NHS
Devon
Clinical Commissioning Group

Clinical Policy Committee

Annual Report

2019-2020

Contents

Dr Nick D'Arcy – Chair's Introduction

This is my first chairman's introduction to an annual report of the Clinical Policy Committee having taken over as chair since the November meeting of the committee. However, I note that it is the seventh annual report of the committee, worth mentioning to underscore the longevity of the committee that results from the successful way it enables the CCG to discharge its legal obligations within a framework of robust evidence scrutiny. This has continued to ensure that the people of Devon have access to effective treatments that deliver good value for the public funds that are invested in them.

This year has seen the recommendation of a significant number of polices for surgical interventions as the CCG has responded to the NHS England evidence based interventions programme. The CCG already had in place polices for the majority of the procedures encompassed within the programme, demonstrating that Devon had a long standing focus on targeting its resources to interventions in a manner that derives greatest value.

Amongst other work, the committee made recommendations to help the Devon health system to implement increased monitoring for retinal toxicity in patients taking long-term hydroxychloroquine for rheumatological and dermatological conditions. The recommendations of the committee balanced the comprehensive monitoring guidelines of the professional society with the capacity of ophthalmology services across the county in a manner proportionate to the risks of this drug and the risks to vision for the many patients with serious eye conditions who the services also need to treat and monitor. However, it is disappointing to note that at the time of writing this still remains a substantial challenge to form a routine part of services.

The committee was also asked to form policy recommendations for the use of continuous glucose monitoring in diabetes patients. This complimented work undertaken the previous year relating to the emergent technology of intermittent interstitial glucose monitoring. Subsequent consideration by the lay member led Clinical Policy Engagement and Consultation panel recommended the production of a broader based patient leaflet explaining the variety of glucose monitoring technologies now available and the CCG's position on providing access to patients to the various forms of this. Whilst it is always disappointing that limited resources mean that there are a potential wider group of patients who may derive some benefits form medical interventions, once again the committee helped the CCG to balance its expenditure across a wide range of healthcare demands and target its resources to circumstances of greatest clinical need and benefit.

The committee welcomed Dr Claire Hooper as a voting member. As well as broad primary care experience, Claire also brings to the committee her insights as the CCG's lead GP for planned care.

Finally, the committee wished Dr Jo Roberts well as he stepped down from the committee at the July meeting in preparation for his planned retirement. Jo had chaired the committee since its inception in 2013 and many members expressed their appreciation and admiration for the way he had led complex and sometimes contended discussions

I look forward to leading the committee as it continues to make policy recommendations to the CCG based upon critical evaluation of evidence of clinical benefit and the value for money that treatments offer.

Dr Nick D'Arcy
Chair, Clinical Policy Committee

1. Introduction

1.1 Through the Clinical Policy Committee NHS Devon Clinical Commissioning Group (CCG) discharges its responsibilities for making local decisions about the funding of medicines and treatments in the NHS.

1.2 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.

1.3 The Committee makes recommendations to the CCG Governing Body, or appropriate group with delegated authority, for approval following clinical discussion of the issues.

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

1.5 This annual report gives an account of the activity and governance of the Clinical Policy Committee in 2019-2020.

2. The process

Committee process and meeting arrangements

2.1 The terms of reference of the Clinical Policy Committee are as given in **Appendix 1**.

2.2 The processes and organisation of the committee are run by the Clinical Effectiveness Team, NHS Devon CCG and are guided by the National Prescribing Centre principles and rationale for local decision making.

2.3 Dr Jo Roberts, who had chaired the Clinical Policy Committee since its inception in 2013, stood down from the committee in July 2019. Since then, Dr Nick D'Arcy has taken over the role of chair to ensure the continued operation of the committee.

2.4 Meetings are usually held in Exeter, in facilities of Devon County Council as a strategic partner.

2.5 Four committee meetings were held in 2019-2020; the agendas for these meetings are shown in **Appendix 2**.

2.6 The committee members' attendance at meetings during the last year 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.

Changes in membership

2.7 Dr Jo Roberts stepped down from the committee in July 2019 and was thanked for the leadership he had provided to the committee since its inception in 2013. The role of chair of the committee has subsequently been taken over by Dr Nick D'Arcy.

2.8 Dr Claire Hooper was welcomed as a new voting member to the committee in November 2019.

Committee development

2.9 Individual development sessions were held for the benefit of the newer members of the committee in February and March 2020. These sessions. comprised key elements of previous committee development sessions to give an overview of decision making considerations together with some greater detail on particular concepts.

Declaration of Interests

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

2.11 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.

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

2.13 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.

2.14 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.

2.15 It is also acknowledged that members of the Clinical Policy Committee should act in accordance with the Principles of Public Life (the Nolan Principles) as set out in the CCG Constitution.

2.16 A record of declared interests is kept by the secretariat and full details are made publicly available in the minutes of the meeting. A register of all declared interests for the year is included in **Appendix 4**.

Public Involvement

2.17 The committee has two voluntary public members, known as lay public members.

2.18 Lay public members help ensure that 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.

Clinical Policy Engagement and Consultation Panel

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

2.20 Meeting approximately two weeks following the Clinical Policy 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 proposed policy recommendation.

2.21 This process and any resulting engagement or consultation precedes the CCG's executive decision-making group taking a final decision on whether to accept a clinical policy recommendation.

2.22 The minutes of meetings are published on the website and regular updates are reported to the Clinical Policy Committee as a standing agenda item.

2.23 Full details of the panel process, terms of reference, minutes and annual report is made publicly available via the NHS Devon CCG website.

Quality and Equality Impact Assessment (QEIA)

2.24 All Clinical Policy Committee policy recommendations have a Quality and Equality Impact Assessment (QEIA) conducted on them as an integral step in the process of policy formation, prior to approval by the CCG.

2.25 The QEIA tool tests the impact of a proposed change through a narrative account and a guided rating scale, across a number of core components. These include the impact of the proposal on patient safety, the clinical effectiveness of patient care, the patient experience of care delivery and the impact of the proposal on other services, patient groups, staff or the organisation. For example, this may include financial or reputational impact. The tool also assesses the impact on those in specific groups as outlined in the Equality Act 2010 and other hard to reach groups.

2.26 Impact is rated using a scale from negative to positive to allow for risks and benefits to be quantified. The total impact is calculated through an estimate of the number of patients affected and the total time for which they will be affected.

2.27 The QEIA also includes details of the measurements that could be used to determine the impact of the proposed change. This may include an examination of prescribing or activity data, regular formulary review/applications, the numbers of patient contacts with the CCG, incidents reported and applications to the Individual Funding Panel for use outside of the policy criteria.

2.28 A flowchart showing how the clinical policy engagement/consultation, QEIA and CCG approval processes operate is shown in **Appendix 5**.

Reporting

2.29 The Clinical Policy Committee makes clinical policy recommendations to the Governing Body of the CCG, or appropriate group with delegated authority, for approval following clinical discussion of the issues.

2.30 In addition to this, ratification of any other formal matters arising from the Clinical Policy Committee, including changes to terms of reference or process, is undertaken by the Governing Body of the CCG, or appropriate group with delegated authority.

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

Appeals process

2.32 The committee operates an appeals process for which a panel of people independent of the original decision are constituted to decide on the validity of the appeal.

2.33 The Clinical Policy Committee appeals process is as set out in **Appendix 6**.

2.34 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.

2.35 The grounds for appeal are (1) whether fair process has been followed by the Clinical Policy Committee in making their 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.

2.36 Appeals which are upheld are referred back to the Clinical Policy Committee for reconsideration of the original application and the findings of the Appeals panel.

2.37 The Appeals panel has not been required to address any appeals during 2019-2020.

NICE Planning Advisory Group (NPAG) updates and annual report

2.38 The Clinical Policy Committee has continued to receive regular updates during 2019-2020 in respect of the CCG's National Institute for Health and Care Excellence (NICE) planning processes. This includes receipt of the minutes and verbal reports from the Chair on the commissioning implications of published Technology Appraisals and Clinical Guidelines.

2.39 The Clinical Policy Committee also received and noted the 2018-2019 NICE Planning Advisory Group Annual Report.

2.40 It was noted that:

- NPAG provides a forum for the CCG to fulfil its statutory commissioning responsibilities in respect of mandatory NICE Technology Appraisals and Highly Specialised Technologies; and to consider the resource and service implications for all newly published NICE guidance and guidelines.
- NICE publishes several different types of guidelines and guidance. A recent growth area has been in Antimicrobial Guidelines which were introduced in October 2017 to help manage common infections and tackle antimicrobial resistance.
- In order for the CCG to comply with its statutory commissioning responsibilities, NPAG ensures that NICE Technology Appraisals and Highly Specialised Technologies are added to the Devon Formulary within 90 days of publication. A process is in place whereby the Formulary Team is notified of NICE Technologies considered by NPAG.
- In year NPAG identified and took forward two areas of particular concern:

    1. Guidance was considered for several procedures involving the use of gynaecological mesh and NPAG was aware of a number of serious safety concerns. These were reported to the Joint Clinical Effectiveness Group (JCEG). Responses received from local trusts regarding the use of mesh identified varied practice. In July 2018 the Government announced a 'pause' in the use of synthetic mesh/tape for two procedural areas, and a Safety Alert was published by NHS Improvement and NHS England. This was considered by NPAG and one of the outputs was a letter from the Chief Nursing Officer to Medical Directors reiterating that all non-restricted mesh procedures should be undertaken with high vigilance and asking for confirmation that appropriate measures were in place.

    2. NPAG noted there was interest from local trusts in providing a number of new surgical treatments for lower urinary tract symptoms (LUTS) caused by benign prostatic hyperplasia (BPH). Local data suggested making Urolift available on a trial-in-service basis was associated with an increase in the total number of procedures performed without a meaningful reduction in numbers of transurethral resection of the prostate (TURPs). There had also been an expansion in Urology departments in recent years with additional consultant numbers, yet they struggle to meet targets including the 62-day cancer treatment target. NPAG therefore questioned whether expansion of services for BPH was

a priority or considered affordable from a financial perspective or deliverable from a clinical capacity perspective.

A meeting took place in September 2018 with local urologists and radiologists, followed by a review of urology services in 2019. As a result, the Clinical Policy Committee was asked to consider a range of new surgical procedures for LUTS due to BPH together at one time in January 2019. The aim was to make recommendations on whether these alternative treatment options would make rational choices to help address the challenges in the local health system, and what form of commissioning and provision would be considered most suitable. These recommendations would then be used in the discussions at senior level for this service across Devon. This resulted in publication of CCG policies setting out the procedures accepted in Devon and the circumstances for their use, and those which are not accepted as treatment options.

Devon Formulary Interface Group (FIG) annual report

2.41 The Clinical Policy Committee received the 2018-2019 Annual Report of the Devon Formulary Interface Groups (FIGs).

2.42 The FIGs collectively deliver 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 drug and treatment choices.

2.43 It was noted that:

- The content of the Devon formulary continues to be reviewed and updated by the FIGs with agreement reached by consensus. The FIGs reflect the natural healthcare communities clustered around the major hospitals in Devon.
- Whilst there is essentially one formulary in Devon, there are variations between recommendations made for North and East Devon, and South and West Devon. These differences allow the Devon Formulary to reflect and support the different needs of the local healthcare communities, local specialist preferences, and local service configuration or provision.
- The merger of the CCGs in April 2019 was not expected to affect the way in which the Devon Formulary is managed or delivered.
- In order to demonstrate compliance with the CCG's statutory obligation to fund and resource medicines and treatments recommended by NICE Technology Appraisal (TA) guidance and NICE Highly Specialised Technology (HST) guidance; 63 TAs and 1 HST were added to the Devon Formulary during the period of the annual report.
- In terms of reviewing and developing formulary content, a number of existing sections were reviewed and updated Devon-wide; examples included acute sinusitis, acute sore throat, acute otitis media, and Lyme disease in the infections chapter.
- Formulary guidance on the management of asthma was also reviewed after publication of a NICE clinical guideline. The FIGs considered existing

recommendations from the British Thoracic Society/Scottish Intercollegiate Guidelines Network (BTS/SIGN), the NICE guideline, and local specialist input. There were times that the two national guidelines differed, and the FIGs worked by consensus to agree Devon wide guidance supported by the acute trust specialists.

- The emollients section was reviewed Devon-wide with input from the CCG's medicines optimisation teams and local dermatology consultants. Updated guidance contains consolidated and reduced product recommendations, with a simplified, limited number of first- and second-line options for a variety of presentations such as creams, ointments and gels. The guidance includes additional supporting information to help prescribers select the most appropriate product type and promotes savings.
- In addition, applications to consider new drugs for inclusion into the Devon Formulary were received by the Formulary Team, these are considered either by the Clinical Policy Committee or by the FIGs according to the Terms of Reference of the Clinical Policy Committee. The Formulary team also receives applications for consideration or removal of products from the formulary or for a change to be made to current formulary preparations such as to the preferred brand or a change in prescribing status.
- Both FIGs considered a range of product applications, proposed changes to formulary products and changes to product status or prescribing advice.
- New drugs which fall outside of the remit of the FIGs to decide upon are considered for commissioning by the Clinical Policy Committee. In year the FIGs agreed formulary entries for the treatments which the Clinical Policy Committee had recommended for commissioning. In the case of a drug not recommended by the Clinical Policy Committee for routine commissioning, this is also reflected in the formulary accordingly.
- With increasing demand on FIG time, there was growth in the use of the virtual e-FIG process over the previous year to make some decisions at pace, or to free up face to face time for more complex discussions or facilitate the medicines optimisation teams to move quickly to deliver savings.
- The FIG also considered national guidance from NHS England on low value items that should not be routinely prescribed in primary care.
- In year the Devon Formulary has shown an increase in use of approximately 30% over the previous year, with over 1.6 million page views in 2018-2019. The formulary app was downloaded almost 2,000 times in that period, taking total downloads since launch to around 8,500 by the end of March 2019.
- At the end of 2017 the Clinical Effectiveness Formulary Team undertook a survey to understand and improve user experience and satisfaction, as a result, a number of next steps were identified. During 2018-2019, the Formulary team worked with Reactor 15 to deliver technical developments and improved functionality, including the addition of a predictive search function that suggests potential search terms based on the initial characters entered in the search box.
- The Clinical Effectiveness Team continue to seek best value in the running costs of the formulary.

- The FIGs are ever evolving to keep up to date with the requirements of the formulary and as such will often reflect on how best the aims of the formulary can be developed. This year the duration of the North and East FIG meetings was increased, and a committee development session took place to consider how best to deliver the aims of the joint formulary.

3. The work programme

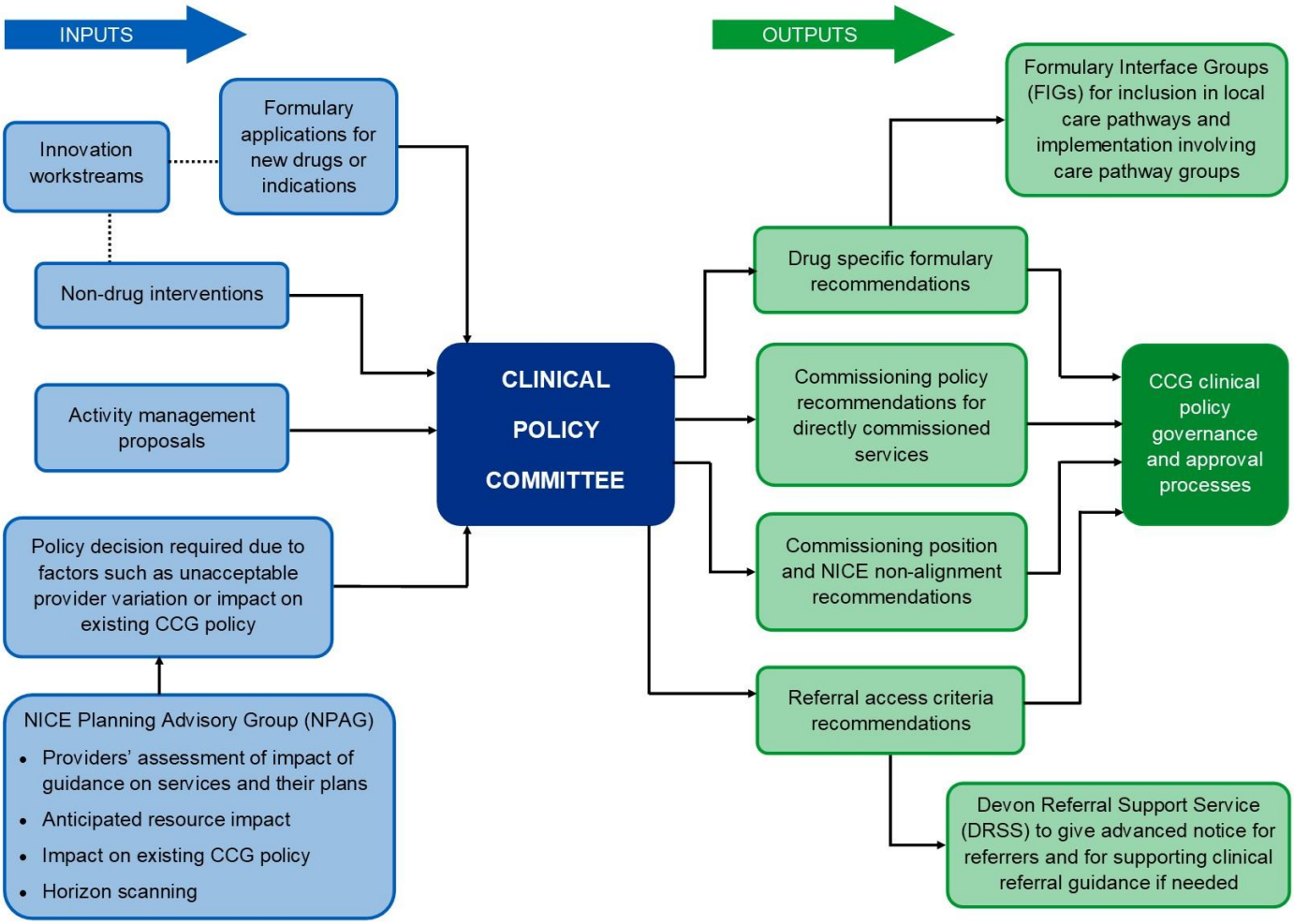
3.1 The work programme of the Clinical Policy Committee is managed by the Clinical Effectiveness Team, NHS Devon CCG.

3.2 In the last year, assessments have been undertaken and presented to the committee by four members of the Clinical Effectiveness Team:

- Matt Howard, Clinical Evidence Manager
- Hilary Pearce, Clinical Effectiveness Pharmacist
- Naomi Scott, Healthcare Evidence Reviewer
- Graham Simpole, Healthcare Evidence Reviewer

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

Figure 1: Clinical Policy Committee inputs and outputs



NHS England Evidence Based Interventions Guidance for CCGs

3.4 A significant portion of the work programme for 2019-2020 has comprised review of existing CCG policies with regard to NHS England statutory Evidence Based Interventions Guidance for CCGs. This has been the case for nine existing policy areas this year for which the Clinical Policy Committee has made recommendations, as indicated in section 4.

3.5 NHS England issued statutory guidance to CCGs on 28 November 2018 to introduce and implement commissioning policies for selected interventions. This was published in partnership with NHS Clinical Commissioners, the Academy of Medical Royal Colleges, NHS Improvement and the National Institute for Health and Care Excellence (NICE). This was following a full 12-week public consultation, which was conducted between July and September 2018.

3.6 The guidance sets out clinical criteria for 17 interventions outlining when they should be commissioned or offered, separated into two categories:

- Four “Category 1” interventions that should not be routinely commissioned, with patients only able to access such treatments where they successfully make an individual funding request (IFR).
- Thirteen “Category 2” interventions that should only be commissioned or performed when specific criteria are met.

3.7 Where local policies are in place, NHSE has stated that they do not intend to reverse legitimate local decision-making; however CCGs will need to be able to demonstrate that they have had regard to the national guidance.

3.8 There has been an ongoing programme of work led by the Clinical Effectiveness Team to consider the NHS England Evidence Based Interventions Guidance for CCGs. This has included NHS England policy recommendations for interventions for which the CCG had no existing policy in place, as well as review of existing CCG policies affected by NHS England recommendations. A significant number of these interventions were considered last year, and the remainder have been considered during 2019-2020.

3.9 It is understood that there is an intention for a second wave of the NHS England Evidence Based Interventions Guidance, which is anticipated to be broader in scope but with number of areas expected to require policy development. NHS England consultation on this second wave has yet to be launched, but any subsequent guidance published is expected to be one of the key inputs influencing the future Clinical Policy Committee work programme.

4. Commissioning recommendations

4.1 Recommendations made by the Clinical Policy Committee in 2019-2020 for approval by the CCG's executive group are as detailed below:

*****following approval by the CCG and completion of all governance processes (including determination of appropriate place in formulary where applicable)

Topic	Date of CPC recommendation	Date of publication*	Final commissioning decision
Surgery for Ganglion Cyst	22 May 2019	14 October 2019	Confirms the circumstances under which treatment for ganglion cyst is routinely commissioned in Devon. *Review of existing policy with regard to NHS England Evidence Based Interventions Guidance for CCGs for "ganglion excision"*
Surgery for carpal tunnel syndrome	22 May 2019	14 October 2019	Confirms the circumstances under which surgery for carpal tunnel syndrome is commissioned in Devon. *Review of existing policy with regard to NHS England Evidence Based Interventions Guidance for CCGs for "carpal tunnel syndrome release"*
Dupuytren's contracture treatment	22 May 2019	14 October 2019	Confirms the circumstances in which Dupuytren's Contracture treatment is commissioned in Devon. *Review of existing policy with regard to NHS England Evidence Based Interventions Guidance for CCGs for "Dupuytren's contracture"*
Glycopyrronium bromide oral solution for the treatment of severe sialorrhoea in children and adolescents aged 3 years and older	24 July 2019	10 October 2019	The routine commissioning of glycopyrronium bromide oral solution is accepted in Devon for the symptomatic treatment of severe sialorrhoea (chronic pathological drooling) in children and adolescents aged 3 years and older with chronic neurological disorders.

Topic	Date of CPC recommendation	Date of publication*	Final commissioning decision
Continuous glucose monitoring in diabetes	24 July 2019	10 October 2019	A 6 month trial of a continuous glucose monitor (CGM) is accepted for patients in Devon with type 1 diabetes who meet the specific initiation and continuation criteria described in the policy.
Tonsillectomy	24 July 2019	28 October 2019	Confirms the circumstances under which tonsillectomy will only be routinely commissioned in Devon. *Review of existing policy with regard to NHS England Evidence Based Interventions Guidance for CCGs for "tonsillectomy for recurrent tonsillitis"*
Myringotomy with or without ventilation tubes (grommets) in adults and children aged 12 years and older	24 July 2019	28 October 2019	Confirms the criteria under which myringotomy with or without ventilation tubes (grommets) will be funded in Devon. *Review of existing policy with regard to NHS England Evidence Based Interventions Guidance for CCGs for "grommets for glue ear in children"*
Myringotomy/grommets with or without adjuvant adenoidectomy for the management of otitis media in children under 12 years	24 July 2019	28 October 2019	Confirms the criteria under which myringotomy/grommets with or without adjuvant adenoidectomy for the management of otitis media in children under 12 years will be funded in Devon. *Review of existing policy with regard to NHS England Evidence Based Interventions Guidance for CCGs for "grommets for glue ear in children"*
Referral for varicose veins	20 November 2019	10 January 2020	Confirms the circumstances in which referral for varicose veins is commissioned in Devon. *Review of existing policy with regard to NHS England Evidence Based Interventions Guidance for CCGs for "varicose vein interventions"*

Topic	Date of CPC recommendation	Date of publication*	Final commissioning decision
Loteprednol (Lotemax®) for the treatment of steroid responsive inflammatory eye conditions	20 November 2019	24 January 2020	The routine commissioning of loteprednol is accepted in Devon for the treatment of steroid responsive inflammatory eye conditions in patients who have a known clinically significant rise in intraocular pressure with other steroid eye drops.
Surgical Management of Heavy Menstrual Bleeding	20 November 2019	20 February 2020	Confirms the circumstances in which referral for the surgical management of heavy menstrual bleeding is commissioned in Devon. *Review of existing policy with regard to NHS England Evidence Based Interventions Guidance for CCGs for "hysterectomy for heavy menstrual bleeding"*
The referral and specialist management of haemorrhoids in adults	20 November 2019	20 February 2020	Confirms the circumstances in which referral and specialist management of haemorrhoids is commissioned in Devon. *Review of existing policy with regard to NHS England Evidence Based Interventions Guidance for CCGs for "haemorrhoid surgery"*
Dupuytren's contracture treatment	Change in policy position noted 11 March 2020	4 March 2020	Policy updated to remove reference to NICE Technology Appraisal guidance 459 on Collagenase clostridium histolyticum for treating Dupuytren's contracture as this has been withdrawn.
Injections for non-specific low back pain without sciatica	11 March 2020	*Pending completion of governance and approval processes*	Spinal injections of local anaesthetic and steroid are not routinely commissioned in Devon for patients with non-specific low back pain (NSLBP).
Radiofrequency denervation	11 March 2020	*Pending completion of governance and approval processes*	Confirms the circumstances in which radiofrequency denervation is routinely commissioned in Devon for patients with chronic low back pain.
Spinal injections for sciatica	11 March 2020	*Pending completion of governance and approval processes*	Confirm the circumstances in which epidural or nerve root block is routinely commissioned in Devon.

Topic	Date of CPC recommendation	Date of publication*	Final commissioning decision
Pitolisant hydrochloride for the treatment of narcolepsy with or without cataplexy in adults	11 March 2020	*Pending completion of governance and approval processes*	The routine commissioning of Pitolisant hydrochloride is accepted in Devon for the treatment of narcolepsy with cataplexy in adults aged 19 years and over who would otherwise be eligible for treatment with sodium oxybate in line with the NHS Devon CCG clinical commissioning policy for sodium oxybate for narcolepsy with cataplexy.
Invicorp® for erectile dysfunction	11 March 2020	*Pending completion of governance and approval processes*	The routine commissioning of Invicorp® is accepted in Devon for the treatment of erectile dysfunction when a patient: • meets the NHS Selected List Scheme (SLS) criteria AND • has failed to respond to eight doses at the maximum tolerated dose with sexual stimulation of two different PDE-5 inhibitors OR is unable to take PDE-5 inhibitors due to a contraindication
Sativex® for the treatment of spasticity in multiple sclerosis	11 March 2020	*Pending completion of governance and approval processes*	The routine commissioning of Sativex® is accepted in Devon for the treatment of moderate to severe spasticity in adults with multiple sclerosis if: • other pharmacological treatments for spasticity are not effective, AND • treatment is initiated and supervised by a physician with specialist expertise in treating spasticity due to multiple sclerosis, AND • the patient achieves at least a 20% reduction in spasticity-related symptoms (on a 0-10 patient numeric rating scale) following a 4-week trial during which the company provides Sativex® according to its pay-for-responders scheme.

5. Communication

Commissioning policies

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

5.2 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. The Clinical Policy Committee Communication Framework is as shown in **Appendix 7**.

5.3 This operates in accordance with the Planned Care Control Centre communications and engagement plan which sets out the communication and engagement activity required at Planned Care Control Centre level and the respective routes and responsibilities. For example, the specific processes for the communication of a policy without Clinical Referral Guidance, a policy with Clinical Referral Guidance and Clinical Referral Guidance without an associated policy.

5.4 The aim of the plan is to keep processes clear and simple, to have consistency of approach, to ensure accuracy, clarity, timeliness and appropriateness of information shared, and to reduce the number of individuals involved in leading on communications and engagement.

5.5 The agreed communication process also ensures that the CCG Patient Advice and Complaints and Communications teams are 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

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

5.7 This annual report will similarly be made publicly available via the CCG website once ratified.

5.8 Details of the Clinical Policy Engagement and Consultation Panel process, terms of reference, minutes and annual report are also publicly accessible via the NHS Devon CCG website.

6. Conclusion

6.1 Through the Clinical Policy Committee, NHS Devon CCG discharges its responsibility for making local decisions about the funding of medicines and treatments for patients in Devon.

6.2 The Clinical Policy Committee has considered 16 evidence assessments in 2019-2020 resulting in 18 commissioning policy recommendations. One existing CCG policy has also been updated in response to the withdrawal of a NICE Technology Appraisal guidance to remove reference to this accordingly.

6.3 The Clinical Policy Committee are asked to receive this annual report as a record of activity and the governance arrangements underpinning the Committee.

6.5 The CCG Governing Body, or appropriate group with delegated authority, is asked to accept and ratify this annual report to endorse the role of the Clinical Policy Committee. Following ratification the report will be made publicly available via the CCG website.

Appendix 1

NHS
Devon
Clinical Commissioning Group

Clinical Policy Committee

TERMS OF REFERENCE

1. Purpose of the Group

1.1 The Clinical Policy Committee (CPC) exists to enable NHS Devon Clinical Commissioning Group to discharge its responsibilities for making local decisions about the funding of medicines and treatments in the NHS.

1.2 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.

2. Functions

The Clinical Policy Committee will:

2.1 Make recommendations to the Clinical Commissioning Group Governing Body, or appropriate group with delegated authority, for approval following clinical discussion of the issues.

2.2 Make recommendations to members of the Clinical Commissioning Group on whether specific treatments represent good value, appropriate, evidence-based choices for adoption into primary care treatment plans via formularies and clinical management pathways.

2.3 Provide a written rationale for the determination of commissioning decisions and recommendations.

2.4 Establish processes for the dissemination of commissioning decisions and recommendations, including the publication of decisions on publicly accessible websites.

2.5 Make recommendations for commissioned services in the context of non-alignment with non-mandatory National Institute for Health and Care Excellence (NICE) guidelines.

2.6 Note reports from the Clinical Commissioning Group's NICE planning processes on the commissioning implications of published Technology Appraisals and Clinical Guidelines.

3. Membership

3.1 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 whilst recognising that the scope of the Clinical Policy Committee extends beyond that of medicines. Members will be expected to contribute the competency sets defined in this guide and summarised in Appendix 1.

3.2 A current membership list will be maintained by the committee secretariat.

3.3 The committee will comprise 18 members as follows:

- Registered Medical Professionals appointed by the Clinical Commissioning Group (x8)
- Lay Public Members (x2)
- Patient Safety and Quality (x1)
- Public Health (x1)
- Contracting (x1)
- Head of Clinical Effectiveness
- Head of Medicines Optimisation
- Secondary Care Clinician (x2) from NHS trusts in Devon
- Secondary Care Chief Pharmacist (x1)

3.4 The eight (8) nominated Registered Medical Professionals will act with delegated executive authority from the Clinical Commissioning Group Governing Body to make commissioning recommendations (voting members).

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

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

3.7 Committee members are expected to aim to attend 100% of meetings. Attendance will be monitored on a rolling annual basis by the secretariat and any identified low attendance (below 66%) highlighted to the Chair to follow up with the member.

3.8 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.

3.9 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.

3.10 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.

4. Meetings and Conduct of Business

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

4.2 The quorum will consist of half of the members being present to include a minimum of 4 voting members. The chair will ascertain who the voting members are before transacting committee business.

4.3 Decision making will compromise 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 Medical Professionals with delegated executive authority from the Clinical Commissioning Group's Governing Body (voting members). 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. At the Chair's discretion a secret ballot may be held. The Chair has a vote. In the absence of a majority view further debate will continue until a majority view can be obtained or the Chair decides to exercise a casting vote.

4.4 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

4.5 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 Groups (FIGs) directly about inclusion or exclusion of the product. Deletions from the formulary which would cause a tension with NICE guidance, existing CPC policy, NHS England policies or result in inequity of access across Devon to specific pharmacologically active therapies should be referred to the Clinical Policy Committee.

4.6 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.

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

4.8 Decisions are effective from the date of publication.

4.9 Meetings may be attended in person or via teleconferencing where services exist.

4.10 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.

5. Officers of the Committee

5.1 A Chair shall be nominated by the Clinical Commissioning Group Governing Body. When absence is anticipated the Chair 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.

5.2 A secretariat from the Clinical Commissioning Group 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.

6. Governance/ Reporting arrangements

6.1 The Committee will operate under delegated authority from and report to the Governing Body of NHS Devon Clinical Commissioning Group.

6.2 The Terms of Reference will be reviewed annually.

7. Declaration of Interests

7.1 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 any potential conflicts of interest.

7.2 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.

ROLES AND FUNCTIONS OF GROUP MEMBERS

(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)

Specific responsibilities of members of the Clinical Policy Committee

Committee Role	Responsible Functions
Chair	**Facilitates decision making process** Agreeing agenda. Ensuring appropriate range of competency exists within the Group. Draws together differing expertise and opinions. Communicates complex decisions in a manner that reflects Group responsibility using language understood by all audiences. **Group (internal) communication** Communicates within the Group 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 Clinical Commissioning Group governing body.
Patient safety 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.
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.
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.
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 clinical policy 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.

	Keeps at the forethought of commissioning 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 (in attendance)	**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** Provides 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 (in attendance)	**Administration** Administers the decision-making process to ensure the Group 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 CPC. 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.

April 2019

Appendix 2

NHS Devon Clinical Commissioning Group

Clinical Policy Committee

AGENDA

Wednesday 22 May 2019, 09.30-12.30

Committee Suite, County Hall, Exeter EX2 4QD

Number	Item	Lead	Appendix	Time
1	Welcome and announcements • Apologies • Confirmation of voting members and Declarations of interest • Notification of Any Other Business	Jo Roberts	Verbal	9.30
2	Minutes of the meeting held on 27 March 2019 and matters/actions arising	Jo Roberts	Appendix 1	9.35
Items for commissioning recommendation				
3	Hydroxychloroquine monitoring schedule	Hilary Pearce	Appendix 2	9.40
4	Review: Policy for Dupuytren's contracture treatment	Naomi Scott	Appendix 3	10.10
5	Review: Policy for surgery for carpal tunnel syndrome	Hilary Pearce	Appendix 4	10.40
6	Review: Policy for surgery for ganglion cyst	Hilary Pearce	Appendix 5	11.10
Other items for consideration				
7	Clinical Policy Committee Annual Report 2018-19	Rebecca Heayn	Appendix 6	11.40
8	Revised Clinical Policy Committee Terms of Reference	Rebecca Heayn	Appendix 7	11.50
9	Update from NICE Planning Advisory Group (NPAG)	Chris Roome	Appendix 8	11.55
10	Clinical Policy Engagement and Consultation Panel Annual Report 2018-19	Rebecca Heayn	Appendix 9	12.05
11	Update from Clinical Policy Engagement and Consultation Panel	Mac Merrett	Appendix 10	12.15
12	Any Other Business		Verbal	
Meeting close				

NHS
Devon
Clinical Commissioning Group

Clinical Policy Committee

AGENDA

Wednesday 24 July 2019, 09.30-12.30

Committee Suite, County Hall, Exeter EX2 4QD

Number	Item	Lead	Appendix	Time
1	Welcome and announcements • Apologies • Confirmation of voting members and Declarations of interest • Notification of Any Other Business	Jo Roberts	Verbal	9.30
2	Minutes of the meeting held on 22 May 2019 and matters/actions arising	Jo Roberts	Appendix 1	Form 9.35
Items for commissioning recommendation				
3	Glycopyrronium bromide oral solution for the symptomatic treatment of severe sialorrhoea (chronic pathological drooling) in children and adolescents aged 3 years and older with chronic neurological disorders	Graham Simpole	Appendix 2	9.40
4	Review: Policies for myringotomy	Matt Howard	Appendix 3	10.10
5	Review: Policy for tonsillectomy	Matt Howard	Appendix 4	10.35
6	Continuous glucose monitoring for patients with type 1 diabetes	Naomi Scott	Appendix 5	11.00
Other items for consideration				
7	Update from Clinical Policy Engagement and Consultation Panel	Mac Merrett	Appendix 6	11.40
8	Any Other Business		Verbal	11.50
Meeting close and lunch				**12.00**

NHS Devon Clinical Commissioning Group

Clinical Policy Committee

AGENDA

Wednesday 20 November 2019, 09.30-12.30

Committee Suite, County Hall, Exeter EX2 4QD

Number	Item	Lead	Appendix	Time
1	Welcome and announcements • Apologies • Confirmation of voting members and Declarations of interest • Notification of Any Other Business	Nick D'Arcy	Verbal	9.30
2	Minutes of the meeting held on 24 July 2019 and matters/actions arising	Nick D'Arcy	Appendix 1	9.35
Items for commissioning recommendation				
3	Review: Policy for surgical management of heavy menstrual bleeding	Naomi Scott	Appendix 2	9.40
4	Review: Referral policy for varicose veins	Naomi Scott	Appendix 3	10.10
5	Review: Policy for referral and specialist management of haemorrhoids in adults	Graham Simpole	Appendix 4	10.40
6	Loteprednol etabonate 0.5% (Lotemax®) for the treatment of steroid responsive inflammatory conditions of the eye	Naomi Scott	Appendix 5	11.10
Other items for consideration				
7	Update from Clinical Policy Engagement and Consultation Panel	Mac Merrett	Appendix 6	11.40
8	Update from NICE Planning Advisory Group (NPAG)	Chris Roome	Appendices 7a & 7b	11.45
9	NICE Planning Advisory Group (NPAG) Annual Report 2018-19	Fiona Dyroff	Appendix 8	11.55
10	Devon Formulary Interface Groups Annual Report 2018-19	Darren Wright	Appendix 9	12.05
11	Any Other Business		Verbal	12.15
Meeting close				

NHS
Devon
Clinical Commissioning Group

Clinical Policy Committee

AGENDA

Wednesday 11 March 2020, 09.30-12.30

Committee Suite, County Hall, Exeter EX2 4QD

Number	Item	Lead	Appendix	Time
1	Welcome and announcements • Apologies • Confirmation of voting members and Declarations of interest • Notification of Any Other Business	Nick D'Arcy	Verbal	9.30
2	Minutes of the meeting held on 20 November 2019 and matters/actions arising	Nick D'Arcy	Appendix 1	9.35
Items for commissioning recommendation				
3	Sativex® for the treatment of spasticity in multiple sclerosis	Naomi Scott	Appendix 2	9.40
4	Pitolisant hydrochloride for the treatment of narcolepsy with or without cataplexy in adults	Graham Simpole	Appendix 3	10.20
5	Invicorp® for erectile dysfunction	Naomi Scott	Appendix 4	10.45
6	Minimally invasive treatments for low back pain with and without sciatica	Chris Roome	Appendix 8	11.10
Other items for consideration				
7	Update to Dupuytren's contracture treatment policy in response to withdrawal of collagenase clostridium histolyticum	Rebecca Heayn	Appendix 5	11.25
8	Update from Clinical Policy Engagement and Consultation Panel	Mark Taylor	Appendix 6	11.30
9	Update from NICE Planning Advisory Group (NPAG)	Chris Roome	Appendices 7a & 7b	11.40
10	Any Other Business		Verbal	11.50
Meeting close				

Appendix 3

ATTENDANCE OF COMMITTEE MEMBERS

Name	Role	Organisation	Meetings attended/ possible
Dr Jo Roberts	Chair, GP Clinical Commissioner *(until July 2019)*	NHS Devon CCG	2 / 2
Dr Nick D'Arcy	Chair, GP Clinical Commissioner *(from November 2019)*	NHS Devon CCG	2 / 4
Dr Glen Allaway	Voting Member	NHS Devon CCG	3 / 4
Richard Croker (as delegate)	Deputy Director for Medicines Optimisation	NHS Devon CCG	1 / 1
Dr Andrew Craig	Voting Member	NHS Devon CCG	3 / 4
Paul Foster (as delegate)	Chief Pharmacist	Torbay and South Devon NHS Foundation Trust	1 / 1
Richard Croker	Deputy Director for Medicines Optimisation	NHS Devon CCG	2 / 4
Dr Tawfique Daneshmend	Consultant Gastroenterologist & Hepatologist	Royal Devon & Exeter NHS Foundation Trust	2 / 4
Paul Foster	Chief Pharmacist	Torbay and South Devon NHS Foundation Trust	3 / 4
Tracey Foss (as delegate)	Chief Pharmacist	Royal Devon & Exeter NHS Foundation Trust	1 / 1
Dr Lucy Harris	Voting Member	NHS Devon CCG	4 / 4
Dr Andrew Harrison	Voting Member	NHS Devon CCG	2 / 4
Peter Rowe (as delegate)	Consultant Nephrologist	University Hospitals Plymouth NHS Trust	1 / 1
Tawfique Daneshmend (as delegate)	Consultant Gastroenterologist & Hepatologist	Royal Devon & Exeter NHS Foundation Trust	1 / 1
Dr Claire Hooper	Voting Member *(from November 2019)*	NHS Devon CCG	2 / 2

Name	Role	Organisation	Meetings attended/ possible
Barbara Jones	Head of Contracting	NHS Devon CCG	4 / 4
Dr Paul Melling	Voting Member	NHS Devon CCG	3 / 4
Peter Rowe (as delegate)	Consultant Nephrologist	University Hospitals Plymouth NHS Trust	1 / 1
Mac Merrett	Lay Public Member		3 / 4
Simon Polak	Deputy Chief Nursing Officer *(until December 2019)*	NHS Devon CCG	1 / 3
Sarah Zanoni (as delegate)	Associate Director of Nursing	NHS Devon CCG	1 / 1
Lorraine Webber	Deputy Director of Quality Assurance and Improvement (Lead Nurse) *(from March 2020)*	NHS Devon CCG	0 / 1
Chris Roome	Head of Clinical Effectiveness	NHS Devon CCG	4 / 4
Dr Alison Round	Voting Member	NHS Devon CCG	2 / 4
Chris Roome (as delegate)	Head of Clinical Effectiveness	NHS Devon CCG	1 / 1
Dr Peter Rowe	Consultant Nephrologist	University Hospitals Plymouth NHS Trust	3 / 4
Mark Taylor	Lay Public Member		3 / 4
Dr Ben Waterfall	Voting Member	NHS Devon CCG	3 / 4
Chris Roome (as delegate)	Head of Clinical Effectiveness	NHS Devon CCG	1 / 1
Dr Emily Youngman	Consultant in Public Health Medicine	Devon County Council	2 / 4
Tracey Polak	Assistant Director/ Consultant of Public Health	Devon County Council	2 / 2

ADDITIONAL ATTENDEES (EXPERTS, GUESTS AND SECRETARIAT)

Name	Role	Organisation
22 May 2019		
Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NHS Devon CCG
Richard Haigh	Consultant Rheumatologist	Royal Devon and Exeter NHS Foundation Trust
Rebecca Heayn	Clinical Effectiveness Governance Manager	NHS Devon CCG
Matt Howard	Clinical Evidence Manager	NHS Devon CCG
Hilary Pearce	Clinical Effectiveness Pharmacist	NHS Devon CCG
Naomi Scott	Healthcare Evidence Reviewer	NHS Devon CCG
Elizabeth Wilkinson	Consultant Ophthalmologist	Northern Devon Healthcare NHS Trust
24 July 2019		
Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NHS Devon CCG
Rebecca Heayn	Clinical Effectiveness Governance Manager	NHS Devon CCG
Matt Howard	Clinical Evidence Manager	NHS Devon CCG
David McGregor	Consultant Paediatrician	Royal Devon and Exeter NHS Foundation Trust
Hilary Pearce	Clinical Effectiveness Pharmacist	NHS Devon CCG
Naomi Scott	Healthcare Evidence Reviewer	NHS Devon CCG
Graham Simpole	Joint Formulary Support Pharmacist	NHS Devon CCG
Becky Smith	Consultant Physician	University Hospitals Plymouth NHS Trust
Neil Walker	Consultant Physician	Royal Devon and Exeter NHS Foundation Trust
20 November 2019		
Andrew Cowan	Consultant Vascular and Endovascular Surgeon	Royal Devon and Exeter NHS Foundation Trust
Frances Dix	Consultant Vascular and Endovascular Surgeon	University Hospitals Plymouth NHS Trust
Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NHS Devon CCG
Alan Elstone	Vascular Specialist Nurse	University Hospitals Plymouth NHS Trust
Rebecca Heayn	Clinical Effectiveness Governance Manager	NHS Devon CCG
Matt Howard	Clinical Evidence Manager	NHS Devon CCG

Name	Role	Organisation
Robert McCarthy	Consultant Vascular Surgeon	Torbay and South Devon NHS Foundation Trust
Ben Peyton-Jones	Consultant Obstetrician and Gynaecologist	Royal Devon and Exeter NHS Foundation Trust
Naomi Scott	Healthcare Evidence Reviewer	NHS Devon CCG
Tamsin Sleep	Consultant Ophthalmologist	Torbay and South Devon NHS Foundation Trust
Graham Simpole	Healthcare Evidence Reviewer	NHS Devon CCG
Darren Wright	Joint Formulary Technician	NHS Devon CCG
11 March 2020		
Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NHS Devon CCG
Michael Foster	Consultant Urologist	Northern Devon Healthcare NHS Trust
Andrew Gunatilleke	Consultant in Pain Management and Anaesthesia	Torbay and South Devon NHS Foundation Trust
Tim Harrower	Consultant Neurologist	Royal Devon and Exeter NHS Foundation Trust
Rebecca Heayn	Clinical Effectiveness Governance Manager	NHS Devon CCG
Jeremy Hobart	Consultant Neurologist	University Hospitals Plymouth NHS Trust
Matt Howard	Clinical Evidence Manager	NHS Devon CCG
Louise Jarrett	MS Clinical Nurse Specialist	Royal Devon and Exeter NHS Foundation Trust
Nick Keysell	GP, DRSS	NHS Devon CCG
Jenny Pye	Specialist Nurse	Torbay and South Devon NHS Foundation Trust
Naomi Scott	Healthcare Evidence Reviewer	NHS Devon CCG
Graham Simpole	Medicines Optimisation Pharmacist	NHS Devon CCG
Adam Zeman	Professor of Cognitive and Behavioural Neurology	University of Exeter Medical School

Appendix 4

DECLARATIONS OF INTEREST REGISTER (APRIL 2019 – MARCH 2020)

Declarations of interest made by committee members

Name of attendee	Role	Meeting Date	Declared interest
Chris Roome	Head of Clinical Effectiveness	11 March 2020	I am co-author of a paper on the cost effectiveness of Sativex (Lu L et al) which NICE based their 2014 recommendations on.

Additional Declarations of Interest (Experts, Guests and Secretariat)

Name of attendee	Role	Meeting Date	Declared interest
Dr Timothy Harrower	Consultant Neurologist	11 March 2020	Contributed to Advisory Boards, prepared training courses and attended conferences for all three Toxins. One current study – Merz Pattern is looking at spasticity management of the lower limb but not in Multiple Sclerosis. All of this work has been for Cervical Dystonia, Migraine and Sialorrhoea not spasticity. Currently unpaid co-founder and director of British Nerotoxin Network.
Professor Jeremy Hobart	Consultant neurologist/ Professor	11 March 2020	We were a site for the MUSEC clinical trial (a cannabinoid but not sativex) and are a site for the upcoming GW studies.
Mr Robert McCarthy	Consultant Vascular Surgeon	20 November 2019	Private Sector Practice – Devonvein Solutions Ltd
Dr David McGregor	Consultant Paediatrician	24 July 2019	Received a bursary of £600.00 from Pfizer to attend BSPED (British Society for Paediatric Endocrinology and Diabetes) in 2017.
Dr Neil Walker	Consultant Physician	24 July 2019	Previously invited to Dexcom Launch meeting in October 2016.

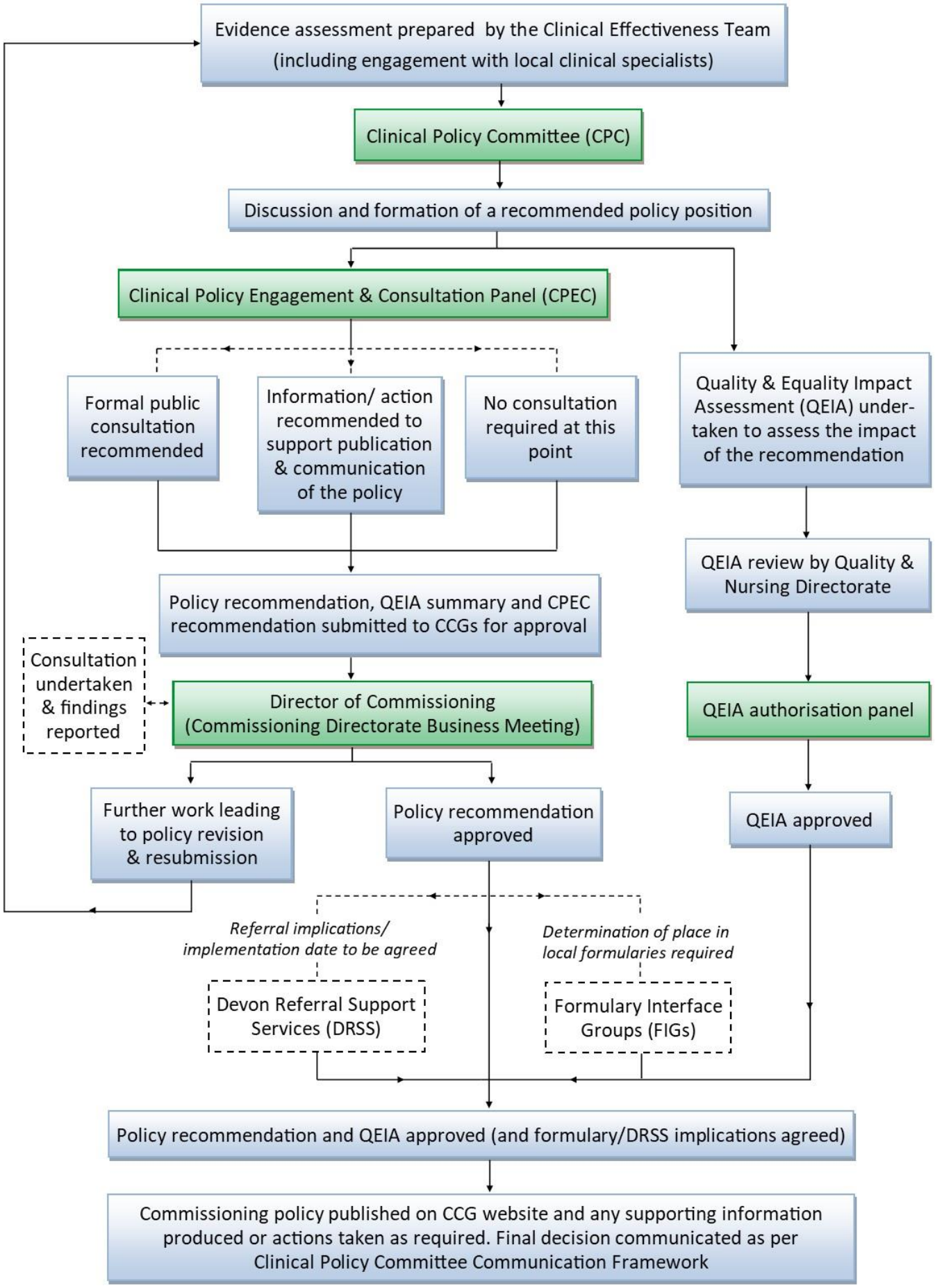
Dr Elizabeth Wilkinson	Medical Ophthalmologist	22 May 2019	Lecturer, advisor and in receipt of conference fees/ travelling grants for pharmaceutical companies e.g. Bayer and Novartis not related to Hydroxychloroquine. Sponsorship from imaging companies received by Royal Society of Medicine by Imaging Companies (Zeiss, Topcon, Heidelberg) for National Diabetic Eye Screening Conference 2019 organised by me. Employed by Health Intelligence as NHS Diabetic Eye Screening Clinical Lead for Devon.

Register of lay committee members' declared interests not related to discussion at CPC meeting

Name of attendee	Role	Details of interests	Date recorded
Mac Merrett	Lay public member	Chair RD&E Cancer User Group. Vice Chair Peninsular Cancer Group. Sit on various Cancer groups within the Peninsular. Representative on the Cancer Alliance. Trustee of Brampford Speke Village Hall Trust	23/08/2015 amended 11/10/2016; 07/06/2017; 01/05/2019
Mark Taylor	Lay public member	Albany Medical Clinic (GP Practice Newton Abbot), member of Patient Participation Group. Foundation Trust member: • Royal Devon & Exeter • Torbay and South Devon • Devon Partnership • Royal Brompton and Harefield Vice-chair Step One Charity (incorporates St Loye's and Community Care Trust SW)	03/05/2017

Appendix 5

Clinical policy engagement/consultation and communication process (April 2019)



Appendix 6

NHS Devon Clinical Commissioning Group

Clinical Policy Committee

APPEALS PROCESS

1. Introduction

1.1 This Appeals process applies to the operation of the Clinical Policy Committee of NHS Devon Clinical Commissioning Group (CCG).

2. Grounds for appeal

2.1 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.

2.2 The grounds for appeals are limited to the following:

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

  The CCG 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**

3. Appeals panel

3.1 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 Committee and the Head of Clinical Effectiveness, NHS Devon CCG. The majority view of the independent

members will decide the final outcome of the appeal. The independent members will be selected from the Governing Body of NHS Devon CCG.

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

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

4. Process

4.1 Appeals should be submitted within two months of notification of the final policy decision of the CCG following consideration of the Clinical Policy Committee recommendation.

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

4.3 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.

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

5. Decisions of the appeals panel

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

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

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

5.4 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 CCG standard complaints procedure.

6. Reconsideration of applications by the committee

6.1 Where an appeal is upheld and the original application referred back to the Clinical Policy 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

6.2 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.

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

7. Complaints

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

7.2 An appeal decision cannot be overturned through the complaints process.

8. 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.

April 2019

Appendix 7

NHS Devon Clinical Commissioning Group

Clinical Policy Committee

Communication Framework

The Clinical Policy Committee operates within the guiding principles published by the Department of Health for processes supporting local decision-making to ensure that all relevant policies and decisions are publicly available on the CCG website, along with details of the decision-making processes and governance arrangements.

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

Local health community dissemination:

- Secondary care only intervention – by standard distribution list to key individuals and groups across the Devon health community
- Referral criteria for routine procedures – in accordance with the Planned Care Control Centre communications and engagement plan with advanced notification of the implementation date
- Primary care relevant drug intervention requiring further consideration through Formulary Interface Groups (FIGs) – communicated after FIG discussions
- Primary care relevant drug intervention that is **not** routinely commissioned – by standard distribution list to include primary care practices

Public availability:

- Published on CCG website

Communication for local health system action:

- Specific communication direct to specialists involved with the process
- To Formulary Interface Groups (FIGs) prompting local treatment pathway development incorporating the commissioning decisions
- Specific notification to CCG communications and patient advice and complaints team to support the response to patient/public queries
- Engagement with Devon Referral Support Services (DRSS) and Planned Care for articulation of commissioning decision into effective referral criteria and the agreement of implementation date