NHS
Northern, Eastern and Western Devon
Clinical Commissioning Group
South Devon and Torbay
Clinical Commissioning Group

Clinical Policy Committee

Annual Report

2016-2017

Date: April 2017

Contents

Dr Jo Roberts
Chair's introduction

Throughout the year the Clinical Policy Committee has continued to be recognised as the authoritative forum for making recommendations for commissioning policy for drug treatments and surgical procedures based upon evidence of clinical benefit, cost effectiveness and financial impact.

The committee membership and working processes have served it well, bringing into place considered, clinically supported positions to help the Devon healthcare system respond to the challenges it faces.

A number of our voting members and one of our public lay members have stepped down from CPC over the year. We thank them for their service in helping maintain the integrity and reputation of CPC and wish them well. We have been joined by GPs Dr Lucy Harris and Dr Glen Allaway as new voting members representing the CCGs and welcome Mark Taylor as our new lay public member. One vacancy remains for a GP voting member in respect of a replacement for Dr Peter Leman for the Western locality of NEW Devon CCG.

The changes that I indicated in the last annual report with the development of Regional Medicines Optimisation Committees (RMOC) are only just about to become a reality. It is now known that four RMOCs will be established and will operate as a single medicines optimisation system for England, generating one output on any given topic, but that output will be advisory in status only. The responsibility for the commissioning of medicines considered by RMOCs remains with the individual statutory commissioning organisations. In the operating model we are assured that 'RMOCs will not have a performance management function with commissioners'.

In response to this I believe that CPC will undoubtedly need to retain a role in reviewing the recommendations and evidence that supports these, in order to make local decisions on commissioning specific medicines. However, with the development of RMOCs and changes in the commissioning landscape as a result of the emergence of Sustainability and Transformation Plans (STP) undoubtedly the role and remit of CPC must evolve to provide appropriate support.

CPC is already in a good position to support the STP as, since inception, it has operated across the geographical area now known as the STP footprint. RMOCs are likely to help rather than replace the role of CPC, whilst ever closer working between commissioning organisations and NHS trust providers through the STP is likely to influence how development work progresses.

In common with much of the NHS, such is the continuing financial situation for both CCGs in Devon that further difficult decisions will be needed on what treatments and procedures to routinely fund, and under what circumstances, in order to achieve a sustainable financial position. I believe that CPC can and must provide one of the resources for making evidence based decisions to evaluate technologies, rigorously assessing value for money against locally determined thresholds of affordability. As such CPC might sit well as one of the work streams of the STP to give it further emphasis and impetus.

Dr Jo Roberts
Chair, Clinical Policy Committee
Clinical Lead for Innovation and Medicines Optimisation
South Devon and Torbay Clinical Commissioning Group

1. Introduction

1.1 Through the Clinical Policy Committee Northern, Eastern and Western (NEW) Devon CCG and South Devon and Torbay CCG work together to carry out their responsibilities for making local decisions about the funding of medicines and treatments in the NHS.

1.2 The Committee make recommendations to the Clinical Commissioning Groups Governing Bodies, or appropriate groups with delegated authority, for approval following clinical discussion of the issues.

1.3 The Committee make recommendations to members of the Clinical Commissioning Groups 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. 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 process is guided by the National Prescribing Centre principles and rationale for local decision making.

2.3 The process and organisation is hosted by NEW Devon CCG and run by the Clinical Effectiveness Team. The Clinical Policy Committee is chaired by Dr Jo Roberts, Clinical Lead for Innovation and Medicines Optimisation for South Devon and Torbay CCG.

2.4 Committee meetings were scheduled for 2016-17 at approximately 6-weekly intervals.

2.5 It was necessary for two of the scheduled committee meetings to be cancelled; in June 2016 and March 2017 respectively. In June 2016 there were a number of pieces of work in preparation which could not be progressed to a final decision as guidance was still awaited on the commissioning positions in respect of these; there was insufficient time and resource to commence new work to be ready for the meeting. The March 2017 meeting was cancelled due to a temporary reduction in clinical effectiveness team staffing numbers. The decision to cancel the meeting, in consultation with leaders in both CCGs, was taken with regard to the relative priority of business to be progressed with the

committee and to enable the team to prioritise delivery through the formulary whilst maintaining business continuity.

2.6 This resulted in five meetings being held by the Clinical Policy Committee in 2016-17. The agendas for the meetings are shown in **Appendix 2**.

2.7 The committee is well supported and attendance at the meetings for the last year is shown in **Appendix 3**.

Changes in membership

2.8 Due to changes at GP practices and other commitments Dr Peter Leman, Dr Darunee Whiting and Dr Phil Melluish stepped down from the committee during the year; the committee expressed their thanks to them for all their hard work. Dr Lucinda Harris from South Devon and Dr Glen Allaway from North Devon were welcomed to the committee. One vacancy remains in respect of a replacement for Dr Peter Leman from the Western Locality, NEW Devon CCG.

Declaration of Interests

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

2.10 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/technology due to be considered along with details of any comparative products, and the respective pharmaceutical company/manufacturer. It also seeks to capture any interests relating to particular clinical areas where non-drug items are due to be discussed.

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

2.12 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.

2.13 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.

2.14 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 Constitutions of the CCGs.

2.15 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

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

2.17 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.

2.18 One of the serving lay public members, Jono Broad, resigned from the committee, attending his last meeting in September 2016. He had been a member of the group for two years as per his original appointment term and identified a change in his circumstances together with the increasing workload for lay members and lack of remuneration from the CCG as factors influencing his decision. He was thanked for all the work he had done for the committee, including for speaking his mind and asking difficult questions.

2.19 The vacancy for a new lay public member to sit on the Clinical Policy Committee and the Clinical Policy Engagement and Consultation Panel was subsequently advertised. As a result of this process, Mark Taylor was appointed to the role and will be joining the committee with effect from 1 April 2017.

The work programme

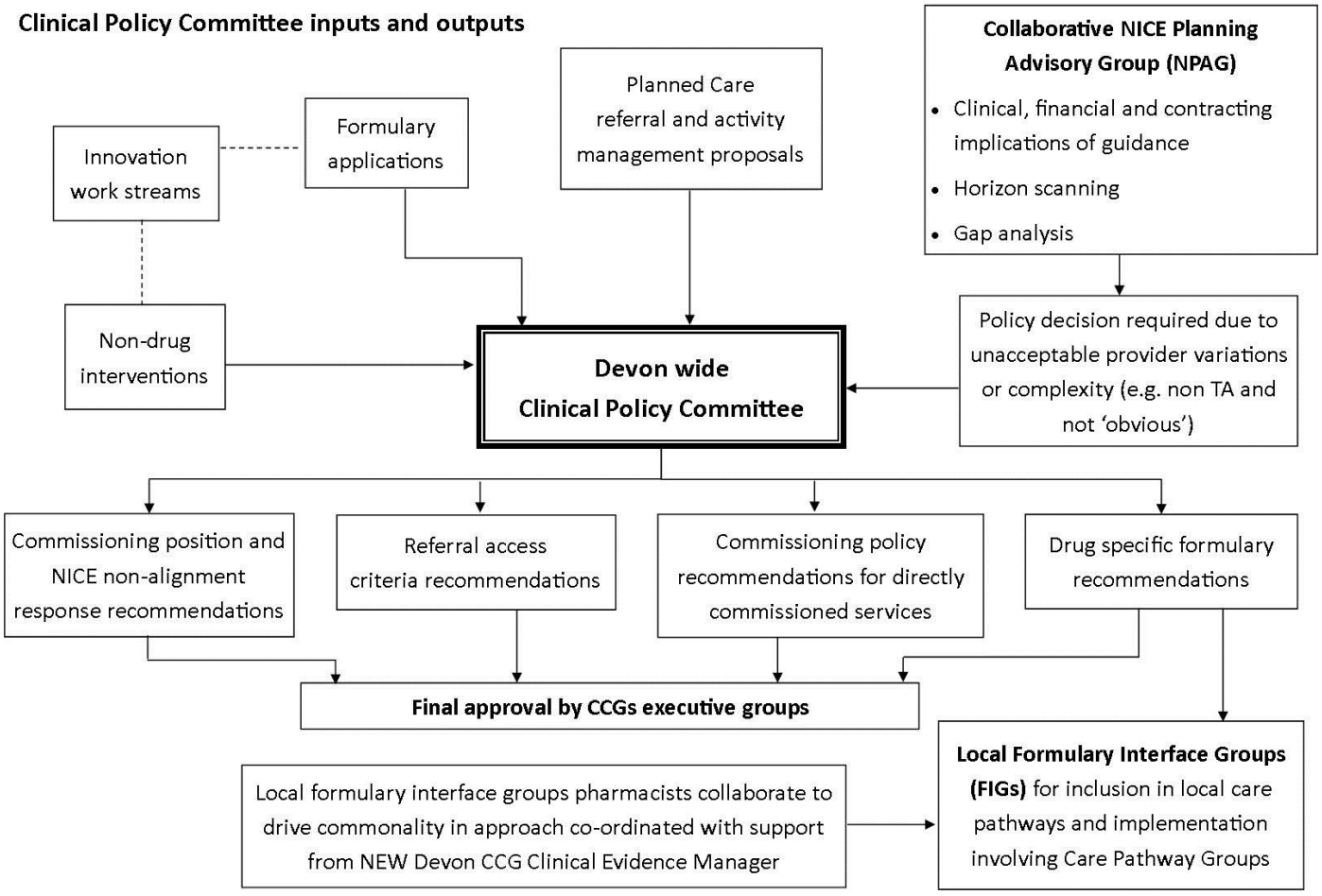
2.20 The work programme of the Clinical Policy Committee is managed by the Clinical Effectiveness Team, NEW Devon CCG.

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

- Louise Crathorne, Clinical Evidence Scientist
- Matt Howard, Clinical Evidence Manager
- Hilary Pearce, Clinical Effectiveness Pharmacist, and
- Petrina Trueman, Clinical Evidence Pharmacist.

2.22 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



Assurance Reporting

2.23 Reporting of any identified risks is undertaken to the CCGs by the Clinical Effectiveness Governance Manager, NEW Devon CCG.

2.24 Ratification of any formal matters arising from the Clinical Policy Committee, including changes to terms of reference, is undertaken by the Governing Bodies of the CCGs, or appropriate groups with delegated authority.

Appeals process

2.25 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.

2.26 The appeals process of the Clinical Policy Committee is as set out in **Appendix 5**.

2.27 An appeal may be made by the original applicant(s) – 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.

2.28 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.

2.29 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.

2.30 An application was received in August 2016 to appeal the decision that the routine commissioning of ulipristal acetate 5mg tablets is not accepted in Devon for intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age.

2.31 The clinical effectiveness team were aware of a concurrent update to NICE clinical guideline CG44 (published 24th August 2016) which included specific recommendations relating to the use of ulipristal acetate 5mg for women with heavy menstrual bleeding and fibroids. Rather than first considering an appeal in the circumstances of the original application, and subsequently considering the implications of the NICE guideline update, it was agreed with the appellant to take a pragmatic approach and ask the committee to re-consider the routine commissioning of ulipristal acetate 5mg tablets in this new context, in line with updated NICE recommendations. The commissioning position was subsequently reconsidered in light of the updated NICE clinical guideline recommendations in January 2017.

2.32 The Appeals panel has therefore not been required to address any appeals during 2016-17.

NICE Planning Advisory Group (NPAG) updates

2.33 The Clinical Policy Committee has continued to receive regular updates during 2016-17 in respect of the CCGs' NICE planning and assurance processes. This includes receipt of the minutes and verbal reports from the Chair on the commissioning implications of published Technology Appraisals and Clinical Guidelines.

Devon Formulary Interface Group (FIG) reports

2.34 The Clinical Policy Committee received an Annual Report of the Devon Formulary Interface Groups at its meeting in July 2016.

2.35 The Devon Formularies promote prescribing which is safe, clinically appropriate and cost-effective in both primary and secondary care, providing guidance on locally recommended drug choices. The Formularies are delivered through the Formulary Interface Groups (FIGs) which reflect natural healthcare communities. Representatives from both primary and secondary care sit on each FIG.

2.36 The report highlighted the work undertaken by the North and East Devon Formulary Interface Group and the South and West Devon Formulary Interface Group for April 2015 to March 2016.

2.37 This included the introduction of a bi-monthly virtual eFIG process to be run in the months when FIG meetings do not take place; the inclusion of some biosimilar biologic medicines into the formulary; the addition of a palliative care chapter to the North and East Devon formulary; and the inclusion of stoma work in the South and West Devon formulary.

2.38 During the year:

- the publication of new or revised national guidance had prompted review of a number of chapters and sections in both formularies.
- forty-one NICE Technology Appraisals and one Highly Specialised Technology have been added to the formularies in line with statutory commissioning responsibilities.
- after approval by the Clinical Policy Committee and the CCGs the FIG consults with appropriate clinicians to position the drug entry within the formularies. Four such decisions took place.
- nineteen new product applications were received.
- the FIGs approved the inclusion of 11 formulary preferred brands. The brands had been identified by the Medicines Optimisation teams and underwent a standardised assessment of key criteria.

2.39 Both the Devon formularies have a geographically tailored website to reflect the decisions of the Formulary Interface Group, available on a single app on both android and Apple® devices. Updates are received by users without the need for manual updates. The website and app was shortlisted as a finalist in the 2015 HSJ ‘Using Technology to Improve Efficiency’ award.

3. Commissioning recommendations

3.1 Recommendations made by the Clinical Policy Committee in 2016-17 for approval by the CCGs' executive groups are as detailed below:

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

Topic	Date of CPC recommendation	Date of publication*	Final commissioning decision
Insulin degludec 100units/ml (Tresiba®) for use in patients with type 1 diabetes	20 April 2016	17 June 2016	The routine commissioning of Insulin Degludec 100units/ml (Tresiba®) for Type 1 Diabetes is not accepted in Devon for the treatment of patients with type 1 diabetes.
Dulaglutide (Trulicity®)for the treatment of type 2 diabetes	20 July 2016	14 October 2016	The routine commissioning of Dulaglutide (Trulicity®) is accepted in Devon for the treatment of type 2 diabetes, for use in line with NICE guideline NG28.
Myringotomy with or without ventilation tubes (grommets) in adults and children aged 12 years and older	20 July 2016	30 October 2016	A Devon-wide policy for myringotomy with or without ventilation tubes (grommets) in adults and children aged 12 years and older has been agreed to ensure consistency in access to treatment for patients with the same clinical circumstances throughout Devon. The policy confirms the criteria under which myringotomy with or without ventilation tubes (grommets) will be funded in Devon.
Myringotomy/grommets with or without adjuvant adenoidectomy for the management of otitis media in children under 12 years	20 July 2016	30 October 2016	A Devon-wide policy for myringotomy/grommets with or without adjuvant adenoidectomy for the management of otitis media in children under 12 years has been agreed to ensure consistency in access to treatment for patients with the same clinical circumstances throughout Devon. The policy 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.

Topic	Date of CPC recommendation	Date of publication*	Final commissioning decision
Tonsillectomy	20 July 2016	30 October 2016	A Devon-wide policy for tonsillectomy has been agreed to ensure consistency in access to treatment for patients with the same clinical circumstances throughout Devon. The policy confirms the circumstances under which tonsillectomy will only be routinely commissioned in Devon.
Ivermectin (Soolantra®) for Rosacea	14 September 2016	29 November 2016	The routine commissioning of ivermectin 1% cream (Soolantra®) is accepted in Devon for the treatment of inflammatory lesions of moderate to severe papulopustular rosacea.
Linaclotide (Constella®) for the symptomatic treatment of moderate-to-severe irritable bowel syndrome with constipation (IBS-C)	14 September 2016	29 November 2016	The routine commissioning of linaclotide (Constella®) is <u>not</u> accepted in Devon for the treatment of irritable bowel syndrome with constipation (IBS-C) in adults.
Degarelix for advanced hormone dependent prostate cancer in patients without spinal metastases	Change in policy position noted 23 November 2016	26 October 2016 (Amendment to policy position expedited for agreement by CCGs executive groups in line with statutory timescales for the commissioning of NICE Technology Appraisals)	The Clinical Policy Committee has adopted and updated the previous decision of the Peninsula Health Technology Commissioning Group in light of the publication of NICE Technology Appraisal 404 which recommends degarelix as an option for treating advanced hormone-dependent prostate cancer in patients *with* spinal metastases. The routine commissioning of degarelix continues to not be accepted in Devon for the management of advanced hormone-dependent prostate cancer in patients *without* spinal metastases.
Surgery for Ganglion Cyst	14 September 2016	23 December 2016	A Devon-wide policy for surgery for ganglion cyst has been agreed to ensure consistency in access to treatment for patients with the same clinical circumstances throughout Devon. The policy confirms the circumstances under which surgery for removal of a ganglion cyst will only be routinely commissioned in Devon.

Topic	Date of CPC recommendation	Date of publication*	Final commissioning decision
Botulinum Toxin A for the management of hemifacial spasm	16 September 2015 23 November 2016	1 March 2017	The routine commissioning of botulinum toxin A is accepted in Devon for the management of hemifacial spasm when the condition causes the patient to be affected to at least a moderate degree by one or more of the criteria specified in the policy.
Botulinum Toxin A for the management of blepharospasm	16 September 2015 23 November 2016	1 March 2017	The routine commissioning of botulinum toxin A is accepted in Devon for the management of blepharospasm when the condition causes the patient to be affected to at least a moderate degree by one or more of the criteria specified in the policy.
Dexamethasone intravitreal implant (Ozurdex®) for the treatment of non-infectious posterior uveitis	23 November 2016	24 January 2017	The routine commissioning of dexamethasone intravitreal implant (Ozurdex®) is accepted in Devon for the treatment of non-infectious posterior uveitis which has not responded adequately to periocular steroid injection in the circumstances specified in the policy.
Guanfacine (Intuniv®) for attention deficit hyperactivity disorder (ADHD) in children and adolescents	23 November 2016	24 January 2017	The routine commissioning of guanfacine prolonged-release capsules (Intuniv®) is not accepted in Devon for the treatment of attention deficit hyperactivity disorder (ADHD) in children and adolescents aged 6-17 years.
Ulipristal acetate 5mg tablets (Esmya®) for intermittent treatment of moderate to severe symptoms of uterine fibroids in line with NICE CG44	18 January 2017	20 March 2017	The routine commissioning of ulipristal acetate 5mg tablets (Esmya®) is accepted in Devon for up to 4 courses of intermittent treatment of moderate to severe symptoms of uterine fibroids in line with the recommendations in NICE clinical guideline CG44.
Brivaracetam (Briviact®) for epilepsy	18 January 2017	20 March 2017	The routine commissioning of brivaracetam as an adjunctive treatment for partial-onset (focal) seizures is accepted in Devon.

Quality and Equality Impact Assessment (QEIA)

3.2 All CCG policies have a Quality and Equality Impact Assessment (QEIA) conducted on the final policy proposal before approval by the CCG Governing Bodies, or appropriate groups with delegated authority. The core components assessed by the tool are:

- Safety – the impact of the proposal on patient safety
- Effectiveness – the impact of the proposal on the clinical effectiveness of patient care
- Experience – the impact of the proposal on the patient experience of care delivery
- Other Impacts – the impact of the proposal on other services, patient groups, staff or reputation of the organisation
- Equality & Diversity – the impact on those in specific groups as outlined in the Equality Act 2010 and also including other hard to reach groups.

3.3 The QEIA tool assesses the impact of the recommendation and, in conjunction with other factors, provides a realistic and practical opportunity for any public consultation to be conducted as determined appropriate.

Clinical Policy Engagement and Consultation Panel

3.4 The Clinical Policy Engagement and Consultation Panel exists to support NEW Devon and South Devon and Torbay CCGs to determine the need for any further engagement or formal public consultation on recommendations made by the Clinical Policy Committee.

3.5 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.

3.6 This process and any resulting engagement or consultation precedes the CCGs' executive decision-making groups taking a final decision on whether to accept a clinical policy recommendation.

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

3.8 Full details of the panel process, terms of reference, minutes and register of interests is made publicly available via the NEW Devon CCG website, on behalf of both CCGs in Devon.

Clinical policy patient support information

3.9 As part of the above panel process, an output is a recommendation for post-decision support communication to accompany publication of the clinical policy. This support information follows a clear and consistent format and is agreed by an editorial sub-group, comprising clinical effectiveness, communications and patient safety and quality/ engagement representatives. This ensures a timely process, drawing on the relevant expertise.

3.10 The process also ensures that the Patient Advice/Experience and Communications teams of the CCGs are fully aware of the intended publication of a clinical policy and supporting patient information to enable them to be prepared and best able to respond to any patient or public queries.

3.11 A flowchart of the clinical policy engagement/consultation and communication process is shown in **Appendix 6**.

4. Costs

4.1 The costs for Clinical Policy Committee meetings held in the last year are shown below.

Clinical Policy Committee meeting costs 2016-17

Meeting date	Venue	Cost
20 April 2016	The Watermark, Ivybridge	£ 94.00
20 July 2016	Committee Room, County Hall, Exeter	£ 40.50
14 September 2016	Committee Room, County Hall, Exeter	£ 30.00
23 November 2016	Committee Room, County Hall, Exeter	£ 31.50
18 January 2017	Committee Room, County Hall, Exeter	£ 30.00

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

4.3 It was acknowledged that this fixed location is better able to accommodate guests, has the most effective teleconferencing facilities

and is generally able to be more responsive to any issues arising as it is the secretariat's office base.

4.4 Where alternative meeting locations have been necessary, the meeting facilities at The Watermark have been used. These are operated by Ivybridge Town Council.

5. Communication

Commissioning policies

5.1 All commissioning policies, categorised by body system, are made publicly available on the NEW Devon CCG website, which hosts these policies on behalf of both CCGs in Devon, at: www.newdevonccg.nhs.uk/who-we-are/medicines-and-treatments/commissioning-policies/100374

5.2 Clinical policy patient support information is similarly made available on the NEW Devon CCG website, on behalf of both CCGs in Devon, at: www.newdevonccg.nhs.uk/information-for-patients/medicines-and-treatments/clinical-policy-patient-support-information/101679. This has been produced to provide clarity for patients, the public and staff about why and how a decision has been taken in respect of commissioning a particular treatment and what it will mean for patients.

5.3 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**.

5.4 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.

5.5 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.

Governance documentation

5.6 Full details of the Clinical Policy Committee including governance documentation (minutes of meetings, terms of reference, appeals process and communication framework) is publicly accessible on the NEW Devon CCG website at: www.newdevonccg.nhs.uk/who-we-are//medicines-and-treatments/clinical-policy-committee/100372

5.7 This annual report will similarly be made publicly available once ratified.

5.8 Details of the Clinical Policy Engagement and Consultation Panel process, terms of reference, minutes and register of interests are also publicly accessible on the NEW Devon CCG website at: www.newdevonccg.nhs.uk/information-for-patients/medicines-and-treatments/local-decision-making/clinical-policy-committee-/clinical-policy-engagement-and-consultation-panel/101713

6. Reflective practice

Committee development

6.1 A committee development session was held in January 2017. In light of the changes in committee membership in November 2016, this sought to pull key elements of previous development sessions together to give members who had recently joined the committee an overview of decision making considerations together with some greater detail on particular concepts.

6.2 Existing members also found this a useful refresher and opportunity for discussion, particularly those who had missed one or more of the previously held development sessions.

6.3 Further committee development is planned for 2017-18. Members have reaffirmed that committee development sessions are helpful to their work on the committee and should continue to be held at suitable junctures.

7. Conclusion

7.1 Through the Clinical Policy Committee the CCGs in Devon discharge their responsibilities for making local decisions about the funding of medicines and treatments collaboratively, ensuring consistency in local decision making for patients in Devon.

7.2 The Clinical Policy Committee has considered 14 evidence assessments in 2016-17 resulting in commissioning recommendations and has adopted and updated one previous decision of the Peninsula Health Technology Commissioning Group in light of the publication of mandatory NICE Technology Appraisal guidance.

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

7.4 The CCGs Governing Bodies, or appropriate groups with delegated authority, are 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 NEW Devon CCG website on behalf of both CCGs in Devon.

APPENDIX 1

Northern, Eastern and Western Devon Clinical Commissioning Group
South Devon and Torbay Clinical Commissioning Group

Clinical Policy Committee

Terms of Reference

1. Purpose of the Group

1.1 The Clinical Policy Committee (CPC) exists to enable Northern, Eastern and Western (NEW) Devon and South Devon and Torbay Clinical Commissioning Groups (CCGs) to collaboratively discharge their responsibilities for making local decisions about the funding of medicines and treatments in the NHS.

1.2 The commissioning organisations have 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 Groups Governing Bodies, or appropriate groups with delegated authority, for approval following clinical discussion of the issues.

2.2 Make recommendations to members of the Clinical Commissioning Groups 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 publically accessible websites.

2.5 To make recommendations for commissioned services in the context on non-alignment with non-mandatory NICE guidelines.

2.6 Note reports, from the Clinical Commissioning Groups' NICE planning and assurance 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 one.

3.2 A current membership list will be maintained by the committee secretariat and published on the website.

3.3 The committee will comprise 19 members as follows:

- Clinician Members of the Clinical Commissioning Groups (x8) (of whom 1 Chair)
- Lay Members (x2)
- Patient Safety and Quality (x1)
- Public Health (x1)
- Contracting (x1)
- Finance (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 Committee membership will comprise eight (8) nominated Clinical Commissioning Group members who will act with delegated executive authority from the Clinical Commissioning Groups' Governing Bodies to make commissioning recommendations (voting members).

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

3.6 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.

3.7 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.

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

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 a minimum of six meetings per year.

4.2 Minutes or draft recommendations are to be sent for comment to appropriate clinicians and the Chair within one month of the meeting, and papers are to be disseminated to committee members prior to each meeting.

4.3 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.

4.4 Decision making will compromise two stages:

- All members of the Group 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 Clinical Commissioning Group members with delegated executive authority (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.

4.5 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 including any patient or public engagement undertaken in relation to the intervention or service
- Cost effectiveness and resource impact

4.6 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.

4.7 Clinicians and service providers will be invited to attend the committee to present the case for commissioning and to participate in the discussions prior to taking a decision. The diversity of work managed by the Committee will require specialist input in order to cover all facets and interests. Therefore consultants and clinical specialists will be invited to represent specialist interests and contribute to the decision-making process.

4.8 Minutes will be produced and published on the website of the secretariat host organisation following approval at the subsequent meeting.

4.9 Decisions are effective from the date of publication.

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

4.11 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 jointly nominated by the Governing Bodies of the Clinical Commissioning Groups. 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 host 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 joint delegated authority from and report to the Governing Bodies of Northern, Eastern and Western (NEW) Devon Clinical Commissioning Group and South Devon and Torbay 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 interest. The Chair will ask that declarations of interest are made known to the committee members to indicate any issues where there is a personal competing interest whether financial, academic or research. A register is to be kept by the Committee Co-ordinator.

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.
Clinical Commissioners	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	Understands 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 and finance	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 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 2015

APPENDIX 2

Northern, Eastern and Western Devon Clinical Commissioning Group
South Devon and Torbay Clinical Commissioning Group

Clinical Policy Committee

Wednesday 20th April 2016, 9.30-12.30

Stowford One, The Watermark, Ivybridge PL21 0SZ

AGENDA

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 24th February 2016 and matters/actions arising	Jo Roberts	Appendix 1	9.35
Items for commissioning recommendation				
3	Functional impairment as a criterion for access to treatment	Hilary Pearce	Appendix 2	9.45
4	Insulin Degludec 100units/ml (Tresiba®) for use in patients with type 1 diabetes	Matt Howard	Appendix 3	10.00
5	Ulipristal acetate 5mg tablets (Esmya®) for intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age	Matt Howard	Appendix 4	10.30
6	Discussions of policy access criteria for Botulinum Toxin A for the management of blepharospasm and for the management of hemifacial spasm	Jo Roberts	Verbal	11.00
Other items for consideration and information				
7	Commissioning policies for biological therapies for rheumatoid arthritis	Rebecca Heayn	Appendix 5	11.15
8	Annual Report 2015-16	Rebecca Heayn	Appendix 6	11.25
9	Update from NICE Planning, Quality and Assurance Group (NPAG)	Chris Roome	Appendix 7	11.35
10	Update from Clinical Policy Engagement and Consultation Panel	Mac Merrett	Appendix 8	11.45
11	Any Other Business		Verbal	11.55
Meeting close				

Northern, Eastern and Western Devon Clinical Commissioning Group
South Devon and Torbay Clinical Commissioning Group

Clinical Policy Committee

Wednesday 20th July 2016, 9.30-12.30

Committee Suite, County Hall, Exeter EX2 4QL

AGENDA

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 20th April 2016 and matters/actions arising	Jo Roberts	Appendix 1	9.35
Items for commissioning recommendation				
3	Dulaglutide (Trulicity®) for the treatment of type 2 diabetes	Matt Howard	Appendix 2	9.40
4	Myringotomy/grommets with or without adjuvant adenoidectomy for the management of otitis media in children under 12 years	Matt Howard	Appendix 3	10.05
5	Myringotomy with or without ventilation tubes (grommets) in adults and children aged 12 years and older	Matt Howard	Appendix 4	10.25
6	Tonsillectomy	Matt Howard	Appendix 5	10.50
7	Update on discussions of policy access criteria for Botulinum Toxin A for the management of blepharospasm and for the management of hemifacial spasm	Matt Howard	Verbal	11.15
Other items for consideration				
8	Joint Formularies Annual Report 2015-16	Carol Webb	Appendix 6	11.20
9	Update from NICE Planning, Quality and Assurance Group (NPAG)	Chris Roome	Appendix 7	11.30
10	Clinical Policy Engagement & Consultation Panel Annual Report 2015-16	Rebecca Heayn	Appendix 8	11.40
11	Update from Clinical Policy Engagement and Consultation Panel	Jono Broad/ Mac Merrett	Appendix 9	11.50
12	Any Other Business		Verbal	12.00
Meeting close				

Northern, Eastern and Western Devon Clinical Commissioning Group
South Devon and Torbay Clinical Commissioning Group

Clinical Policy Committee

Wednesday 14th September 2016, 9.30-12.30

Committee Suite, County Hall, Exeter EX2 4QL

AGENDA

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 20th July 2016 and matters/actions arising	Jo Roberts	Appendix 1	9.35
Items for commissioning recommendation				
3	Ivermectin (Soolantra®) for Rosacea	Petrina Trueman	Appendix 2	9.45
4	Linaclotide (Constella®) for the treatment of irritable bowel syndrome with constipation (IBS-C) in adults	Matt Howard	Appendix 3	10.15
5	Surgery for Ganglion Cyst	Hilary Pearce	Appendix 4	10.45
Other items for consideration				
6	Update from NICE Planning, Quality and Assurance Group (NPAG)	Chris Roome	Appendix 5	11.00
7	Update from Clinical Policy Engagement and Consultation Panel	Mac Merrett	Appendix 6	11.10
8	Any Other Business		Verbal	11.20
Meeting close				

Northern, Eastern and Western Devon Clinical Commissioning Group
South Devon and Torbay Clinical Commissioning Group

Clinical Policy Committee

Wednesday 23rd November 2016, 9.30-12.30

Committee Suite, County Hall, Exeter EX2 4QL

AGENDA

Number	Item	Lead	Appendix	Time
1	Welcome and announcements • Welcome to new members • 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 14th September 2016 and matters/actions arising	Jo Roberts	Appendix 1	9.40
Items for commissioning recommendation				
3	Guanfacine (Intuniv®) for attention deficit hyperactivity disorder (ADHD) in children and adolescents	Petrina Trueman / Matt Howard	Appendix 2	9.50
4	Dexamethasone intravitreal implant (Ozurdex®) for the treatment of non-infectious posterior uveitis	Louise Crathorne	Appendix 3	10.20
5	Botulinum Toxin A for the management of blepharospasm and for the management of hemifacial spasm	Matt Howard	Appendix 4	10.50
Other items for consideration				
6	Degarelix for advanced hormone-dependent prostate cancer	Rebecca Heayn	Appendix 5	11.10
7	Update from NICE Planning, Quality and Assurance Group (NPAG)	Chris Roome	Appendices 6a & 6b	11.25
8	Update from Clinical Policy Engagement and Consultation Panel	Mac Merrett	Appendix 7	11.35
9	Update on Lay Public Member vacancy	Chris Roome	Verbal	11.45
10	Any Other Business		Verbal	11.55
Meeting close				

Northern, Eastern and Western Devon Clinical Commissioning Group
South Devon and Torbay Clinical Commissioning Group

Clinical Policy Committee

Wednesday 18th January 2017, 9.30-12.30

Committee Suite, County Hall, Exeter EX2 4QL

AGENDA

Number	Item	Lead	Appendix	Time
PART ONE – REGULAR BUSINESS				
1	Welcome and announcements • Apologies • Confirmation of voting members and Declarations of interest • Notification of Any Other Business	Ali Round	Verbal	9.30
2	Minutes of the meeting held on 23rd November 2016 and matters/actions arising	Ali Round	Appendix 1	9.35
Items for commissioning recommendation				
3	Ulipristal acetate 5mg tablets (Esmya®) for intermittent treatment of moderate to severe symptoms of uterine fibroids in line with NICE CG44	Matt Howard	Appendix 2	9.45
4	Brivaracetam (Briviact®) for epilepsy	Hilary Pearce	Appendix 3	10.15
Other items for consideration				
5	Update from Clinical Policy Engagement and Consultation Panel	Mac Merrett	Appendix 4	10.45
6	Any Other Business		Verbal	10.50
Break				
PART TWO – COMMITTEE DEVELOPMENT SESSION (venue Otter Room, County Hall, Exeter)				
	Committee member development session	Chris Roome		11.00
Meeting close				

APPENDIX 3

ATTENDANCE OF COMMITTEE MEMBERS

Name	Role	Organisation	Meetings attended/ possible
Dr Jo Roberts VOTING MEMBER	Chair, GP Clinical Commissioner	South Devon & Torbay CCG	4 / 5
Paul Foster (as delegate)	Chief Pharmacist	Torbay and South Devon NHS Foundation Trust	1 / 1
Dr Glen Allaway VOTING MEMBER *(from November 2016)*	GP Clinical Commissioner	NEW Devon CCG	2 / 2
Dr Mick Braddick VOTING MEMBER	GP Clinical Commissioner	NEW Devon CCG	5 / 5
Jono Broad *(to September 2016)*	Lay Member		2 / 3
Lorna Collingwood-Burke	Chief Nursing Officer	NEW Devon CCG	0 / 5
Andrew Kingsley (as delegate)	Lead Nurse Healthcare Acquired Infections	NEW Devon CCG	5 / 5
Dr Andrew Craig VOTING MEMBER	GP Clinical Commissioner	NEW Devon CCG	5 / 5
Richard Croker	Head of Medicines Optimisation	NEW Devon CCG	2 / 5
Dr Tawfique Daneshmend	Consultant Gastroenterologist & Hepatologist	Royal Devon & Exeter NHS Foundation Trust	3 / 5
Miles Earl	Contract Accountant	NEW Devon CCG	3 / 5
Paul Foster	Chief Pharmacist	Torbay and South Devon NHS Foundation Trust	3 / 5
Simon Mynes (as delegate)	Director of Pharmacy	Plymouth Hospitals NHS Trust	1 / 1
Dr Andrew Gunatilleke	Consultant in Pain Management & Anaesthesia	Torbay and South Devon NHS Foundation Trust	3 / 5
Dr Glen Matfin (as delegate)	Consultant in Diabetes and Endocrinology	Plymouth Hospitals NHS Trust	1 / 1

Name	Role	Organisation	Meetings attended/ possible
Dr Lucinda Harris VOTING MEMBER *(from November 2016)*	GP Clinical Commissioner	South Devon and Torbay CCG	2 / 2
Barbara Jones	Head of Locality Contracting	NEW Devon CCG	2 / 5
Rob Cowdry (as delegate)	Contracts Governance Manager Commissioning	NEW Devon CCG	1 / 1
Dr Peter Leman VOTING MEMBER *(to September 2016)*	GP Clinical Commissioner	NEW Devon CCG	1 / 3
Chris Roome (as delegate)	Head of Clinical Effectiveness	NEW Devon CCG	2 / 2
Dr Phil Melluish VOTING MEMBER *(to September 2016)*	GP Clinical Commissioner	South Devon & Torbay CCG	3 / 3
Mac Merrett	Lay Member		5 / 5
Samantha Morton	Head of Contracting and Procurement	South Devon & Torbay CCG	0 / 5
Tracey Kerslake (as delegate)	Contract Manager/ Funding	South Devon & Torbay CCG	1 / 1
Tracey Polak	Assistant Director/ Consultant of Public Health	Devon County Council	0 / 5
Dr Mark Kealy (as delegate)	Consultant in Public Health	Devon County Council	4 / 4
Dr Sarah Ogilvie (as delegate)	Consultant in Public Health	Devon County Council	1 / 1
Chris Roome	Head of Clinical Effectiveness	NEW Devon CCG	5 / 5
Dr Alison Round VOTING MEMBER	GP Clinical Commissioner	NEW Devon CCG	4 / 5
Chris Roome (as delegate)	Head of Clinical Effectiveness	NEW Devon CCG	1 / 1

Name	Role	Organisation	Meetings attended/ possible
Dr Ben Waterfall VOTING MEMBER	GP Clinical Commissioner	NEW Devon CCG	4 / 5
Richard Croker (as delegate)	Head of Medicines Optimisation	NEW Devon CCG	1 / 1
Dr Darunee Whiting VOTING MEMBER *(to September 2016)*	GP Clinical Commissioner	NEW Devon CCG	0 / 3
Richard Croker (as delegate)	Head of Medicines Optimisation	NEW Devon CCG	1 / 1

ADDITIONAL ATTENDEES (EXPERTS, GUESTS AND SECRETARIAT)

Name	Role	Organisation
20th April 2016		
Daniel Flanagan	Consultant Physician	Plymouth Hospitals NHS Trust
Alex Degan	Planned Care Lead GP	NEW Devon CCG
Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NEW Devon CCG
Rebecca Heayn	Clinical Effectiveness Governance Manager	NEW Devon CCG
Matt Howard	Clinical Evidence Manager	NEW Devon CCG
Hilary Pearce	Clinical Effectiveness Pharmacist	NEW Devon CCG
Petrina Trueman	Clinical Evidence Pharmacist	NEW Devon CCG
20th July 2016		
Louise Crathorne	Clinical Evidence Scientist	NEW Devon CCG
Ioannis Dimitropoulos	Consultant in Diabetes, Endocrinology & General Internal Medicine	Plymouth Hospitals NHS Trust
Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NEW Devon CCG
Rebecca Heayn	Clinical Effectiveness Governance Manager	NEW Devon CCG
Matt Howard	Clinical Evidence Manager	NEW Devon CCG
Beverley Parker	Head of Planned Care	South Devon and Torbay CCG

James Rainsbury	Consultant ENT Manager	Plymouth Hospitals NHS Trust
Carol Webb	Joint Formularies Technician	NEW Devon CCG
14th September 2016		
Louise Crathorne	Clinical Evidence Scientist	NEW Devon CCG
Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NEW Devon CCG
Lucinda Harris	Clinical Lead	DRSS
Rebecca Heayn	Clinical Effectiveness Governance Manager	NEW Devon CCG
Matt Howard	Clinical Evidence Manager	NEW Devon CCG
Nick Kennedy	Consultant Gastroenterologist	Royal Devon and Exeter NHS Foundation Trust
Emily McGrath	Consultant Dermatologist	Royal Devon and Exeter NHS Foundation Trust
Petrina Trueman	Clinical Evidence Pharmacist	NEW Devon CCG
23rd November 2016		
Daniel Byles	Consultant Ophthalmologist	Royal Devon and Exeter NHS Foundation Trust
Louise Crathorne	Clinical Evidence Scientist	NEW Devon CCG
Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NEW Devon CCG
Muriel Gijsel	Consultant Child & Adolescent Psychiatrist	Devon Integrated Children's Services
Jonathan Graham	Consultant Paediatrician	Torbay and South Devon NHS Foundation Trust
Rebecca Heayn	Clinical Effectiveness Governance Manager	NEW Devon CCG
Matt Howard	Clinical Evidence Manager	NEW Devon CCG
Peter Simcock	Consultant Eye Surgeon	Royal Devon and Exeter NHS Foundation Trust
Petrina Trueman	Clinical Evidence Pharmacist	NEW Devon CCG
18th January 2017		
Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NEW Devon CCG
Rebecca Heayn	Clinical Effectiveness Governance Manager	NEW Devon CCG
Matt Howard	Clinical Evidence Manager	NEW Devon CCG
Hilary Pearce	Clinical Effectiveness Pharmacist	NEW Devon CCG
Ben Peyton-Jones	Consultant Obstetrician and Gynaecologist	Royal Devon and Exeter NHS Foundation Trust
Martin Sadler	Consultant Neurologist	Plymouth Hospitals NHS Trust
Peter Scott	Consultant Obstetrician and Gynaecologist	Plymouth Hospitals NHS Trust

APPENDIX 4

DECLARATIONS OF INTEREST REGISTER (APRIL 2016 – MARCH 2017)

Declarations of interest made by committee members

Name of attendee	Role	Meeting Date	Declared interest
Dr Mick Braddick VOTING MEMBER	GP Clinical Commissioner	20 April 2016	Hopes to have an active retirement and would be disappointed if the NHS could not provide support if required.
Richard Croker	Head of Medicines Optimisation	14 September 2016	Worked as a paid advisor for Galderma UK, Galen and Sterling Anglian, (Macrogol), (Soolantra, Roxel)
Dr Ali Round VOTING MEMBER	GP Clinical Commissioner	20 July 2016	Spouse has hearing impairment.

Additional Declarations of Interest (Experts, Guests and Secretariat)

Name of attendee	Role	Meeting Date	Declared interest
Louise Crathorne	Clinical Evidence Scientist	20 July 2016 14 September 2016	Previously provided advice on systematic review methodology e.g. for HTA methods at company/ sponsored seminars where buffet lunch provided no projects undertaken related to any of the topics lists on agenda or July CPC. In a previous post received fees for review of methods in review of economic evaluation from Almirall (NICE submission). This was for a different product than that discussed at CPC on 14 September 2016.
Alex Degan	Planned Care Lead GP	20 April 2016	Brother is employed by Eli Lilly as Regional Digital Manager. Has shared in various pharmaceutical companies through tracker funds. Spouse has shares in Astra Zeneca and also has shares in various pharmaceutical companies through tracker funds. GP practice is a member of a federation of practices in Mid Devon called Mid Devon Healthcare – the federation is a potential provider of services in the future.

Name of attendee	Role	Meeting Date	Declared interest
Daniel Flanagan	Consultant Physician	20 April 2016	Advisory Board attendance for NovoNordisk and MSD within the past 3 years. Lecture fees from NovoNordisk, Sanofi and Lilly within the past 3 years. Payment for attendance at international conference by NovoNordisk within the past 3 years.
Muriel Gijsel	Consultant child Psychiatrist	23 November 2016	Shire Pharmaceuticals Limited sponsored meeting attended.
Lucinda Harris	GP	14 September 2016	Spouse is an orthopaedic surgical trainee in the Southwest. He does not undertake any private practice.
Matt Howard	Clinical Evidence Manager	20 July 2016 14 September 2016	In previous post, attended various CPD events where hospitality/refreshments etc. may have been sponsored by various manufacturers.
Mark Kealy	Consultant in Public Health Medicine	14 September 2016	Prescribed Ivermectin on a number of occasions for disseminated scabies.
Nick Kennedy	Consultant Gastroenterologist	14 September 2016	Gave an invited talk on withdrawal of anti-TNF therapy to a regional meeting of gastroenterologists in February 2016 for this an honorarium was received from Actavis. Actavis has now rebranded as Allergan. Has not had any commercial involvement with Almirall or anything directly related to linaclotide.
Emily McGrath	Consultant Dermatologist	14 September 2016	Galderma have represented themselves and provided lunch at 2 dermatology meetings regionally in the past 12 months when Soolantra has been discussed.
Glen Matfin	Consultant in Diabetes and Endocrinology	20 July 2016	Was an investigator for dulaglutide pen and was author on paper in 2013/14.
Simon Mynes	Director of Pharmacy Plymouth Hospitals NHS Trust	20 April 2016	Support from Sanofi to attend European Association of Hospital Pharmacists (EAHP) conference in 2011.

Name of attendee	Role	Meeting Date	Declared interest
Ben Peyton Jones	Consultant Obstetrician and Gynaecologist	18 January 2017	Work as paid adviser to above manufacturing company Espiner Medical (Surgical device) In receipt of equipment manufacturing company/ companies. Surgical device In receipt of lecture fees in excess of £150 in the last year from above pharmaceutical/ manufacturing company/companies. Espiner Medical (Surgical device) – running course on Sub-total hysterectomies
Martin Sadler	Consultant Neurologist	18 January 2017	• *Received gifts, benefits or sponsorship of any kind, whether refused or accepted work over £25 or several small gifts worth a total of over £100 form the above or closely related pharmaceutical / manufacturing company/companies.* • *Hospitality received where the drug(s) /device(s)/intervention(s)/treatment(s) under consideration were discussed by a representative of a drug/manufacturing company/companies.* • *Any of the above interests for a competitor of this drug/device/intervention.* Department has received support for academic meetings and regional study days for trainees from several drug companies including UBC. I have received an honorarium for chairing part of an epilepsy meeting that was sponsored by UCB. I have agreed to speak at a further meeting sponsored by UCB in 2017. I have spoken at a national academic meeting where the drug stands included one sponsored by UCB. Other drug companies that make AEDs and drugs for other neurological diseases were also present at the regional and national meetings. I have collected data for a study on perampanel and I am collecting data for a study on lacosamide and other AEDs but this is not a commercially sponsored study. I am a PI in SANAD 2 a non-commercial sponsored trial of a range of AEDs.

Register of committee members' contact with healthcare industry not related to discussion at CPC meeting

Name of attendee	Role	Details of contact	Date recorded
Dr Jo Roberts VOTING MEMBER	Chair GP Clinical Commissioner	Meeting with Novartis re degludec	April 2016
		Meeting with Roche diagnostics for INR training event	May 2016
		Business update meeting with GSK	May 2016
		Meeting with INRstar for INR training	June 2016
		Meeting with Astra Zeneca	June 2016
		Meeting in conjunction with Roche and INRstar at Newton Abbot racecourse (venue paid by companies	June 2016
		Meeting with Pfizer to discuss application for MEGs to support COPD project	June 2016
		Locality COPD meetings sponsored by Pfizer	July 2016
		Meeting with Astra Zeneca meeting re diabetes and ticegralor	June 2016
		Meeting with Bayer regarding contour next	August 2016
		Meeting with Chiesi to discuss application for MEGs to support COPD project	August 2016
		Meeting novonordisk regarding diabetes support	August 2016
		Support to Healthera to progress research following SBRI grant	August 2016
		Support to Kernow Health Solutions towards developing patient record for SBRI grant	August 2016
		Meeting with Bayer general update	September 2016
		Locality COPD meetings sponsored by Pfizer and Chiesi	September 2016

		MEGS £38307 granted to SD&T CCG by Pfizer to support COPD project	October 2016
		Meeting with Helicon health care	October 2016
		Meeting with Apollo analytics	October 2016
		Locality COPD meetings sponsored by Pfizer and Chiesi	October 2016
		Locality COPD meetings sponsored by Pfizer and Chiesi	November 2016
		Meeting with Teva regarding Braltus	November 2016
		Meeting with Telecon regarding aquamax	November 2016
		Demonstration regarding optimisation Rx	November 2016
		Meeting with Boehringer INgelheim regarding triotropium	December 2016
		Eclipse radar demonstration	December 2016
		Review meeting with Astra Zeneca	January 2017
		Meeting with Merck	March 2017
		Meeting with Roche regarding diabetes care	March 2017
Andrew Kingsley	HCAI Lead Nurse	Provided infection prevention opinion on disinfection wipes to Shermond365 (unpaid) Provided infection prevention opinion on construction of pressure relieving device to Hutchinson Wound Tech Limited (unpaid) Lead a leg ulcer services market place engagement event – included NHS and some private providers.	20 July 2016

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

Name of attendee	Role	Details of interests	Date recorded
Jono Broad	Lay member	Working with the SWAHSN as a patient advisor on medicines optimisation and patient safety. Involved with the NHS Leadership Academy for patient engagement. School Governor for Ashleigh Road Primary School Lecturer for Northern Devon Healthcare Preceptor programme and Essential skills for Support workers programme. Associate Non-Executive Director for Northern Devon Healthcare Trust *(from 01/02/2016)*	14 August 2015 31 December 2015
Mac Merrett	Lay member	Chair RD&E Cancer User Group. Vice Chair Peninsular Cancer Group. Member of Citizen Assembly. Sit on various Cancer groups within the Peninsular. Parish Councillor. Representative on the Cancer Alliance.	23 August 2015 11 October 2016

APPENDIX 5

Northern, Eastern and Western Devon Clinical Commissioning Group
South Devon and Torbay 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 Northern, Eastern and Western (NEW) Devon and South Devon & Torbay Clinical Commissioning Groups (CCGs).

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 CCGs are 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 CPC and the Head of Clinical Effectiveness, NEW 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 Bodies of NEW Devon CCG and South Devon and Torbay 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 NEW Devon and South Devon & Torbay CCGs.

4. Process

4.1 Appeals should be submitted within two months of notification of the final policy decision of the CCGs 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 NEW 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 CCGs, 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 NEW 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.

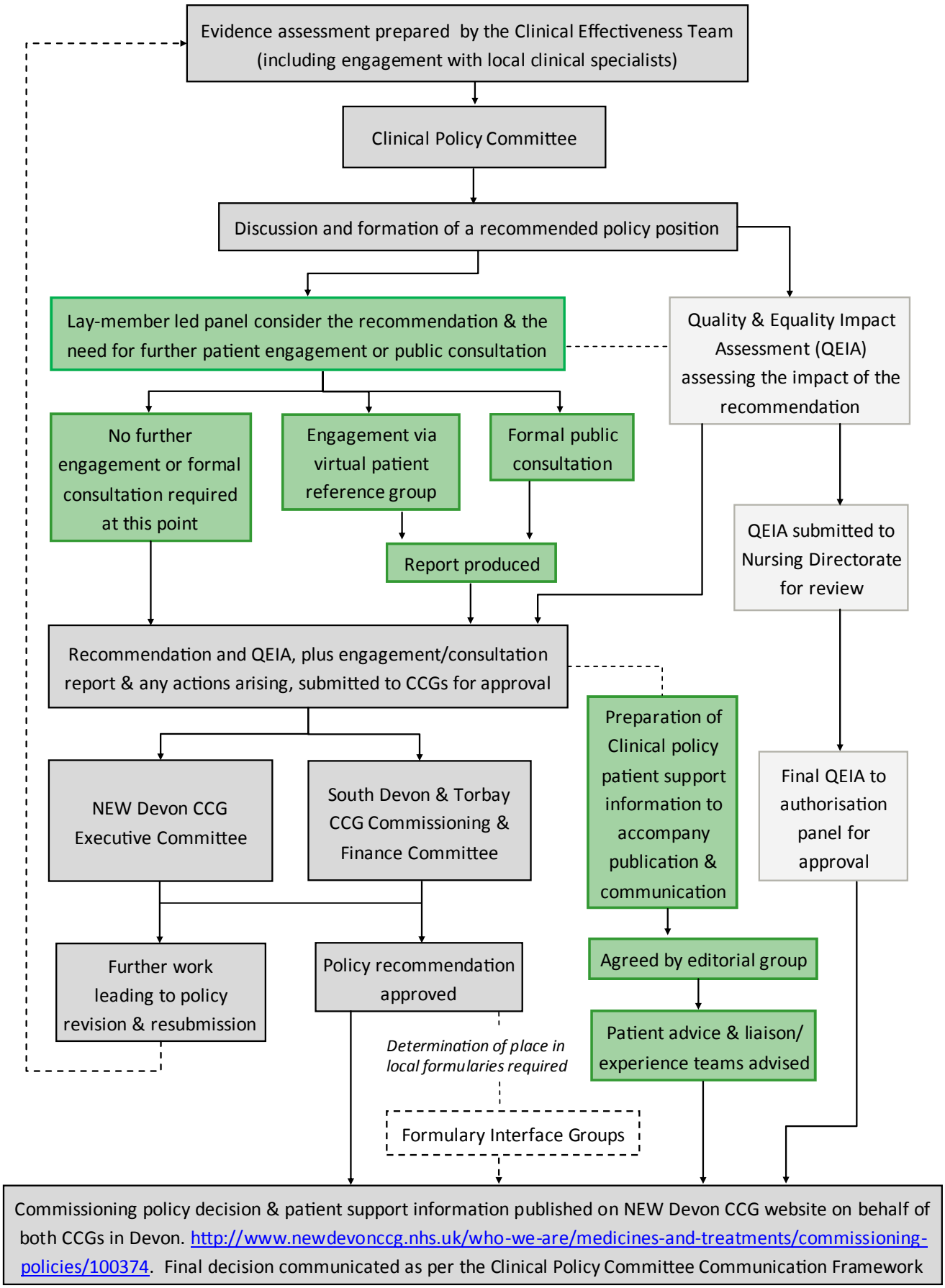
National Institute for Health and Clinical Excellence. Guide to the technology appraisal appeal process. August 2010.

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 2015

Clinical policy engagement/consultation and communication process



Northern, Eastern and Western Devon Clinical Commissioning Group
South Devon and Torbay 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 NEW Devon CCG website, along with details of the decision-making processes and governance arrangements.

A communication framework is in place as set out 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 – communicated by standard distribution list to key individuals and groups across the Devon health community

Referral criteria for routine procedures – communicated 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 – communicated by standard distribution list to include primary care practices

Public availability:

Published on NEW Devon CCG website

Communication for local health system action:

Specific communication direct to specialists involved with the process

Communication to Formulary Interface Groups prompting local treatment pathway development incorporating the commissioning decisions

Specific notification to CCG communications and patient advice/ experience teams to support the response to patient/public queries

Engagement with Devon Referral Support Services (DRSS) and Planned Care Control Centre for articulation of commissioning decision into effective referral criteria and the agreement of an implementation date