition, it will not fund it at that point in time as it is not affordable at that point in time, or does not otherwise have sufficient priority according to NHS England strategic priorities. In this circumstance, the proposition would be reconsidered as part of the next prioritisation round.

2.4.4 Propositions that are cost-neutral or cost-saving

Propositions that are cost-saving or cost-neutral do not need to go through the relative prioritisation process. Propositions with a small budget impact will, for these purposes, be considered as cost-neutral.

In these instances, CPAG re-assesses the propositions against the commissioning qualifying principles (as noted in 2.4.2 and in the Annex) to reconfirm that they qualify.

CPAG will then consider all relevant documentation relating to the policy proposition or service development in order to reach an overall judgement on whether the strength of the evidence of the clinical benefit to the relevant patient group supports a recommendation for routine commissioning or not for routine commissioning.

CPAG will then make a recommendation to the SCOG, which has decision-making responsibility for cost-neutral and cost-saving policy and service specification propositions. SCOG will consider whether they agree with CPAG's recommendations by assuring that CPAG has followed the correct process, and that their decision-making is consistent with the stated principles. Once SGOG has made their final decision, the SSCC is notified for information.

2.5 Publication of outcome of the service development process

Once a final decision has been made on whether the policy proposition or service specification proposition is 'for routine commissioning' or 'not for routine commissioning', the decision and relevant documentation will be published on the NHS England website within the relevant Programme of Care and Clinical Reference Group section.

2.6 Interim Clinical Commissioning Policy Statements

2.6.1 Policy Statements

There may be circumstances in which NHS England wishes to implement a commissioning policy ahead of the final Service Development decision. In these circumstances, NHS England could issue an interim Clinical Commissioning Policy Statement i.e. a clinical commissioning policy which would apply in a defined interim period until a final commissioning position has been reached through the service development process.

These policy statements will go through the clinical build phase, including evidence review, the impact analysis phase and the decision phase. However, they will not be subject to public consultation.

Following consideration by CPAG in the decision phase, NHS England may publish a policy statement defining NHS England's policy position to routinely commission or not to routinely commission for a stated period.

Once the policy statement for the interim commissioning position is in place, a full clinical commissioning policy may be developed. Once the service development process has been completed, the new clinical commissioning policy would replace the previous policy statement.

2.6.2 Urgent policy statements

One of the circumstances in which NHS England can implement a policy statement for interim use is when a clinical commissioning policy needs to be developed, but the clinical situation of one or more patients within the eligible patient group is so urgent that it would not be appropriate to wait for a decision to be made through the full service development process, i.e. the patient(s) are at risk of imminent significant and irreversible clinical deterioration.

In such circumstances, the urgent policy proposition may proceed more quickly through the clinical build and the impact analysis phases. This means that the proposition would be subject to a **light touch evidence review**, whereby the Clinical Panel will consider the evidence provided by the clinician as part of the preliminary policy proposition (which must at least comprise the top three publications on the proposed intervention) and a **rapid impact assessment** will be carried out without public consultation.

To be assessed through this process, the following criteria will need to be met:

- There is no NHS England clinical commissioning policy or agreed interim commissioning position defined through a published policy statement;

- There is no NICE Technology Appraisal for the treatment and indication;

- The treatment is urgent because one or more patients within the eligible patient group is at risk of suffering imminent significant and irreversible clinical deterioration (life threatening or major loss of function) before the date on which a decision would be made on a full service development proposition within the next planned relative prioritisation round); and

- The evidence provided demonstrates that that the requested treatment will benefit the patient group and, on a more detailed analysis, is likely to demonstrate value for money.

For those urgent policy statements which meet these criteria, Clinical Panel will recommend to introduce the proposed service development on an interim basis through an '**urgent policy statement'**.

The urgent policy statement may be for routine commissioning for a defined period of time. If this is the case, the proposition will be taken through the full service development process if it is not the subject of a NICE appraisal.

If the urgent policy statement is 'not for routine commissioning' the proposition still may be taken through the service development process, if Clinical Panel determines that there is adequate clinical evidence to justify developing the clinical build.

2.7 Rare Diseases

Every year a small number of policy and service specification propositions are likely to relate to treatments for rare conditions. These treatments may be cost-saving or cost-neutral, or may require new investment. In recognition of the fact that the evidence base for treatments for rare conditions may be more limited, CPAG may agree to recommend the prioritisation of such treatments and service specifications where there is limited published evidence on clinical effectiveness.

For policy and service specification propositions relating to highly specialised services for rare conditions, an additional summary from the Rare Diseases Advisory Group (RDAG) will be provided to CPAG, to describe the feasibility of generating evidence of the clinical benefit to the relevant patient group given the rare nature of the condition.

The RDAG report also describes the feasibility of generating additional clinical evidence through the provision of the proposed intervention compared with the evidence presented to support the policy or service specification proposition. Where it is deemed that the generation of further evidence is feasible, and the evidence presented is insufficient, CPAG will be advised accordingly. Conversely, if the limited evidence available is considered to be reflective of the rarity of the condition, and generation of additional evidence is deemed unfeasible, CPAG would be provided with that advice.

This is to inform CPAG consideration of the proposed intervention or service specification in relation to other proposals considered within the commissioning

round, and consequently its recommendations to SCOG as to whether the proposed intervention or service specification should be routinely commissioned or not routinely commissioned.

3 Annex

3.1 Summary of principles used in Service Development policy

Process Principles

- NHS England will follow its normal good practice in making prioritisation decisions in a transparent way, documenting the outcomes at all stages of the
- NHS England will involve the diversity of stakeholders including the public and patients in the development of proposals and take appropriate account of their view;
- NHS England will take into account all relevant guidance
- Compliance with the duties set out in the Equality Act (2010) and Health and Social Care Act (2012) by delivery of an equality

Qualifying principles

- NHS England will only give priority to treatments or interventions where the intervention is likely to offer equal or greater benefit than other forms of care routinely commissioned by the NHS for the same patient group;
- While considering the benefit of stimulating innovation, NHS England will not confer higher priority to a treatment or intervention solely on the basis it is the only one available; and
- The intervention must be available to all patients within the same patient group, other than for clinical contra-indication.

Prioritisation principles

- NHS England will normally only accord priority to treatments or interventions where there is adequate and clinically reliable evidence to demonstrate clinical effectiveness
- NHS England will normally only accord priority to treatments or interventions where there is measureable benefit to the relevant patient groups
- NHS England may agree to fund interventions for rare conditions where there is limited published evidence on clinical effectiveness
- The treatment or intervention should demonstrate value for money

Strategic principles

- Does the drug, device or intervention significantly:
- Benefit the wider health and care system?
- Advance parity between mental and physical health?
- Offer the benefit of stimulating innovation?
- Reduce health inequalities and promote equality?

3.2 Summary of NHS England decision-making and advisory bodies involved in the service development process

Body	Function
Clinical Panel	Provides assurance that clinical advice is built on a sound evidence base
National Programme of Care Board	Provides leadership and oversight of the service development work programme
Rare Diseases Advisory Group	Makes recommendations to the CPAG about the commissioning of highly specialised services
Clinical Priorities Advisory Group	Makes recommendations to SCOG on the investment or disinvestment on service change
Specialised Commissioning Oversight Group	Determines the available resources and the commissioning implications of the service change
Specialised Services Commissioning Committee	Advise NHS England Board on development and implementation of strategy for specialised commissioning, agree specialised commissioning priorities and work programmes and receive assurance that these are delivered.