NHS Devon

NHS Devon Clinical Policy Recommendation Committee

Annual Report

2023-24

One Devon

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Contents

Dr Glen Allaway – Chair's Introduction

The CPRC has met 3 times in the year 2023-24 rather than the scheduled 6 times. The Committee only meets when the secretariat has produced the briefing documentation and papers to convene a meeting, acting in response to inputs into the process (as described elsewhere in this annual report) which have largely been unchanged. Clearly there are many possible reasons why this may occur, and I think it is necessary to recognise an ICB that is going through a period of significant and prolonged reorganisation. The financial challenge affecting the Devon health system has meant the there is considerable difficulty progressing plans that require financial investment in services. This has been compounded by organisational changes that have been enforced on ICBs as a result of ministerial action. Nevertheless, the Committee has recommended 8 new or updated commissioning policy positions for adoption by the ICB across a diverse range of clinical areas and in response to a range of policy drivers. It is important that the Committee has continued to meet to give a mechanism which enables the ICB to meet its statutory obligations in relation to establishing policy positions.

In my Chair's introduction last year I encouraged interested clinicians to come forward to join the Committee and support us to continue this important work on behalf of the patients we serve. This report notes that there continues to be vacancies on the Committee both for primary and secondary care clinicians and the steps that are being taken to try and address these. It is through the commitment of the current members that we have been able to hold meetings that have satisfied the quoracy requirements of the Terms of Reference, and I extend my heartfelt thanks to the relatively small number of individuals that enable this important function to continue. I am hopeful that next year I can write an introduction to a report that lists the new members we have welcomed during 2024-25.

The central challenge that the CPRC helps the ICB and the wider Devon health system meet will not change. There will continue to be more demand for healthcare, new and expensive treatments, and constrained funding and resources in the local NHS. By recourse to an appraisal of evidence of effectiveness, the input of clinical opinion and analysis of resource implications of various options, CPRC will play a vital role in guiding the use of precious resources to obtain good value healthcare for the people of Devon.

Dr Glen Allaway
Chair, Clinical Policy Recommendation Committee

Introduction

Through the Clinical Policy Recommendation Committee NHS Devon Integrated Care Board (ICB) discharges its responsibilities for making local decisions about the funding of medicines and treatments in the NHS.

The commissioning organisation has a legal duty to have in place arrangements for making decisions and adopting policies on whether particular health care interventions are to be made available for patients for which the commissioner is responsible. This duty includes the requirement to provide a written statement of the reasons for a general policy on whether a specific intervention is to be made available.

The Committee makes recommendations to the ICB Executive, or appropriate group/individuals with delegated authority, for ratification following discussion of the clinical effectiveness, cost effectiveness and budgetary impact issues.

The Committee makes recommendations to members of the ICB on whether specific treatments represent good value, appropriate, evidence-based choices for adoption into primary care treatment plans via the Formulary and clinical management pathways.

This annual report gives an account of the activity and governance of the Clinical Policy Recommendation Committee in 2023-24.

The process

Committee process and meeting arrangements

The process and organisation of the committee is run by the Clinical Effectiveness Team, NHS Devon and is guided by the National Prescribing Centre principles and rationale for local decision making [now part of the National Institute for Health and Care Excellence (NICE)].

The Terms of Reference of the Committee are included in **Appendix 1**.

Three meetings of the Committee were convened, the agendas for which are shown in **Appendix 2**.

The Committee members' attendance is shown in **Appendix 3**, along with details of guests who attended for the discussion of specific items or to support the work of the Committee, and those attending in the capacity as an observer.

Declaration of Interests

The Clinical Policy Recommendation Committee operates a formal process for the declaration and handling of conflicts of interests.

Committee members, secretariat, guests and clinical specialists are required to complete a Declaration of Interests form prior to the start of each meeting. This specifies the drug, treatment or technology due to be considered along with details of any comparative products, and the respective pharmaceutical company or manufacturer. It also seeks to capture any interests relating to particular clinical areas where non-drug items are due to be discussed.

Details are also captured and recorded of any other healthcare industry contact members have had since the last meeting.

All declared interests are considered by the Chair and appropriate disclosures made to the Committee at the beginning of the meeting. Where there are no interests to declare, a 'nil' return is required.

Following consultation with other members the Chair will decide to what extent a member who has declared an interest should participate in the discussion and determination of the issue. It is recognised that individuals may have some interaction with the healthcare industry and while these should be declared it does not necessarily preclude membership and involvement in discussions.

Members of the Committee should also observe the Nolan Principles of Public Life, as set out in the Constitution.

A record of declared interests is kept by the secretariat and full details are made publicly available in the minutes of the meeting. There were no declared interests at any of the meetings held this year.

Changes to membership and current vacancies

Susan Masters, Deputy Chief Nursing Officer stepped down from the Committee in December 2023.

Two long-standing clinical voting member vacancies remain. There are also outstanding secondary care clinical advisory member vacancies.

The Terms of Reference were reviewed when the ICB formed and reflect the changing context in the legislation which refers to clinical leadership and sets out an aspiration to include a wider range of professionals. They permit a wider group membership, potentially including both medical and non-medical clinical colleagues. There is also provision for additional secondary care advisory members, who may be drawn from across all secondary care providers who are part of the ICS and could include any clinical speciality (both medical and non-medical). However there have been significant challenges in filling the outstanding vacancies on the Committee despite approaches via Trust Medical Directors and the Associate Medical Director for Primary Care.

These membership issues and the risks they pose to the resilience and quoracy of the Committee, and therefore its ability to fulfil its functions on behalf of the ICB, have been escalated within the organisation via the Chief Medical Officer and the Executive

team. A business case has subsequently been progressed via the ICB's Vacancy Control Panel to support filling clinical voting member vacancies and ensure committee resilience. However challenges remain with filling secondary care advisory member roles on the committee.

Public Involvement and the Clinical Policy Engagement and Consultation Panel

The Committee has two voluntary lay public members, who help to ensure the Committee balances the healthcare needs of specific patient groups with the requirement to resource a comprehensive health service. They serve to assist with the broader public perspective during the decision-making process, ensuring that the public interest is acknowledged and taken into account when the Committee makes its decisions.

The lay public members are also integral to the Clinical Policy Engagement and Consultation Panel, which exists to support the ICB to determine the need for any further engagement or formal public consultation on recommendations made by the Clinical Policy Recommendation Committee.

Meeting approximately three weeks following the Committee, the lay member led panel routinely considers the wider public interest issues to determine the need for any further engagement or formal public consultation on the policy recommendation.

This process and any resulting engagement or consultation precedes the ICB executive decision-making group taking a final decision on whether to ratify a clinical policy recommendation.

Regular updates are reported to the Clinical Policy Recommendation Committee as a standing agenda item. In addition, the Committee received the Clinical Policy Engagement and Consultation Panel (CPEC) Annual Report 2022-2023.

This noted that:

- The panel has continued its function to support the organisation in determining the need for any further engagement or formal public consultation on clinical policy recommendations made by the Committee, prior to a final decision being taken by the organisation.
- Two panel meetings were held during the shorter reporting period, considering 10 clinical policy recommendations across a range of topics. Specific recommendations were made on the proposed updates to the policies for Assisted Conception and Continuous Glucose Monitoring (CGM).
    - When the proposed update to the Assisted Conception policy was considered, the subjective nature of a 'stable' relationship was discussed, along with the appropriateness of a clinician making a judgement on this to determine eligibility to access assisted reproduction. There was concern that the definition was open to interpretation, and therefore potential challenge. The ICB was asked to consider further engagement work on this, within the context of other non-clinical factors relating to the social nature of relationships, which are a growing area and are broader than clinical factors

for infertility. The ICB took a decision to approve the policy amendment, noting that fertility specialists indicated that this was workable from their perspective and was consistent with the majority of other ICB areas. However, the wider issues relating to non-clinical and societal factors were flagged with the communications team to scope and consider how future engagement and/or consultation might be undertaken in this area.

- Consideration of the updated policy for CGM highlighted the need for the previously produced clinical policy patient support information to be reviewed for ongoing relevance and updated as needed to support the publication and communication of any changes to commissioning policy.

Quality and Equality Impact Assessment (QEIA)

All Clinical Policy Recommendation Committee policy recommendations are subject to a Quality and Equality Impact Assessment (QEIA), which is reviewed and approved by the ICB's QEIA Panel, as an integral step in the process of policy formation.

The QEIA tool assesses the impact on quality from the perspective of the patient (Safety/ Effectiveness/ Experience); seeks to review and consider system and other impacts as a result of the proposed change and considers Equality as part of the NHS's statutory duty of healthcare delivery.

A flowchart showing the clinical policy governance and approval process is included in **Appendix 4**.

Reporting

The Committee makes clinical policy recommendations to the ICB Executive, or appropriate group/individuals with delegated authority, for approval following discussion of the clinical effectiveness, cost effectiveness and budgetary impact issues.

Ratification of any other formal matters arising from the Committee, including changes to terms of reference or process, is similarly undertaken by the ICB Executive, or appropriate group/individuals with delegated authority.

Reporting of any identified risks is undertaken by the Clinical Effectiveness Governance Manager in accordance with the organisation's risk reporting procedures.

Appeals process

The Committee operates an appeals process as set out in **Appendix 5**.

The grounds for appeal are (1) whether fair process has been followed by the Clinical Policy Recommendation Committee in making its recommendation and (2) a material inaccuracy in or omission from the evidence considered by the Committee that would make a substantive difference to the appraisal in relation to the medicine or treatment on which a recommendation was made.

An appeal may be made by the original applicant(s). An applicant is considered to be a clinician who has participated in the process leading to the original recommendation, either through submitting written evidence and clinical views at the appropriate times during the preparation of Committee papers or attending the Committee meeting at which the recommendation was made.

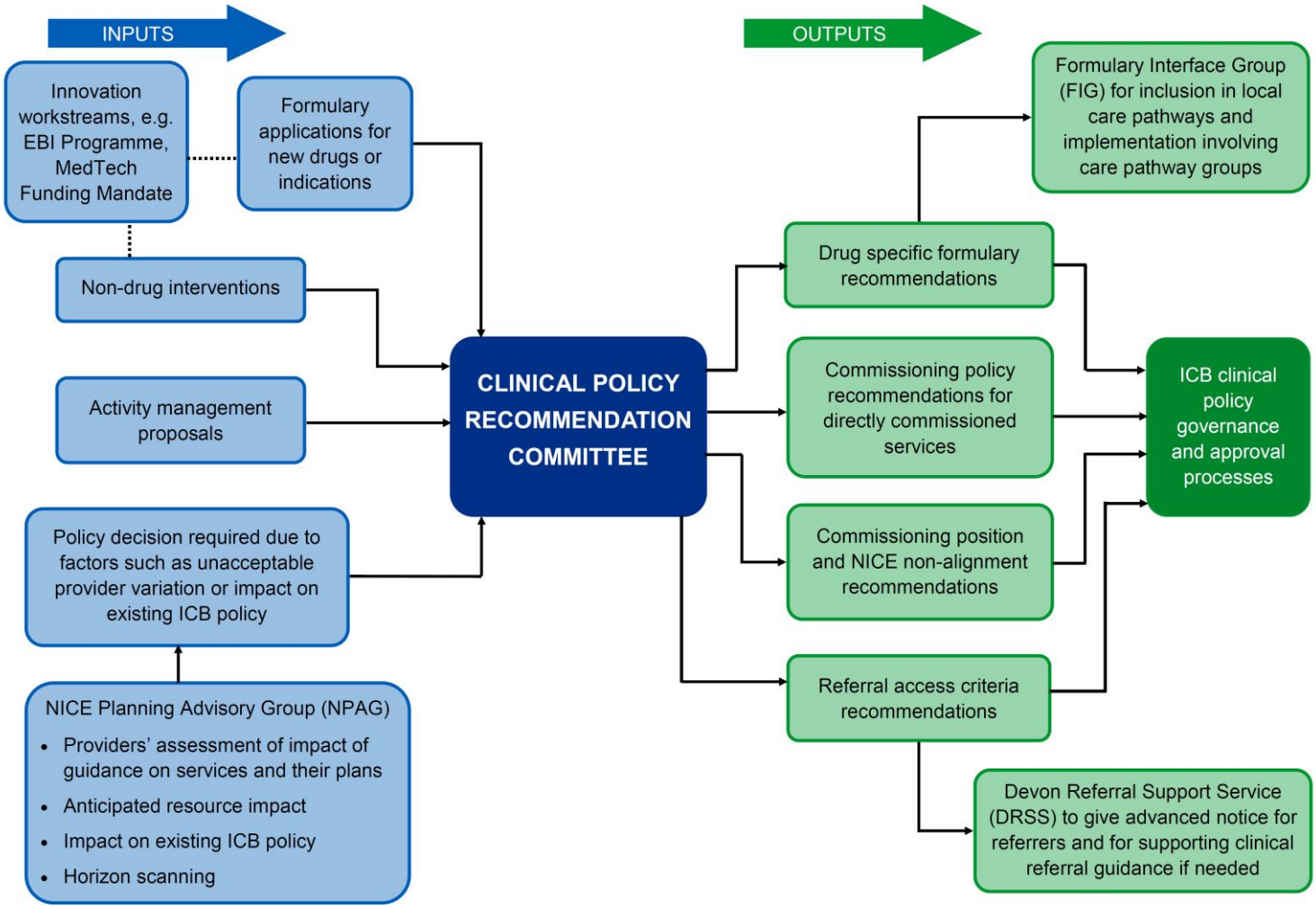
Appeals which are upheld, by a panel of people independent of the original decision, are referred back to the Committee for reconsideration of the original application and the findings of the panel. No appeals have been received during 2023-2024.

The work programme

The work programme of the Clinical Policy Recommendation Committee is managed by the Clinical Effectiveness Team, NHS Devon.

The work programme is proactive and responsive to a number of sources as shown in figure 1, below.

Figure 1: Clinical Policy Recommendation Committee inputs and outputs



Devon Investment Process

A Devon Investment Process has been agreed for the management and approval of investment across the Devon system to ensure that financial recovery is sustained. There has been consideration and discussion between finance, strategy, and clinical effectiveness colleagues of the application of this process to the ICB's process for clinical commissioning policy development.

The principles of both are consistent with one another, but there has been consideration of the practicalities of building this in as a key stage of the process in a meaningful way for the organisation, i.e. utilising health technology assessment scoping work to outline clinical, cost effectiveness and budget impact considerations. A proposal is being worked up accordingly outlining how routine consideration by the Devon Investment Group will be incorporated into the ICB's processes for clinical policy development, with overall oversight and ratification of the consequences of decisions to progress or not to progress work by the Executive Team.

Academy of Medical Royal Colleges Evidence Based Interventions (EBI) Guidance

The Committee work programme has continued to respond to the Academy of Medical Royal Colleges (AoMRC) Evidence Based Interventions (EBI) guidance, with 2 policy recommendations having been developed with regard interventions included in list 3 during 2023-24.

The Clinical Effectiveness Team has engaged with the consultation on the revised approach to the development of subsequent EBI guidance and proposals, including opportunities to be involved with the EBI Commissioner Forum which has been established as a source of commissioner advice to NHS England and the AoMRC.

It is anticipated that this will continue to be a workstream which will contribute to the work programme of the Committee where clinical policy development is an appropriate output.

NICE Planning Advisory Group (NPAG) updates and annual report

The Committee has continued to receive regular updates as a standing agenda item from the ICB's NICE Planning Advisory Group (NPAG) process. This includes receipt of the minutes and verbal reports from the Chair on the commissioning implications of published Technology Appraisals guidance and other guidelines.

The Committee received and noted the 2022-2023 NICE Planning Advisory Group (NPAG) Annual Report, in particular that:

- It provides assurance of how the organisation, via NPAG, fulfils its statutory commissioning responsibilities in respect of mandatory NICE Technology Appraisals and Highly Specialised Technologies and considers the resource and service implications for newly published NICE guidance and guidelines.

- Over the past year, NICE published 201 new and updated guidelines. Mandatory guidance accounts for nearly half of NICE's published guidance. There has also been an increase in the average number of pieces of guidance considered per NPAG meeting. The general trend is also for a year-on-year increase in the volume of guidance considered by NPAG since it was formed in 2013.
- NPAG routinely considers NICE forward plans of guidance expected to be issued over the next three months and highlights those with the potential to have a significant resource, cost implication or other impact, such as on existing commissioning policy or other commissioning workstreams
- The team produces a monthly NICE bulletin detailing newly published and updated NICE guidance for the month, which is published and widely disseminated for local awareness. It also includes a list of current open NICE consultations for the benefit of those that may be interested in engaging upcoming topics.
- There is also ongoing engagement by the team with national guidance and initiatives which link with NICE guidance to be able to support the organisation with relevant actions – such as the MedTech Funding Mandate and the Evidence Based Interventions Programme.
- The group welcomed a number of observers to their meetings to enhance their understanding of the group and the ICB's NICE processes for the benefit of their roles. These were from a range of teams within NHS Devon, as well as Foundation Pharmacists from Royal Devon University Healthcare NHS Foundation Trust.
- A noted growth area for NICE is the publication of Healthcare Technology Evaluations (HTEs), which set out conditional recommendations while more evidence is generated to address any uncertainties. The aim is to support quicker access to promising health technologies that address national unmet need. The group supports the ambition to improve patient care through adoption of this approach; however, is also mindful of the potential challenges for the local health system and implications for patients in Devon if technologies conditionally supported are subsequently not recommended for routine adoption in the NHS.
- The planned delegation of NHS England functions to ICBs may have an impact on the future business of the group, with an increase in the areas for which the ICB is the responsible commissioner shaping the volume, depth and content of the papers brought to the meeting, as well as the discussion, implications and the subsequent actions which may be required.

Devon Formulary Interface Group (FIG) annual report

The Committee received the Devon Formulary Interface Group (FIG) Annual Report 2022-2023, noting that:

- The FIG delivers the Devon Formulary to promote prescribing which is safe, clinically appropriate, and cost-effective in both primary and secondary care by providing guidance on locally recommended treatment choices. It is also responsible for deciding whether a medicine requires formal "Shared Care" guidelines and for agreeing the clinical content of those guidelines.

- The Devon Formulary has a bespoke website which is geographically tailored to reflect the decisions of the Devon FIG. Although the S&W and N&E Devon FIGs merged in February 2021, the two presentations of the Formulary website have been retained whilst content is reviewed, and recommendations harmonised.
- The focus of the Devon FIG has been to maintain a reliable and up-to-date resource while considering every opportunity to harmonise recommendations across both presentations. Devon Formulary recommendations have been steadily converging, and recommendations between localities are now more similar than different. Although a Devon-wide perspective is already adopted when developing or updating formulary guidance and recommendations, some variation remains for variety of reasons. This supports a consistent approach to prescribing across the county, whilst promoting safe, effective, and economic prescribing in primary and secondary care.
- The FIG considered several individual product applications which provided financial savings (totalling almost £1million) and/or clinical benefits (such as products to support patients with swallowing difficulties or those requiring enteral feeding).
- The FIG agreed formulary entries for three treatments which the CPRC had recommended for commissioning. These were included in the formulary once the final policy had been ratified. As were two ICB ratified CPRC recommendations not to routinely commission a treatment.
- In order to demonstrate compliance with the organisation's statutory obligation to fund and resource medicines and treatments recommended by NICE guidance; 78 Technology Appraisals and 5 Highly Specialised Technologies were added to the Devon Formulary during the period of the annual report.
- The Formulary also plays an important role in supporting safe use of medicines. The FIG considered advice for treatments in MHRA Drug Safety Updates and in letters and drug alerts sent to Healthcare Professionals.
- Website traffic has increased substantially year on year since its launch and the clinical content has expanded to meet more of the needs of users. As a result, the underpinning infrastructure requires upgrading; a new Devon Formulary and Referral website is in development. The new website will provide improved features such as advanced searching functionality, a browsable A-Z drug list, and a revitalised design.
- The Devon Formulary and Referral App was no longer able to support the volume of information and the frequency of updates required, it was therefore withdrawn in the summer of 2022 as the new website will be optimised for use on mobile devices.

Communication

Commissioning policies

All commissioning policies are made publicly available on the NHS Devon website.

A communication framework is in place for the timely and effective dissemination of concise, targeted information to the key individuals and groups who need to know about the decisions.

This operates in accordance with the principles previously agreed with the Planned Care Control Centre to ensure clarity of the respective routes and responsibilities for communication across the local health community.

The approach ensures effective internal communication with relevant colleagues to plan communications, and promotes a consistency of approach to ensure accuracy, clarity, timeliness, and the appropriateness of information shared.

The agreed communication process also ensures that the NHS Devon patient experience team is fully aware of the publication of a clinical policy and any other relevant or supporting information to enable them to be prepared and best able to respond to any patient or public queries.

Governance documentation

Full details of the Clinical Policy Recommendation Committee including governance documentation is publicly accessible via the NHS Devon website. This includes minutes of meetings, the terms of reference, the appeals process and annual reports.

Commissioning recommendations

Recommendations made by the Clinical Policy Recommendation Committee in 2023-24 and approved by the ICB are as detailed below:

Topic	Date of CPRC recommendation	Date of publication	Final commissioning decision
High Intensity Focussed Ultrasound (HIFU) for recurrent prostate cancer	26 April 2023	29 August 2023	High Intensity Focussed Ultrasound (HIFU) for recurrent prostate cancer is *not accepted* for routine commissioning in Devon. *Review and update of previous policy in light of NICE NG131 on Prostate cancer.*
Cryotherapy for recurrent prostate cancer	26 April 2023	29 August 2023	Cryotherapy for recurrent prostate cancer is *not accepted* for routine commissioning in Devon. *Review and update of previous policy in light of NICE NG131 on Prostate cancer.*
Botulinum Toxin A for the management of focal hyperhidrosis	26 April 2023	16 November 2023	The routine commissioning of botulinum toxin A for the management of hyperhidrosis is only accepted in Devon for patients with severe axillary hyperhidrosis. Patients must have a Hyperhidrosis Disease Severity Scale (HDSS) score of 3 or 4 (sweating is barely tolerable/intolerable and frequently/always interferes with daily activities) despite at least six weeks of topical aluminium chloride and self-management strategies, AND a resting sweat production of at least 100mg/5minutes (per axilla). *Updates and replaces the previous policy on focal hyperhidrosis which was considered to no longer be reflective of clinical practice at providers within Devon. Updated guidance for clinicians on topical and oral treatments for the management of hyperhidrosis is included in the Devon Formulary.*

Topic	Date of CPRC recommendation	Date of publication	Final commissioning decision
Lurasidone for schizophrenia in adults	28 June 2023	29 September 2023	The commissioning of Lurasidone is accepted in Devon for the management of schizophrenia in adults where patients have not responded to, or not tolerated, separate trials of amisulpride AND aripiprazole; OR QTc prolongation has been identified AND the patient has previously not responded to, or not tolerated, aripiprazole. *Review and update of previous policy for lurasidone for schizophrenia following an application from local specialists to use lurasidone later in the treatment pathway.*
Lurasidone for schizophrenia in children and adolescents	28 June 2023	29 September 2023	The commissioning of lurasidone is accepted in Devon for the management of schizophrenia in children and adolescents aged 13 to 17 years where previous treatment with aripiprazole was ineffective OR not tolerated. For patients initiated on lurasidone under the criteria of this policy who later transition to adult mental health services within Devon and require continued treatment with an antipsychotic for schizophrenia, lurasidone will continue to be commissioned for that individual. *Consideration of the use of lurasidone for schizophrenia in children and adolescents at the same time as review of the previous policy for lurasidone for schizophrenia (in adults).*
Breast Implant Removal and Replacement	6 September 2023	29 February 2024	Confirms the circumstances in which breast implant removal and replacement is commissioned in Devon. *Review and update of previous policy with regard to Academy of Medical Royal Colleges Evidence Based Interventions Guidance on the removal and replacement of breast implants.*

Topic	Date of CPRC recommendation	Date of publication	Final commissioning decision
Circumcision	6 September 2023	29 February 2024	Confirms the circumstances in which circumcision is commissioned in Devon. *Review and update of previous policy with regard to Academy of Medical Royal Colleges Evidence Based Interventions Guidance on penile circumcision in patients under the age of 16 years.*
Botulinum Toxin for urinary incontinence due to detrusor overactivity	6 September 2023	9 September 2023	The routine commissioning of bladder wall botulinum toxin injection for use in adult male and female patients with urinary incontinence due to detrusor overactivity is accepted in Devon, when used in accordance with the relevant NICE clinical guideline. *No clinical change. Minor amendments to the policy rationale only for governance purposes to acknowledge that CG171 on Urinary incontinence in women has subsequently been updated by NG123 on Urinary incontinence and pelvic organ prolapse in women and to recognise changes to some of the specialised commissioning arrangements since the ICBs were formed.*

Conclusion

Through the Clinical Policy Recommendation Committee, NHS Devon ICB has discharged its responsibility for making local decisions about the funding of medicines and treatments for patients in Devon.

The Committee has considered evidence assessments and reports resulting in 8 new or updated commissioning policy recommendations in 2023-24.

The items considered by the committee resulted from a range of inputs, including updated NICE guidance, Academy of Medical Royal Colleges Evidence Based Interventions Guidance, acknowledged changes in clinical practice, and requests from local clinicians and NHS colleagues for treatments to be considered to provide clarity on their availability for patients in Devon.

The Committee secretariat will work with the Devon Investment Process groups to evolve mechanisms through which clinical service developments are prioritised within the Devon health system identifying the need for any commissioning policies to compliment these plans.

The Terms of Reference include scope for both medical and non-medical clinical members, along with provision for additional secondary care advisory members from across the ICS from any clinical speciality (both medical and non-medical).

Despite this, there have been significant challenges in filling the outstanding vacancies on the Committee, despite approaches via trust Medical Directors and the Associate Medical Director for Primary Care to facilitate expressions of interest.

These membership issues and the risks they pose to the resilience and quoracy of the Committee, and therefore its ability to fulfil its functions on behalf of the ICB, have been escalated within the ICB via the Chief Medical Officer and the Executive team. A business case has subsequently been progressed via the ICB's Vacancy Control Panel to support filling clinical voting member vacancies and ensure committee resilience. However challenges remain with filling secondary care advisory member roles on the committee.

Appendix 1

NHS Devon

Clinical Policy Recommendation Committee Terms of Reference

Purpose

The Clinical Policy Recommendation Committee exists to enable the Integrated Care Board (ICB) for Devon to discharge its responsibilities for making local decisions about the funding of medicines and treatments in the NHS.

The commissioning organisation has a legal duty to have in place arrangements for making decisions and adopting policies on whether particular health care interventions are to be made available for patients for which the commissioner is responsible. This duty includes the requirement to provide a written statement of the reasons for a general policy on whether a specific intervention is to be made available.

Role

To make policy recommendations to the ICB Executive Committee, or appropriate group with delegated authority, for ratification following discussion of the clinical effectiveness, cost effectiveness and budgetary impact issues.

Responsibilities

- To make recommendations to the to the ICB Executive Committee, or appropriate group with delegated authority, on whether specific treatments represent good value, appropriate, evidence-based choices for adoption into primary care treatment plans via the formulary and clinical management pathways.
- To provide a written rationale for the determination of commissioning decisions and recommendations.
- To establish processes for the dissemination of commissioning decisions and recommendations, including the publication of decisions on publicly accessible websites.
- To make recommendations for commissioned services in the context of non-alignment with non-mandatory National Institute for Health and Care Excellence (NICE) guidelines.

- To note reports from the NICE planning processes on the commissioning implications of published Technology Appraisals and Clinical Guidelines.
- To note reports from the Devon Formulary Interface Group.

Membership

The committee will comprise 20 members as follows:

- Registered Clinical Professionals (x8) appointed by the ICS
- Lay Public Members (x2)
- Nursing and Quality (x1)
- Public Health (x1)
- Contracting (x1)
- Devon ICB Head of Clinical Effectiveness (x1)
- Devon ICB Head of Medicines Optimisation (x1)
- Secondary Care Clinician (x4) from NHS trusts in Devon
- Secondary Care Chief Pharmacist (x1)

The eight nominated Registered Clinical Professionals will act with delegated executive authority to make commissioning recommendations (voting members).

The other committee members will contribute to the decision-making process in an advisory capacity.

The committee includes lay membership to ensure the public interest is reflected in decision making.

Chair

A Chair shall be nominated by the ICS Medical Director.

It is the role of the Chair of the Committee to confirm that the members have all the relevant competencies in order for the Committee to undertake the business on the agenda. The committee membership will reflect the descriptions provided in the Local decision-making Competency Framework of the National Prescribing Centre (now part of the National Institute for Health and Care Excellence (NICE)), whilst recognising that the scope of the Clinical Policy Recommendation Committee extends beyond that of medicines. Members will be expected to contribute the competency sets summarised in Appendix 1.

Quorum

The quorum will consist of half of the members being present to include a minimum of four voting members. The chair will ascertain who the voting members are before transacting committee business.

Attendance and deputies

Voting members may nominate deputies, who should be current, non-lay, advisory members of the committee. A deputy can only deputise for one voting member at any given meeting.

Deputies may also attend the committee to represent non-voting members. It is the responsibility of the committee member to ensure that the deputy is appropriately briefed and possesses the required competencies.

When the Chair anticipates being absent, they will nominate an existing committee member to deputise for that meeting. Otherwise the committee will nominate a Chair from those committee members present on the day.

Committee members are expected to aim to attend all meetings. Attendance will be monitored on a rolling annual basis by the secretariat and any identified low attendance (less than ⅔) highlighted to the Chair to follow up with the member.

Follow up will be at the Chairs discretion but will take into consideration such matters as the reasons for non-attendance, any issues with fulfilling the role, and the nomination of a suitable deputy for planned non-attendance.

Administration

The frequency of meetings shall be determined by need, but it is expected that there will be six meetings per year.

Meetings may be held face-to-face or virtually via Microsoft Teams.

A secretariat from the Clinical Effectiveness Team will provide administrative, professional and technical support such as taking minutes, recording and following up administrative actions, and presenting scientific and professional assessments to the committee.

Minutes will be produced and published on the website following approval at the subsequent meeting.

Declarations of Interest

All members of the committee and attendees will be expected to complete a declaration of interests. The Chair will consider these and ensure that declarations are made known to the committee members to indicate the nature and extent of any potential conflicts of interest.

The Chair has responsibility for agreeing how to manage any conflict of interest in the context of the meeting. Possible actions may include, but are not limited to:

- Asking conflicted individuals to leave the meeting when the relevant matter(s) are being discussed.

- Allowing conflicted individuals to participate in some of the discussion but excluding them from developing recommendations and decision-making on the matter(s). For example, this may be appropriate where the individual has important relevant knowledge and experience of the matter(s) under discussion, which it would be of benefit for the meeting to hear.
- Noting the interest but allowing the individual to remain and participate in both the discussion and in any decision-making.

All declarations of interests will be reported in the minutes, along with details of any resulting actions and how any identified conflicts were agreed to be managed within the context of the meeting. A register of all interests will be kept by the committee secretariat.

Observers

The committee is not a public meeting and as such is not open to general members of the public and commercial representatives. Observers are welcomed in their capacity as a healthcare professional, or an individual otherwise involved in supporting the local health community, to enhance their understanding of the committee for the benefit of their role.

Attendance at a committee meeting as an observer is by prior agreement with the secretariat, and it is expected that this would be at the request of, and accompanying, a committee member.

Conduct of business

Decision making will comprise two stages:

- All members of the committee may participate in discussions and debate about the possible outcomes of a commissioning decision.
- Final policy recommendations will be formed through a voting process of the Registered Clinical Professionals with delegated executive authority (voting members). Where the Chair is a voting member, they have the option to retain their vote or to delegate this. This is to be declared at the start of the meeting. Where a consensus is not apparent the Chair will consider whether further discussion is likely to lead to a consensus before taking a majority view from the voting members to be final. In the absence of a majority view further debate will continue until a majority view can be obtained. At the Chair's discretion a secret ballot may be held.

Decisions will be reached after considering an assessment of the information which is known about the proposed intervention. This will be presented in a standardised format and will present information on:

- The reason for the proposal – clinical need and impact on patient care
- Technical details of the intervention
- Details of the health problem for which the intervention is proposed, including an estimate of likely numbers affected
- National strategic direction

- Evidence supporting efficacy of the intervention
- Information known about the safety of the intervention
- Current service
- Details of stakeholder engagement undertaken in relation to the intervention or service
- Cost effectiveness and resource impact

Where a product contains the same active ingredient and delivers a therapeutically equivalent dosage to an existing formulary product in a cost advantageous manner the formulary team should make proposals to the Formulary Interface Group (FIG) directly about inclusion or exclusion of the product. Deletions from the formulary which would cause a tension with NICE guidance, existing clinical commissioning policy, NHS England policies or result in inequity of access across Devon to specific pharmacologically active therapies should be referred to the Clinical Policy Recommendation Committee.

The diversity of work managed by the committee will require specialist input in order to cover all facets and interests. Therefore clinical specialists and service providers will be invited to attend the committee to present the case for commissioning and contribute to the decision-making process.

Clinical policy decisions are effective from the date of publication.

Appeals

The committee will operate an appeals process in respect of recommendations made by the committee. A panel of people independent of the original decision will be constituted to decide on the validity of the appeal. Appeals which are upheld will be referred back to the committee for reconsideration.

Accountability and Reporting

The committee will make its policy recommendation to the ICB Executive Committee, or appropriate group with delegated authority, for ratification and acceptance as commissioning policy of NHS Devon ICB.

The committee will report to the ICB Executive Committee, or appropriate group with delegated authority.

Review

The Terms of Reference will be reviewed annually.

Appendix 1: Roles and Responsibilities

Specific responsibilities of members of the Clinical Policy Recommendation Committee

Committee Role	Responsible Functions
Chair	**Facilitates decision making process** Agreeing agenda. Ensuring appropriate range of competency exists within the Committee. Draws together differing expertise and opinions. Communicates complex decisions in a manner that reflects Committee responsibility using language understood by all audiences. **Committee (internal) communication** Communicates within the Committee to ensure that relevant views are considered at appropriate points in the meeting. **Deliberation, reasoning and ethical judgment** Ensure clear articulation of reasons for and against a proposal.
All	Engagement in deliberative processes to support ethical judgment in decision making. Understands and questions personal assumptions and assumptions of other members of the committee. Understanding of the organisations' ethical framework. Understands the wide variety of evidence and the role it may play in making judgements.
Voting Members	Engage in and facilitate deliberative processes to support ethical judgement in decision-making. Make a population-based commissioning decision based upon judgment and opinion formed in the deliberative processes. Ensure that commissioning decisions are recognised by the Devon Integrated Care Board.
Head of Clinical Effectiveness	Understand the assessment of evidence and issues important in the interpretation of clinical evidence and cost effectiveness information. Understands quantitative and qualitative research methodologies. Ability to engage in technical clinical discussions with clinicians. Ability to compare needs and benefits of treatments across groups of patients within the context of the health needs of the population.

	Understands the appropriate use of data sources used to inform the decision-making process.
Head of medicines optimisation & Secondary care chief pharmacist	Specialist knowledge on range of procurements and supply systems for medicines. Specialist knowledge on the licensing, legislation and systems governing prescribing, supply and administration of medicines and treatments. Understands the principles and governance arrangements necessary for the safe and effective use of medicines.
Secondary care clinicians	Bring an understanding of the general processes of care across the broad range of secondary care clinical specialisms and support services. Understanding of secondary care internal operational mechanisms and how they interface with primary care. Facilitation of communication between the committee and its secretariat with clinical specialists in secondary care. The promotion of secondary care clinical specialist participation in the process of clinical commissioning policy formation. The promotion of commissioning decisions into practice at secondary level and their monitoring.
Contracting	Understands the financial and contractual arrangements across the range of service providers. Assesses the contractual and financial implications of decisions and imbeds the commissioning intent into the contracting processes. Understands the relationship between finance and commissioning. Understands the interdependence of the local health economy and takes into consideration the impact that changes made in one part may have on other parts.
Nursing and Quality	Understands the principles of safe and effective commissioning. Understand the governance and safety arrangements that may be necessary to ensure the intervention or service is commissioned appropriately. Ability to summarise succinctly, with underpinning evidence, complex legislative, governance and safety implications to inform decision making. Understands the impact on quality of care, resources and expenditure that a proposal may have.

	Understands the NHS requirements for engagement with patients and the public and where appropriate the use of formal consultation.
Public Health	Understand epidemiological data and its appropriate use in decision making. Ability to assess and compare the needs of individual patients or groups of patients within the overall context of the health needs of the population. Understands and has access to sources of relevant clinical economic and population information including information provided by stakeholders.
Lay Public Members	Ensures that in all aspects of the Committee business the public interest of the local population is represented in discussion and decision making. Brings an understanding of what patients, carers and the public may consider to be important when considering the advantages, disadvantages and availability of treatments. Ensures an open and accountable debate which is inclusive of all sectors of the community we serve. Brings an appreciation of the benefits to the community as a whole of an inclusive, patient centred local NHS that uses its resources fairly and wisely.
Clinical Effectiveness professional and scientific support	**Assessment of evidence** Scopes the problem to identify best available evidence. Synthesises evidence from a range of standard sources. Maps epidemiology of the disease in question. Assesses impact of different options at individual patient, pathway, and population level. Interprets and presents the clinical and non-clinical evidence so the Group members can understand the process. Writes and presents reports clearly and succinctly using appropriate terminology that the committee can understand. **Financial and commissioning information data** Summarises financial, contractual and performance data. Communicates options and works with commissioning, contracting and finance staff following the meeting to ensure the commissioning intention is realised. **External Communication and engagement** Engagement with stakeholder groups. **Governance and Safety** Assess evidence relating to safe use of the technology. Assess the impact of procurement and supply arrangements.

	Assess the impact on patient adherence with treatment. Presents information in a format understood by decision-making group.
Secretariat	**Administration** Administers the decision-making process to ensure the Committee meets at appropriate times, members have the relevant information, actions and decisions are recorded. Ensuring compliance with legal and ethical responsibilities relevant to local decision making. Information governance, data protection, management of documents and records. Organise agenda, plan meetings, circulate papers, record keeping, post meeting actions. Produce and distribute minutes. Maintain audit trail of documents. Enquiry handling. **Screening Requests** Assessment of topic for suitability for submission to Committee. Identify when written submission is lacking essential information. Knows about the suite of existing commissioning policies. **External Communication and engagement** Engagement with stakeholder groups. Communication of decisions. Handles Freedom of Information (FOI) requests.

(Reference: Local decision-making Competency framework – for groups involved in making local decisions about the funding of medicines and treatment in the NHS, National Prescribing Centre 2012)

Appendix 2

NHS Devon

Clinical Policy Recommendation Committee Agenda

Wednesday 26 April 2023, 09.30-11.30
via Microsoft Teams

No.	Item	Lead	Appendix	Time
1	Welcome and announcements • Apologies • Confirmation of voting members • Declarations of Interests • Notification of Any Other Business	Glen Allaway	Verbal	09.30
2	Approval of previous minutes Review of actions and matters arising	Glen Allaway	Appendix 1	09.35
Items for commissioning recommendation				
3	High Intensity Focussed Ultrasound (HIFU) and Cryotherapy for recurrent prostate cancer	Amy Rice	Appendices 2a and 2b	09.40
Break (5 minutes)				**10.30**
4	Focal hyperhidrosis	Amy Rice	Appendix 3	10.35
Other items for consideration				
5	Update from NICE Planning Advisory Group (NPAG)	Chris Roome	Appendices 4a and 4b	11.00
6	Update from Clinical Policy Engagement and Consultation Panel (CPEC)	Mac Merrett	Appendix 5	11.10
7	Clinical Policy Recommendation Committee Annual Report 2022-23	Rebecca Owen	Appendix 6	11.15
8	Any Other Business		Verbal	11.25
Meeting close				

NHS Devon

Clinical Policy Recommendation Committee Agenda

Wednesday 28 June 2023, 09.30-11.00
via Microsoft Teams

No.	Item	Lead	Appendix	Time
1	Welcome and announcements • Apologies • Confirmation of voting members • Declarations of Interests • Notification of Any Other Business	Glen Allaway	Verbal	09.30
2	Approval of previous minutes Review of actions and matters arising	Glen Allaway	Appendix 1	09.35
Items for commissioning recommendation				
3	Lurasidone for schizophrenia in adults	Amy Rice	Appendix 2	09.40
4	Lurasidone for schizophrenia in children and adolescents	Amy Rice	Appendix 3	10.05
Other items for consideration				
5	Update from NICE Planning Advisory Group (NPAG)	Chris Roome	Appendix 4	10.30
6	NPAG Annual Report 2022-23	Rebecca Owen	Appendix 5	10.35
7	Update from Clinical Policy Engagement and Consultation Panel (CPEC)	Mac Merrett	Appendix 6	10.45
8	CPEC Annual Report 2022-23	Rebecca Owen	Appendix 7	10.50
9	Any Other Business		Verbal	11.00
Meeting close				

NHS Devon

Clinical Policy Recommendation Committee Agenda

Wednesday 6 September 2023, 09.30-11.00
via Microsoft Teams

No.	Item	Lead	Appendix	Time
1	Welcome and announcements • Apologies • Confirmation of voting members • Declarations of Interests • Notification of Any Other Business	Glen Allaway	Verbal	09.30
2	Approval of previous minutes Review of actions and matters arising	Glen Allaway	Appendix 1	09.35
Items for commissioning recommendation				
3	Breast Implant Removal and Replacement	Amy Rice	Appendix 2	09.40
4	Penile circumcision	Amy Rice	Appendix 3	10.05
Other items for consideration				
5	Botulinum Toxin for urinary incontinence due to detrusor overactivity	Rebecca Owen	Appendix 4	10.30
6	Update from NICE Planning Advisory Group (NPAG)	Chris Roome	Appendices 5a & 5b	10.35
7	Update from Clinical Policy Engagement and Consultation Panel (CPEC)	Mac Merrett	Appendix 6	10.45
8	Formulary Interface Group (FIG) Annual Report 2022-23	Darren Wright	Appendix 7	10.50
9	Any Other Business		Verbal	11.00
Meeting close				

Appendix 3

ATTENDANCE OF COMMITTEE MEMBERS

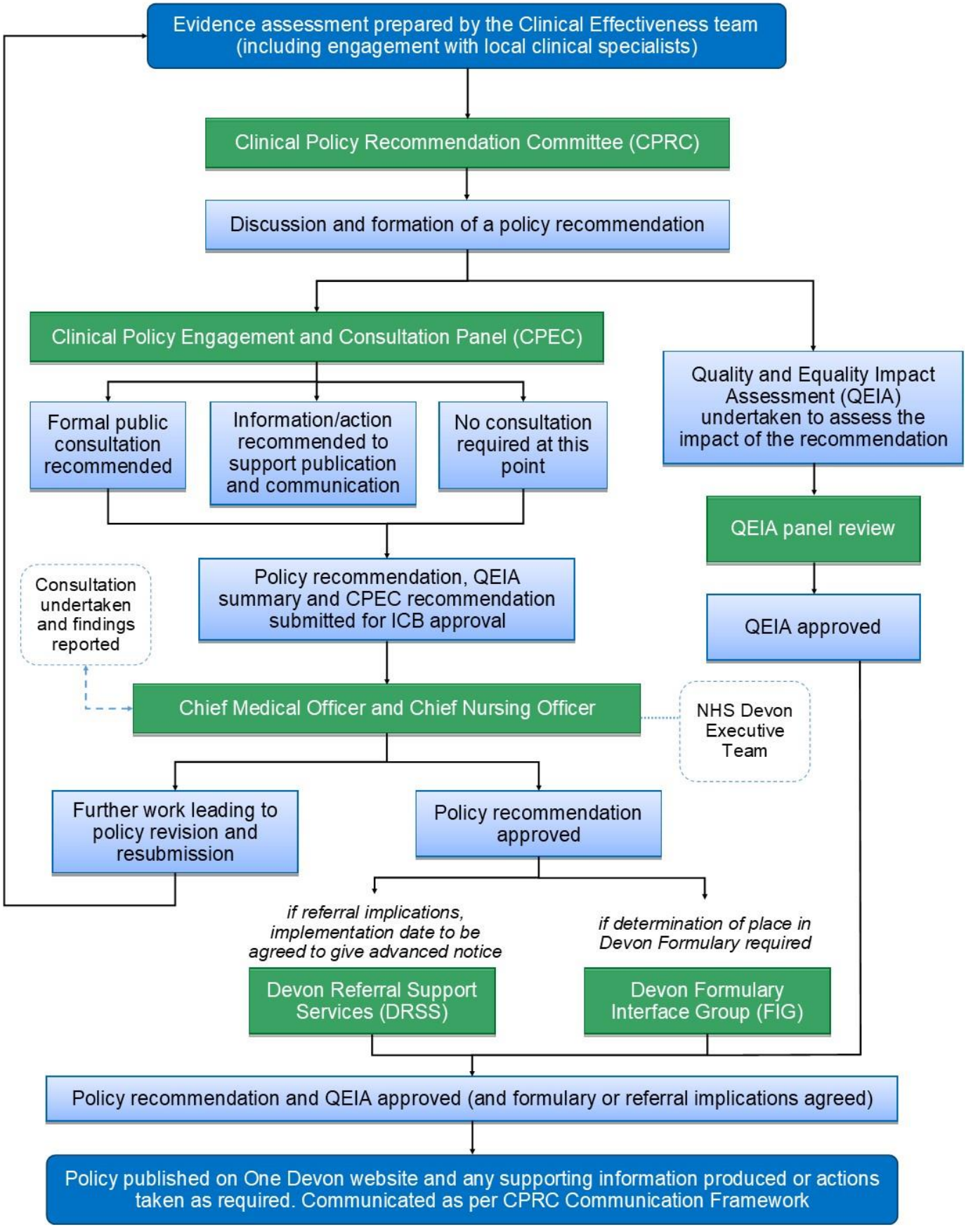
Name	Role	Organisation	Meetings attended
Dr Glen Allaway	Chair and Voting Member	NHS Devon	3 / 3
Dr Kay Brennan	Voting Member	NHS Devon	1 / 3
Susan Masters *(as delegate)*	Deputy Chief Nursing Officer	NHS Devon	2 / 2
Dr Andrew Craig	Voting Member	NHS Devon	3 / 3
Richard Croker	Deputy Director for Medicines Optimisation	NHS Devon	1 / 3
Paul Foster	Clinical Director of Pharmacy and Prescribing	Torbay & South Devon NHS Foundation Trust	0 / 3
Dr Lucy Harris	Voting Member	NHS Devon	3 / 3
Dr Claire Hooper	Voting Member	NHS Devon	2 / 3
Chris Roome *(as delegate)*	Head of Clinical Effectiveness	NHS Devon	1 / 1
Barbara Jones	Head of Contracting	NHS Devon	1 / 3
Susan Masters	Deputy Chief Nursing Officer	NHS Devon	2 / 3
Dr Paul Melling	Voting Member	NHS Devon	2 / 3
Chris Roome *(as delegate)*	Head of Clinical Effectiveness	NHS Devon	1 / 1
Mac Merrett	Lay Public Member		2 / 3
Chris Roome	Head of Clinical Effectiveness	NHS Devon	3 / 3
Mark Taylor	Lay Public Member		3 / 3
Dr Emily Youngman	Consultant in Public Health Medicine	Devon County Council	3 / 3

ADDITIONAL ATTENDEES (EXPERTS, GUESTS, SECRETARIAT AND OBSERVERS)

Name	Role	Organisation
Dr Charles Dixon	Consultant Psychiatrist	Devon Partnership NHS Trust
Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NHS Devon
Harriet Enoch	Registrar in Public Health	Torbay Council
Amanda Gulbranson	Lead Pharmacist	Children and Family Health Devon
Matt Howard	Clinical Evidence Manager	NHS Devon
Rebecca Owen	Clinical Effectiveness Governance Manager	NHS Devon
Dr Dominique Parslow	Consultant Clinical Oncologist (Uro-oncology and hepato-pancreato-biliary)	University Hospitals Plymouth NHS Trust
Amy Rice	Clinical Effectiveness Pharmacist – Commissioning Projects Lead	NHS Devon
Sam Trethewey	Speciality Registrar on placement with Public Health Devon	Devon County Council
Darren Wright	Joint Formulary Specialist Pharmacy Technician	NHS Devon

Appendix 4

Clinical policy governance and approval process



Appendix 5

NHS Devon

Clinical Policy Recommendation Committee Appeals process

Introduction

This appeals process applies to the operation of the Clinical Policy Recommendation Committee of NHS Devon Integrated Care Board (ICB).

Grounds for appeal

An appeal may be made by the original applicant(s). An applicant is considered to be a clinician who has participated in the process leading to the original recommendation, either through submitting written evidence and clinical views at the appropriate times during the preparation of committee papers or attending the committee meeting at which the recommendation was made.

The grounds for appeals are limited to the following:

- **Ground one: whether fair process has been followed by the Clinical Policy Recommendation Committee in making their recommendation.**

  The ICB is committed to following a fair process throughout local decision making. This ground relates only to the fairness of the process followed. A decision with which an appellant does not agree is not unfair for that reason.

- **Ground two: a material inaccuracy in or omission from the evidence considered by the committee that would make a substantive difference to the appraisal in relation to the medicine or treatment on which a recommendation was made.**

Appeals panel

Appeals will be considered by a panel. The panel will comprise at least 3 individuals independent of the original recommendation who will decide whether the appeal is upheld. These members will be aided in their discussion by the chair of the Clinical Policy Recommendation Committee and the Head of Clinical Effectiveness, NHS Devon ICB. The majority view of the independent members will decide the final outcome of the appeal.

The independent members of the appeals panel will elect a chairperson for the consideration of each appeal.

The administration of the appeals panel will be managed by the Clinical Policy Recommendation Committee secretariat on behalf of NHS Devon ICB.

Process

Appeals should be submitted within two months of notification of the final policy decision of NHS Devon ICB following consideration of the Clinical Policy Recommendation Committee recommendation.

Requests for appeal should be submitted to the Clinical Policy Recommendation Committee secretariat in writing.

The request for appeal should clearly state the ground(s) on which the appeal is being made, the aspect(s) of the commissioning decision or process being appealed against, and the reasons why the aspects being appealed against fall within the specified ground(s) of appeal. Enough detail should be given to demonstrate an arguable case.

The secretariat will provide appropriate documents on which to submit the appeal. Please contact the secretariat via d-icb.clinicaleffectiveness@nhs.net for an appeal submission form.

Reapplications will not be accepted within 12 months of the original decision unless the applicant can establish material changes in circumstances.

Decision of the appeals panel

If the appeal is rejected the original policy decision will stand.

If the appeal is upheld the application will be referred back to a future meeting of the Clinical Policy Recommendation Committee for reconsideration of the original application and the findings of the appeals panel.

Decisions of the appeals panel will be communicated to the appellant by the Chair of the appeals panel.

If the appellant is unhappy with the decision of the appeals panel, they will have the opportunity to make a complaint in line with the NHS Devon ICB standard complaints procedure.

Reconsideration of applications by the committee

Where an appeal is upheld and the original application referred back to the Clinical Policy Recommendation Committee for reconsideration, the appellant will be invited to:

- submit any supporting evidence or documentation to the secretariat for circulation to committee members prior to the meeting at which the appeal is scheduled
- attend the meeting at which the appeal is scheduled for the part of the meeting pertaining to the appeal
- present any data or points of argument that they wish during the meeting

In line with standard operating procedures, the appellant will be required to complete a declaration of interests form prior to attendance at the committee meeting.

The outcome of the committee's reconsideration will be communicated to the appellant and, following approval by the ICB, to the local health community as per the Clinical Policy Recommendation Committee communication framework.

Complaints

Complaints about the operation of the Clinical Policy Recommendation Committee will be dealt with in line with the standard complaints procedure of NHS Devon ICB.

An appeal decision cannot be overturned through the complaints process.

References

National Institute for Health and Clinical Excellence. Developing and updating local formularies: Good practice guidance. December 2012.

National Institute for Health and Clinical Excellence. Guide to the technology appraisal appeal process. August 2010.

NHS South West. Cancer Drugs Fund Appeals and Complaints process. 2011.

North East Treatment Advisory Group. Process for appealing recommendations made by the North East Treatment Advisory Group. June 2012.