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

Clinical Policy Committee

Annual Report

2014-2015

Date: April 2015

Contents

Dr Jo Roberts
Chair's introduction

In my Chair's introduction to the annual report last year I wrote: "I am keen that the reputation of the Clinical Policy Committee to take respected decisions grows, and that it becomes a valued choice for evaluating a wide range of health technologies to support the commissioning processes for the whole of Devon."

I am pleased to report that this desire has been fulfilled and the Clinical Policy Committee is now an indispensable committee supporting commissioning across both CCGs in Devon. The Clinical Policy Committee is a firmly established committee which has consolidated its acknowledged position to provide clinically supported, evidence based decisions and recommendations in challenging areas of policy making for the CCGs. In an increasingly difficult financial environment the long standing focus on clinical evidence and cost effectiveness of interventions has been supplemented with considering how to balance clinical and service benefits with short term affordability constraints.

The expertise of the committee and the robust underpinning processes and governance arrangements that the clinical effectiveness team maintain were identified as providing the structure within which to progress tough decisions relating to the availability of treatments within the NHS in Devon. The broadened remit of the committee also included providing recommendations on the position the CCGs should adopt in the context of non-mandatory NICE guidelines. The committee and its supporting infrastructure have risen well to these challenges and give the organisations an appropriately constituted process that can be relied upon to make clinically appropriate population based commissioning recommendations which encompass the public interest.

During the year the committee welcomed two new voting GP members, Ben Waterfall from North Devon and Peter Leman for Western Devon, replacing Steve Hunt and Keith Gillespie (who moved abroad). The advisory membership of the committee has continued to serve the needs of the committee well and we are delighted to have retained two lay members on the committee helping to ensure attention to the broad public interest perspective in committee business.

I firmly expect that the Clinical Policy Committee will continue to provide a committee of excellence to help the CCGs to commission clinically appropriate affordable services for the populations they serve.

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 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 determines whether the Clinical Commissioning Groups will make funding available to commission specific treatments and healthcare interventions from provider organisations. This is within financial limits delegated from the Governing Bodies.

1.3 The Committee makes 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. It approves policy documents that define the clinical circumstances under which clinical services, procedures and interventions will be commissioned.

1.4 The Committee is additionally a forum for cross-CCG clinical discussion and formation of a recommendation on any other issues related to services for which decisions need to be taken by the commissioning organisations. This may include, for example, recommendations for service provision for existing commissioned treatments and decisions to be taken in the context of recommendations in NICE clinical guidelines.

2. The Process

Terms of reference

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

2.2 The terms of reference were revised and changes ratified by the CCGs in July 2014 to allow the Clinical Policy Committee to additionally provide a forum for cross CCG clinical discussion.

2.3 The result of this revision is that subsequent committee meeting business has been conducted in two parts:

- Part one business consists of consideration and decision making in respect of the commissioning of specific treatments and healthcare interventions.

- Part two business consists of clinical discussion of any other items for which decision making needs to be undertaken by the commissioning organisations. The output is recommendations to the Clinical Commissioning Groups' executive groups for final decision making. The Clinical Policy Committee is advised of the outcome of the final decision making and whether the committee's recommendations have been accepted.

2.4 Other updates were also made to reflect the agreement of procedural and governance arrangements in respect of expected attendance levels of members, the provision of deputies and specification of the role and function of the lay members.

Nomination of deputies to represent voting members

2.5 The committee were in agreement that voting members may nominate deputies, who should be current, non-lay, advisory members of the committee. The lay members of the committee asked that the terms of reference specify that this should only relate to non-lay members as they felt that being asked to act in a voting capacity would conflict with their role in representing the public interest of the local population.

Future changes to the process of clinical policy formation via the Clinical Policy Committee

2.6 It is proposed that further changes will be made to the process of clinical policy formation via the Clinical Policy Committee for 2015-16. These are described more fully in section 7 and, at the time of preparation of this report, the revised terms of reference for future working are pending ratification by the CCGs' Governing Bodies, or appropriate groups with delegated authority.

Committee process and meeting arrangements

2.7 The process is guided by the National Prescribing Centre principles and rationale for local decision making.

2.8 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.

2.9 Seven meetings were convened by the Clinical Policy Committee in 2014-15. The agendas for the meetings are shown in **Appendix 2**.

2.10 Meetings were held at approximately 6 weekly intervals across a rotation of locations including Exeter, Ivybridge and Cullompton.

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

Declaration of Interests

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

2.13 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.

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

2.15 All declared interests are considered by the Chair and disclosed to the committee at the beginning of the meeting. Where there are no interests to declare, a 'nil' return is required.

2.16 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.

2.17 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.

2.18 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

2.19 There are two current serving voluntary public representatives, also known as lay members, on the Committee.

2.20 Lay members bring an understanding of the necessity to balance the healthcare needs of specific patient groups with the requirement to resource a comprehensive health service. They provide the committee

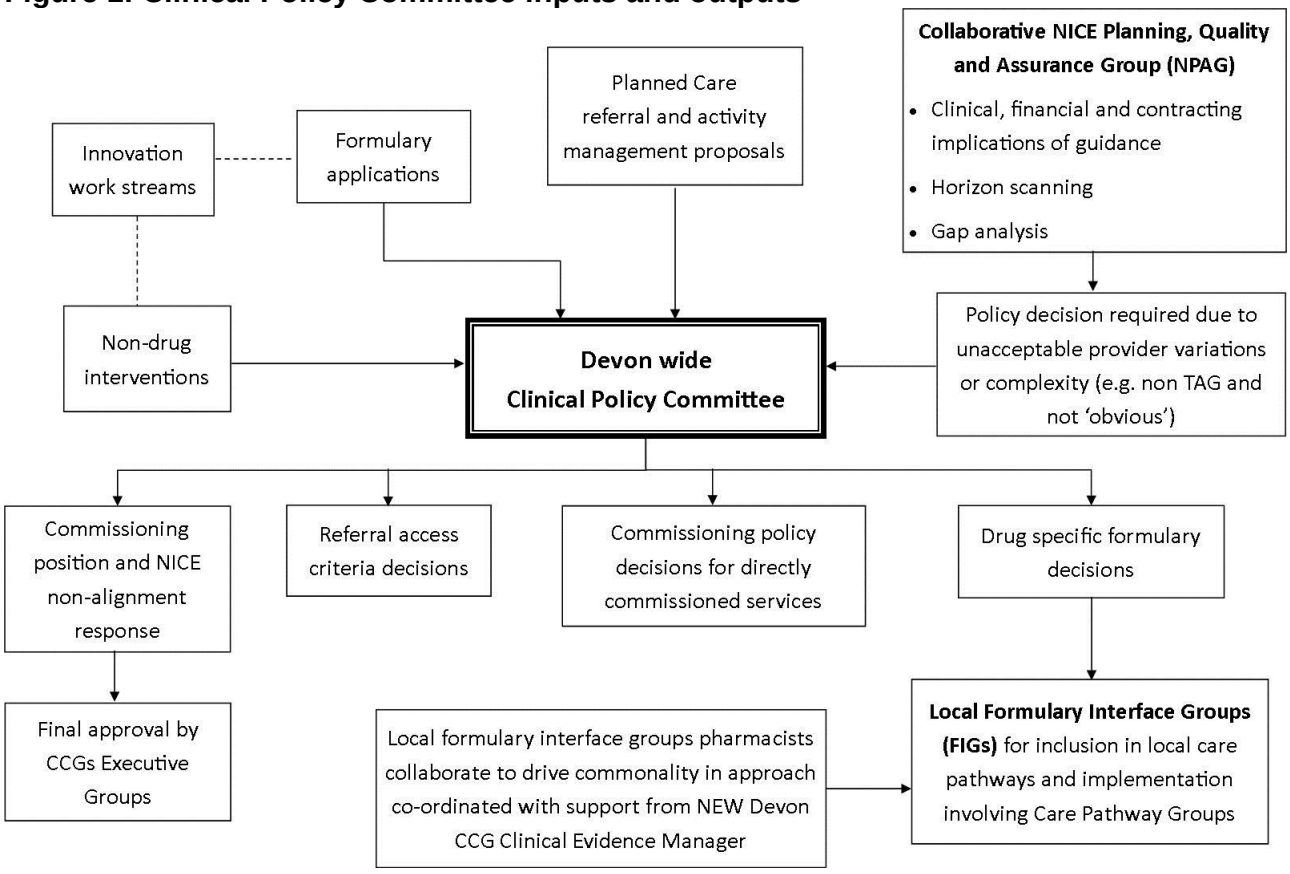
with the broader public's perspective during the decision making process, ensuring that the public interest is acknowledged and taken into account when the Committee makes its decisions.

The work programme

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

2.22 This is proactive and responsive to a number of sources as shown in figure 1, below.

Figure 1: Clinical Policy Committee inputs and outputs



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

- Emma Hewitt, Joint Formularies Support Pharmacist
- Hilary Pearce, Clinical Effectiveness Pharmacist
- Bethan Rogers, Clinical Evidence Pharmacist, and
- Petrina Trueman, Joint Formularies Pharmacist.

Assurance Reporting

2.24 Reporting of any outstanding risks, and associated assurance summaries, is undertaken to the CCGs by the Clinical Effectiveness Governance Manager, NEW Devon CCG.

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

Appeals process

2.26 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.

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

2.28 An appeal may be made by the original applicant(s) – a clinician who has participated in the process leading to the original decision, 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 decision was taken.

2.29 The grounds for appeal are 1) whether fair process has been followed by the Clinical Policy Committee in making their decision 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 decision was made.

2.30 Appeals which are upheld are referred back to the committee for reconsideration.

2.31 The appeals panel has not been required to address any appeals during 2014-15.

3. Commissioning decisions and recommendations

Ratification of commissioning decisions

3.1 To ensure that the organisations were meeting their statutory responsibilities, commissioning policy decisions were ratified by the Governing Body of NEW Devon CCG and the Quality Committee of South Devon and Torbay CCG.

3.2 This was an interim measure until the Legislative Reform Order to the National Health Service Act 2006 (as amended by the Health and Social Care Act 2012), was made allowing CCGs to specifically exercise their powers jointly by way of a joint decision making body.

3.3 The Legislative Reform (Clinical Commissioning Groups) Order 2014, made on 10 September 2014, came into force on 1 October 2014.

3.4 All commissioning policy decisions made prior to this have been ratified by the Governing Body of NEW Devon CCG and the Quality Committee of South Devon and Torbay CCG. Subsequent decisions of the Clinical Policy Committee have not required formal ratification.

Part 1 business – decisions

3.5 Commissioning policy decisions made by the Clinical Policy Committee in 2014-15 are as detailed below.

Clinical Policy Committee Commissioning decisions 2014-15		
Drug or technology	**Commissioning position**	**Date of decision**
Aripiprazole long-acting (depot) injection for schizophrenia	Commissioning policy in place	22 October 2014
Avanafil for erectile dysfunction	Not routinely commissioned	18 March 2015
Surgery for carpal tunnel syndrome	Commissioning policy in place	10 September 2014
Dapoxetine for premature ejaculation	Not routinely commissioned	16 July 2014
Dymista® for moderate to severe allergic rhinitis	Not routinely commissioned	3 December 2014
Fidaxomicin (Dificlir®) for the treatment of adults with *Clostridium difficile* infection	Not routinely commissioned	16 July 2014
Surgery for hallux valgus (bunion)	Commissioning policy in place	4 February 2015
Jaydess® levonorgestrel 13.5mg intrauterine system	Commissioning policy in place	4 February 2015
Lisdexamfetamine for the management of attention deficit hyperactivity disorder (ADHD) in children and adolescents	Commissioning policy in place	4 June 2014
Lixisenatide for the treatment of type 2 diabetes *(review of previous commissioning decision)*	Commissioning policy in place	18 March 2015
Olanzapine long-acting (depot) injection for schizophrenia	Commissioning policy in place	22 October 2014
Paliperidone long-acting (depot) injection for schizophrenia	Commissioning policy in place	22 October 2014
Tocilizumab subcutaneous injection for rheumatoid arthritis	Commissioning policy in place	22 October 2014

Part 2 business recommendations

3.6 Recommendations made by the Clinical Policy Committee in 2014-15 for commissioning decision-making by the CCGs' executive groups are as detailed below.

Clinical Policy Committee Commissioning recommendations 2014-15		
Topic	**Date of recommendation**	**CCGs commissioning decision**
Referral for varicose veins	10 September 2014 To CCGs executive groups for final decision November 2014	To keep the existing policy which commissions referral for specialist opinion for patients who have varicose veins that are causing complications. This policy targets the CCG resources to those patients who have symptoms and complications but we do not have the resources to treat only those who have symptoms without complications. Extension of the existing policy to include referral for all symptomatic varicose veins was considered a low priority for investment.
Aspirin for the prophylaxis of Venous Thromboembolism following Elective Hip Replacement and Elective Knee Replacement	3 December 2014 To CCGs executive groups for final decision March 2015	To accept the recommendation that individual Providers should be given the option to include aspirin as part of a multimodal Venous thromboembolism (VTE) prophylaxis strategy following appropriate individual risk assessment and patient consultation
Assisted Conception	3 December 2014 and 4 February 2015 To CCGs executive groups for final decision March 2015	To accept the policy recommendations on assisted conception, which include: • an in vitro fertilisation (IVF) cycle should consist of one fresh and one frozen embryo transfer. • the current elective single embryo transfer policy is updated such that single embryo transfer should be undertaken if 2 or more top quality embryos are available; no more than 2 embryos should be transferred per transfer episode; and the cryopreservation of remaining embryos resulting from IVF treatment will be funded for up to one year. • stimulated intrauterine insemination (IUI) should not be routinely offered to patients with unexplained infertility, mild

Topic	Date of recommendation	CCGs commissioning decision
		endometriosis or ‘mild male factor infertility’ who are having regular unprotected sexual intercourse. • implantation in the surrogate mother should be funded. • for same-sex couples, failure to conceive after six privately funded cycles of artificial insemination within the past 12 months should be the indication for NHS fertility assessment.
Cryopreservation to preserve fertility	3 December 2014 and 4 February 2015 To CCGs executive groups for final decision March 2015	To accept the policy recommendations on cryopreservation to preserve fertility, which include: • expanding the eligibility criteria to include patients who are about to start teratogenic treatment which is likely to continue for their reproductive life. • to allow for renewal of storage for up to a maximum of 10 years by application to the relevant CCG. • removal of the existing restriction on funding for cryopreservation to women under the age of 40 years and men under the age of 60 years. • amendment of the ‘sterilisation’ criterion wording in the existing policy so that it relates to the individual rather than ‘one or both partners’ and removal of the restriction to individuals ‘with no children living with them or no experience of parenting’. • removal of the specific restriction preventing transgender patients from receiving funding for cryopreservation.
Annual mammography for women at risk of familial breast cancer	4 February 2015	Recommendation to be submitted for CCG approval May 2015
Referral for the surgical management of heavy menstrual bleeding	18 March 2015	Recommendation submitted for CCG approval April 2015

Equality Impact Assessments

3.7 To ensure best practice, Equality Impact Assessments have been undertaken for each commissioning policy decision of the Clinical Policy Committee by the Clinical Effectiveness Governance Manager. These have been submitted to the Equality and Diversity Manager, along with the policy to which it relates, for agreement before being published on the NEW Devon CCG website on behalf of both CCGs at: www.newdevonccg.nhs.uk/who-we-are/medicines-and-treatments/commissioning-policies/equality-impact-assessments/100397

3.8 An Equality Impact Assessment (EIA) is a systematic way of seeing how any policies may affect groups of people differently based on the protected characteristics of diversity. EIAs are similar to risk assessments. In the same way a risk assessment would be taken forward, an EIA allows the assessor to identify potential problems and resolve or minimise them where possible.

Introduction of the Quality and Equality Impact Assessment (QEIA) tool

3.9 During the year, the EIA process has been brought into a Quality and Equality Impact Assessment (QEIA) tool developed by NEW Devon CCG. This combines the Quality and Equality Impact Assessments into one tool that can be used to assess both areas. 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.

3.10 A Quality and Equality Impact Assessment (QEIA) is completed for each decision or recommendation made by the Clinical Policy Committee, assessing the impact of the proposal in the domains listed above. This QEIA is shared with the Quality Team for approval, with the Equality Impact Assessment (EIA) aspect of the tool subsequently published on the NEW Devon CCG website on behalf of both CCGs.

4. Costs

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

Clinical Policy Committee meeting costs 2014-15

Meeting date	Venue	Cost
4 June 2014	The Watermark, Ivybridge	£119.20
16 July 2014	The Hayridge Centre, Cullompton	No charge
10 September 2014	Committee Room, County Hall, Exeter	£20.00
22 October 2014	The Watermark, Ivybridge	£60.00
3 December 2014	Committee Room, County Hall, Exeter	£35.00
4 February 2015	Committee Room, County Hall, Exeter	£35.00
18 March 2015	The Watermark, Ivybridge	£70.00

4.2 Meetings have been rotated between venues across the CCGs' footprint and held in facilities of Devon County Council as a strategic partner. The meeting facilities at The Watermark are operated by Ivybridge Town Council.

5. Communication

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 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 6**.

5.3 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

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

6. Reflective practice

Committee development sessions

6.1 A committee development session was held in September 2014. This built on the two sessions held in the previous year where the committee considered its role in determining the allocation of healthcare resources by considering clinical evidence and weighing potentially competing factors.

6.2 During the session the committee considered factors pertinent to assessing the value for money of a health care intervention through formal health economic methodology and wider societal considerations of relevance to decision making.

Changes to committee business

6.3 Committee members considered how the committee arrangements could adapt to meet the changing needs of the organisations. In particular the CCGs had identified a need for a group to consider decisions that need to be taken in the context of recommendations in NICE clinical guidelines and also decisions relating to existing commissioned treatments embedded in service provision.

6.4 This led to a proposal to split the future business of meetings into two parts. Part one would comprise the current function of decision making in respect of the commissioning of specific treatments and healthcare interventions, and part two would allow for clinical discussion and recommendations to be formed for senior management groups on any other items for which decision making needs to be undertaken by the commissioning organisations.

Specification of the role and function of the lay members

6.5 The terms of reference were revised to ensure that details of the role and function of the lay members was reflected. This was agreed in collaboration with the lay members who were able to give the benefit of their experience on the committee in clarifying their key role and function.

Expected attendance levels and nomination of deputies to represent voting members

6.6 Following presentation of the first annual report, the committee discussed their expectations of committee member attendance at meetings as no minimum attendance level had been set previously. It was agreed that committee members, or a nominated deputy, are

expected to attend 100% of meetings. Any attendance below 66% would be followed up with the member by the Chair.

6.7 The importance of the nomination of a deputy where a member is unable to attend a meeting was acknowledged in order to ensure quoracy. The committee were in agreement that voting members should nominate deputies and considered that these should be current, non-lay, advisory members of the committee. Members also determined a deputy can only deputise for one voting member at any given meeting. The lay members of the committee asked that the terms of reference specify that this should only relate to non-lay members as they felt that being asked to act in a voting capacity would conflict with their role in representing the public interest of the local population.

7. Future changes

Review of meeting arrangements for 2015-16

7.1 A review of meeting timings and venues was undertaken in February 2015. This was prompted by the suggestion that future meetings should be extended to better accommodate the increased volume of business and allow sufficient time for a full discussion of items to take place. There was also some discussion of the meeting venues and the debate between having a fixed venue (which brings a number of practical benefits) and rotating between venues across Devon.

7.2 It was acknowledged that when based in Exeter the committee is better able to accommodate guests, has the use of effective teleconferencing facilities and is generally able to be more responsive to any issues arising as it is the secretariat's office base.

7.3 Members were contacted to ascertain their preferences for future meetings. This revealed that the majority preference was for future meetings to be held at a fixed location in Exeter and from 9.30am-12.30pm.

Proposed revision to the future process for clinical policy formation via the Clinical Policy Committee

7.4 In response to the challenges faced by the organisations to commission sustainable healthcare services within the financial resources available, a revised process for clinical policy formation has been set out. This seeks to meet the needs of both of the collaborating CCGs with minimal disruption to existing decision making processes.

7.5 At the time of preparation of this report, the revised terms of reference for future working and updated appeals process are pending ratification by the CCGs' Governing Bodies, or appropriate groups with delegated authority.

7.6 The effect of the proposed revision to the process for clinical policy formation is that all output from the Clinical Policy Committee in future will be a policy recommendation, rather than the current mix of decisions and recommendations.

7.7 A single process will ensure consistency in approach across all areas for clinical discussion, whether this is consideration of the routine commissioning of a new drug or treatment, changes to access criteria or changes recommended by non-mandatory NICE guidelines.

Enabling Quality and Equality Impact Assessment (QEIA) of proposed policies

7.8 Review of the Quality and Equality Impact Assessment (QEIA) process means that in future all CCG policies will have a QEIA assessment conducted on the final policy proposal before approval by the CCG Governing Bodies, or appropriate groups with delegated authority.

7.9 The revised process allows for completion of the Quality and Equality Impact Assessment (QEIA) tool as an integral step following the minded recommendation of the Clinical Policy Committee. This will assess 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.

Provision for public consultation

7.10 The proposed process includes specific provision for assessing the impact of the recommendation/proposed changes and for determining the need for public consultation.

7.11 When determined appropriate, public consultation will be conducted following the clinical discussion and recommendation of the Clinical Policy Committee. The need for consultation will thus be a routine step following the minded recommendation of the Clinical Policy Committee, before this is submitted for approval by the CCGs.

7.12 The timing of this element within the overall process is appropriate as it is at a sufficiently formative stage that no final decision has been taken by the CCGs. Consultation will comprise the context within which the discussion has arisen, the purpose behind the recommendation, the

options considered by the Clinical Policy Committee and the preferred option.

7.13 A framework for public consultation is being developed to ensure an effective, lawful consultation process. This will follow best practice and ensure proportionality of the type and scale of consultation to the potential impacts of the recommendation being made.

8. Conclusion

8.1 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.

8.2 The Clinical Policy Committee has taken 13 commissioning decisions in 2014-15 and made recommendations to the CCGs executive groups for approval in six areas.

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

8.4 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.

1.3 The Clinical Policy Committee is additionally a forum for cross CCG clinical discussion and formation of a recommendation on any other issues related to services for which decisions need to be taken by the commissioning organisations. This may include, for example recommendations for service provision for existing commissioned treatments and decisions to be taken in the context of recommendations in NICE clinical guidelines.

2. Functions

The Clinical Policy Committee will:

2.1 Working within financial limits delegated from the Governing Bodies, determine whether the commissioning organisations will make funding available to commission specific treatments and healthcare interventions from provider organisations.

2.2 Approve policy documents that define the clinical circumstances under which clinical services, procedures and interventions will be commissioned.

2.3 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.

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

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

2.6 For treatments and interventions which are expected to exceed delegated budgetary authority, report via an agreed process to the Clinical Commissioning Groups' Governing Bodies as to whether commissioning would be recommended by the committee.

2.7 Note reports, from the Clinical Commissioning Groups' NICE planning and assurance processes, on the commissioning implications of published Technology Appraisals and Clinical Guidelines.

2.8 Make recommendations to the Clinical Commissioning Groups' executive teams for final decision making following clinical discussion of the issues for which commissioning decisions need to be taken.

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 18 members as follows:

- Clinician Members of the Clinical Commissioning Groups (x8) (of whom 1 Chair and 1 deputy Chair)
- Lay Members (x2)
- Patient Safety and Quality (x1)
- Public Health (x1)
- Contracting/Finance (x1)
- Head of Clinical Effectiveness
- Head of Medicines Optimisation

- Secondary Care Clinician (x2)
- Secondary Care Chief Pharmacist (x1)

3.4 Committee membership will comprise 8 nominated Clinical Commissioning Group members who will act with delegated executive authority from the Clinical Commissioning Groups' Governing Bodies to take commissioning decisions (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 Meeting business will be conducted in two parts:

- Part one will consist of consideration and decision making in respect of the commissioning of specific treatments and healthcare interventions.
- Part two, as required, will consist of clinical discussion of any other items for which decision making needs to be undertaken by the commissioning organisations. The output will be recommendations to the Clinical Commissioning Groups' executive teams for final decision making. The

Clinical Policy Committee will be advised of the outcome of the final decision making and whether the committee's recommendations have been accepted.

4.5 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 the commissioning decision or recommendation. 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 decision-making.

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

4.7 Decisions are effective from the date of publication.

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

In relation to part one business:

4.9 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.
- The Clinical Commissioning Group members with delegated executive authority (voting members) will take a final decision on behalf of the commissioning organisations. 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.

4.10 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

4.11 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.

4.12 The committee will operate an appeals process in respect of decisions on the commissioning of treatments and interventions for which 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 and deputy Chair shall be jointly recommended by the Governing Bodies of the Clinical Commissioning Groups. In the absence of the Chair and deputy Chair the committee should nominate an attending member to chair the meeting.

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	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/ 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 Member	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.

Clinical Effectiveness professional and scientific support *Continued.*	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.

July 2014

APPENDIX 2

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

Clinical Policy Committee

Wednesday 4th June 2014, 10.00-12.00

Henlake Suite, The Watermark, Ivybridge PL21 0SZ

AGENDA

Number	Item	Lead	Appendix	Time
PART ONE – REGULAR BUSINESS				
1	Welcome and announcements • Apologies • Introduction of new lay member • Confirmation of voting members and Declarations of interest • Notification of Any Other Business	Jo Roberts		10.00
2	Minutes of the meeting held on 5th March 2014 and matters/actions arising	Jo Roberts	Appendix 1	10.05
3	Lisdexamfetamine for attention deficit hyperactivity disorder (ADHD) in children and adolescents	Hilary Pearce	Appendix 2	10.10
4	Dilatation and curettage for dysfunctional uterine bleeding	Hilary Pearce	Appendix 3	10.35
5	Local Medicines Evaluation in Service proposal	Jo Roberts	Appendix 4	10.40
6	Clinical Policy Committee Annual Report 2013-14	Rebecca Heayn	Appendix 5	10.50
7	Update from NICE Planning, Quality and Assurance Group (NPAG)	Chris Roome	Appendices 6a, 6b & 6c	11.00
8	Any Other Business and tea/coffee			11.05
~~**PART TWO – COMMITTEE DEVELOPMENT**~~ **SESSION**		***- Deferred -***		
9	Addressing the value for money: do we need a Cost/QALY or is it the ICER on the cake?	Chris Roome		11.10
Meeting close				

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

Clinical Policy Committee

Wednesday 16th July 2014, 10.00-12.00

The Hayridge Centre, Cullompton EX15 1DJ

AGENDA

Number	Item	Lead	Appendix	Time
1	Welcome and announcements • Apologies • Confirmation of voting members and Declarations of interest • Notification of Any Other Business	Keith Gillespie		10.00
2	Minutes of the meeting held on 4th June 2014 and matters/actions arising	Keith Gillespie	Appendix 1	10.05
3	Fidaxomicin for *Clostridium difficile* infection	Bethan Rogers	Appendix 2	10.10
4	Dapoxetine for premature ejaculation	Emma Hewitt	Appendix 3	10.35
5	Taking decisions in the context of recommendations in NICE clinical guidelines	Chris Roome	Appendix 4	11.00
6	Update from NICE Planning, Quality and Assurance Group (NPAG)	Chris Roome	Appendices 5a & 5b	11.25
7	Addition of lay member to roles and functions of group members	Rebecca Heayn	Appendix 6	11.30
8	Member attendance levels and nominated deputies	Rebecca Heayn	Appendix 7	11.40
9	Any Other Business			11.50
Meeting close				

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

Clinical Policy Committee

Wednesday 10th September 2014, 10.00-12.00

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	Jo Roberts		10.00
2	Minutes of the meeting held on 16th July 2014 and matters/actions arising	Jo Roberts	Appendix 1	10.05
Items for committee recommendation (Part 2 business)				
3	Referral for varicose veins	Hilary Pearce	Appendices 2a & 2b	10.10
Items for commissioning decision making (Part 1 business)				
4	Surgery for carpal tunnel syndrome	Hilary Pearce	Appendix 3	10.40
Other items for consideration				
5	Update from NICE Planning, Quality and Assurance Group (NPAG)	Chris Roome	Appendices 4a & 4b	10.55
6	Any Other Business			
PART TWO – COMMITTEE DEVELOPMENT SESSION				
7	Addressing the value for money: do we need a Cost/QALY or is it the ICER on the cake?	Chris Roome		11.00
Meeting close				

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

Clinical Policy Committee

Wednesday 22nd October 2014, 9.30-12.00

Henlake Suite, 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		9.30
2	Minutes of the meeting held on 10th September 2014 and matters/actions arising	Jo Roberts	Appendix 1	9.35
3	Legislative Reform (Clinical Commissioning Groups) Order 2014 update	Rebecca Heayn	Appendix 2	9.40
4	Future meeting dates	Rebecca Heayn	Appendix 3	9.45
5	Update from NICE Planning, Quality and Assurance Group (NPAG)	Chris Roome	Appendices 4a & 4b	9.50
Item for committee recommendation (Part 2 business)				
6	Aspirin for the Prophylaxis of Venous Thromboembolism Following Elective Hip Replacement and Elective Knee Replacement	Chris Roome	Item deferred Verbal update	10.00
Item for commissioning decision making (Part 1 business)				
7	Second-generation antipsychotic depot injections for schizophrenia	Hilary Pearce	Appendix 5	10.10
Break				
8	Subcutaneous Tocilizumab for rheumatoid arthritis	Hilary Pearce	Appendix 6	11.30
Other items for consideration				
9	Any Other Business			11.55
Meeting close				

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

Clinical Policy Committee

Wednesday 3rd December 2014, 9.30-12.00

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 22nd October 2014 and matters/actions arising	Jo Roberts	Appendix 1	9.35
3	Update from NICE Planning, Quality and Assurance Group (NPAG)	Chris Roome	Item deferred	
4	Update on committee recommendation on referral for patients with varicose veins	Chris Roome	Verbal	9.40
Item for committee recommendation (Part 2 business)				
5	Aspirin for the prophylaxis of Venous Thromboembolism following Elective Hip Replacement and Elective Knee Replacement	Bethan Rogers	Appendix 2	9.45
Items for commissioning decision making (Part 1 business)				
6	Dymista® for moderate to severe allergic rhinitis	Emma Hewitt	Appendix 3	10.30
Item for committee recommendation (Part 2 business)				
7	Fertility: policy recommendations • Assisted Conception • Cryopreservation to preserve fertility	Bethan Rogers	Appendices 4a - 4h	10.55
Other items for consideration				
8	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 2nd February 2015, 10.00-12.00

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	10.00
2	Minutes of the meeting held on 3rd December 2014 and matters/actions arising	Jo Roberts	Appendix 1	10.05
3	Update from NICE Planning, Quality and Assurance Group (NPAG)	Chris Roome	Appendices 2a & 2b	10.10
Item for committee recommendation (Part 2 business)				
4	Annual mammography for women at risk of familial breast cancer	Hilary Pearce	Appendix 3	10.15
Items for commissioning decision making (Part 1 business)				
5	Surgery for hallux valgus (bunions)	Hilary Pearce	Appendix 4	10.40
6	Jaydess® levonorgestrel 13.5mg intrauterine system	Petrina Trueman	Appendix 5	10.45
Items for committee recommendation (Part 2 business)				
7	Fertility policies – agreement of final committee recommendations on: • Assisted Conception • Cryopreservation to preserve fertility	Bethan Rogers	Appendices 6a to 6e	11.10
8	~~Lipid modification: cardiovascular risk assessment and the modification of blood lipids for the primary and secondary prevention of cardiovascular disease~~	Petrina Trueman *- Item deferred -*	Appendix 7	11.30
Other items for consideration				
9	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 March 2015, 10.00-12.00

Henlake Suite, 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	10.00
2	Minutes of the meeting held on 4th February 2015 and matters/actions arising • Lipid modification (update)	Jo Roberts	Appendix 1	10.05
Item for committee recommendation (Part 2 business)				
3	Referral for the Surgical Management of Heavy Menstrual Bleeding	Bethan Rogers/ Rachel Tyler	Appendix 2	10.15
Items for commissioning decision making (Part 1 business)				
4	Review of the commissioning decision on Lixisenatide for the treatment of type 2 diabetes	Petrina Trueman	Appendix 3	10.35
5	Avanafil for Erectile Dysfunction	Bethan Rogers	Appendix 4	10.55
Other items for consideration				
6	Assessment and removal of benign skin and subcutaneous lesions	Hilary Pearce/ Chris Roome	Verbal	11.20
7	Update from NICE Planning, Quality and Assurance Group (NPAG)	Chris Roome	Appendices 5a & 5b	11.35
8	Proposed changes to the process of clinical policy formation via the Clinical Policy Committee	Rebecca Heayn	Appendix 6	11.40
9	Any Other Business		Verbal	11.55
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	6 / 7
Samantha Morton (as delegate)	Head of Contracting and Procurement	South Devon & Torbay CCG	1 / 1
Dr Mick Braddick VOTING MEMBER	GP Clinical Commissioner	NEW Devon CCG	7 / 7
Jono Broad	Lay Member		7 / 7
Lorna Collingwood-Burke	Chief Nursing Officer	NEW Devon CCG	0 / 7
Andrew Kingsley (as delegate)	Lead Nurse Healthcare Acquired Infections	NEW Devon CCG	5 / 7
Dr Andrew Craig VOTING MEMBER	GP Clinical Commissioner	NEW Devon CCG	7 / 7
Richard Croker	Head of Medicines Optimisation	NEW Devon CCG	4 / 7
Bryan Foreshew (as delegate)	Interface Pharmacist	NEW Devon CCG	1 / 1
Larissa Sullivan (as delegate)	Interface Pharmacist	NEW Devon & South Devon & Torbay CCGs	1 / 1
Dr Tawfique Daneshmend	Consultant Gastroenterologist & Hepatologist	Royal Devon & Exeter NHS Foundation Trust	3 / 7
Paul Foster	Chief Pharmacist	South Devon Healthcare NHS Foundation Trust	3 / 7
Simon Mynes (as delegate)	Director of Pharmacy	Plymouth Hospitals NHS Trust	1 / 1
Dr Keith Gillespie VOTING MEMBER	GP Clinical Commissioner *(until September 2014)*	NEW Devon CCG	2 / 3
Chris Roome (as delegate)	Head of Clinical Effectiveness	NEW Devon CCG	1 / 1
Dr Andrew Gunatilleke	Consultant in Pain Management & Anaesthesia	South Devon Healthcare NHS Foundation Trust	5 / 7
Dr Stephen Hunt VOTING MEMBER	GP Clinical Commissioner *(until October 2014)*	NEW Devon CCG	1 / 4

Name	Role	Organisation	Meetings attended/ possible
Dr Peter Leman VOTING MEMBER	GP Clinical Commissioner *(from October 2014)*	NEW Devon CCG	3 / 4
Dr Phil Melluish VOTING MEMBER	GP Clinical Commissioner	South Devon & Torbay CCG	7 / 7
Mac Merrett	Lay Member		7 / 7
Samantha Morton	Head of Contracting and Procurement	South Devon & Torbay CCG	6 / 7
Rob Cowdry	Contracts Governance Manager, Commissioning	NEW Devon CCG	1 / 1
Tracey Polak	Assistant Director/ Consultant of Public Health	Devon County Council	1 / 7
Julia Chisnell (as delegate)	Public Health Registrar	Devon County Council	2 / 2
Mark Kealy (as delegate)	Consultant in Public Health	Devon County Council	1 / 1
Anna Richards (as delegate)	Consultant in Public Health	Devon County Council	1 / 1
Chris Roome	Head of Clinical Effectiveness	NEW Devon CCG	7 / 7
Dr Alison Round VOTING MEMBER	GP Clinical Commissioner	NEW Devon CCG	4 / 7
Richard Croker (as delegate)	Head of Medicines Optimisation	NEW Devon CCG	2 / 2
Dr Ben Waterfall VOTING MEMBER	GP Clinical Commissioner *(from February 2015)*	NEW Devon CCG	2 / 2
Dr Darunee Whiting VOTING MEMBER	GP Clinical Commissioner	NEW Devon CCG	5 / 7
Chris Roome (as delegate)	Head of Clinical Effectiveness	NEW Devon CCG	1 / 1

ADDITIONAL ATTENDEES (EXPERTS, GUESTS AND SECRETARIAT)

Name	Role	Organisation
4th June 2014		
John Bronze	Commissioner for Diagnostics	NEW Devon CCG
Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NEW Devon CCG
Gareth Franklin	Clinical Guidance Manager	NEW Devon CCG
Rebecca Heayn	Clinical Effectiveness Governance Manager	NEW Devon CCG
Hilary Pearce	Clinical Effectiveness Pharmacist	NEW Devon CCG
Bethan Rogers	Clinical Evidence Pharmacist	NEW Devon CCG
16th July 2014		
Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NEW Devon CCG
Dr James Greig	Consultant Microbiologist	Plymouth Hospitals NHS Trust
Rebecca Heayn	Clinical Effectiveness Governance Manager	NEW Devon CCG
Emma Hewitt	Joint Formularies Pharmacist	NEW Devon CCG
Dr Philip Kell	Consultant Physician in Sexual Health	Torbay Sexual Medicine Service
Dr Richard Pearcy	Consultant Urologist	Plymouth Hospitals NHS Trust
Bethan Rogers	Clinical Evidence Pharmacist	NEW Devon CCG
Dr Ray Sheridan	Consultant Physician	Royal Devon & Exeter NHS Foundation Trust
Petrina Trueman	Joint Formularies Pharmacist	NEW Devon CCG
10th September 2014		
Simon Ashley	Consultant Vascular Surgeon	Plymouth Hospitals NHS Trust
Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NEW Devon CCG
Rebecca Heayn	Clinical Effectiveness Governance Manager	NEW Devon CCG
Hilary Pearce	Clinical Effectiveness Pharmacist	NEW Devon CCG
David Williams	Consultant Vascular Surgeon	Northern Devon Healthcare NHS Trust
22nd October 2014		
Dr Elizabeth Adams	Consultant Psychiatrist	Plymouth Community Healthcare
Dr Christine Brown	Consultant Psychiatrist	Devon Partnership NHS Trust

Name	Role	Organisation
Tina Campbell	Pharmacist/Associate Director of Medicines Management	Devon Partnership NHS Trust
Steve Cooke	Chief Pharmacist/Controlled Drug Accountable Officer	Plymouth Community Healthcare
Dr Michael Cooper	Consultant Psychiatrist	Plymouth Community Healthcare
Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NEW Devon CCG
Dr Keith Gilhooly	Consultant Psychiatrist	Devon Partnership NHS Trust
Rebecca Heayn	Clinical Effectiveness Governance Manager	NEW Devon CCG
Hilary Pearce	Clinical Effectiveness Pharmacist	NEW Devon CCG
3rd December 2014		
Dr Thomas Beech	ENT Consultant	NDHC NHS Foundation Trust
Mr John Charity	Associate Specialist in Trauma and Orthopaedics	RD&E NHS Foundation Trust
Dr Caroline Court	Consultant in Public Health Medicine	Cornwall Council
Rebecca Cowie	Principal Embryologist	RD&E NHS Foundation Trust
Sally Doidge	Senior Embryologist	RD&E NHS Foundation Trust
Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NEW Devon CCG
Mr Keith Eyres	Consultant Orthopaedic Surgeon	RD&E NHS Foundation Trust
Rebecca Heayn	Clinical Effectiveness Governance Manager	NEW Devon CCG
Emma Hewitt	Joint Formularies Pharmacist	NEW Devon CCG
Mr Mike Hockings	Clinical Director / Consultant Orthopaedic Surgeon	SDHC NHS Foundation Trust
Mr Jonathan Howell	Consultant Orthopaedic Surgeon	RD&E NHS Foundation Trust
Dr Simon Jameson	Orthopaedic Fellow	RD&E NHS Foundation Trust
Dr Lisa Joels	Consultant Gynaecologist	RD&E NHS Foundation Trust
Emma Kain	Speciality Registrar	Cornwall Council
Mr Jonathan Keenan	Consultant Orthopaedic Surgeon	Plymouth Hospitals NHS Trust
Mr Jonathan Lord	Consultant in Obstetrics and Gynaecology	Royal Cornwall Hospital Trust
Joe Maguire	Medication Safety Pharmacist	RD&E NHS Foundation Trust
Miss Gurpreet Pandher	Consultant Obstetrician and Gynaecologist	SDHC NHS Foundation Trust
Bethan Rogers	Clinical Evidence Pharmacist	NEW Devon CCG
Dr Jacqueline Ruell	Consultant Haematologist	RD&E NHS Foundation Trust

Name	Role	Organisation
Dr Nicola Rymes	Consultant Haematologist	SDHC NHS Foundation Trust
Mr Andrew Temple	Consultant Orthopaedic Surgeon	NDHC NHS Foundation Trust
4th February 2014		
Carole Brewer	Consultant Clinical Geneticist	RD&E NHS Foundation Trust
Jane Bush	Associate Specialist	The Centre (Exeter, Mid & East Devon)
Di Cameron	Trust Breast Physician	RD&E NHS Foundation Trust
Rachael Currie	Consultant Breast Radiologist	RD&E NHS Foundation Trust
Sam Cush	Patient Communications Specialist	NEW Devon CCG
Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NEW Devon CCG
Rebecca Green	Consultant Radiologist	South Devon Healthcare
Rebecca Heayn	Clinical Effectiveness Governance Manager	NEW Devon CCG
Karen Hillman	Clinical Nurse Specialist Breast Care	North Devon District Hospital
Matt Howard	Clinical Evidence Manager	NEW Devon CCG
Kathy Huxham	Service Manager	RD&E NHS Foundation Trust
Maggie Jenkin	Advanced Practitioner Radiographer	Plymouth Hospitals Trust
Hilary Pearce	Clinical Effectiveness Pharmacist	NEW Devon CCG
Bethan Rogers	Clinical Evidence Pharmacist	NEW Devon CCG
Richard Stackhouse	Specialist Doctor with Interest in Family Health	South Devon Healthcare
Petrina Trueman	Joint Formularies Pharmacist	NEW Devon CCG
18th March 2014		
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
Prof. Ann Millward	Consultant Diabetologist	Plymouth Hospitals NHS Trust
Hilary Pearce	Clinical Effectiveness Pharmacist	NEW Devon CCG
Bethan Rogers	Clinical Evidence Pharmacist	NEW Devon CCG
Petrina Trueman	Joint Formularies Pharmacist	NEW Devon CCG
Dr Rachel Tyler	GP/Clinical Lead Western Locality/DRSS GP Referral Facilitator	NEW Devon CCG/DRSS

APPENDIX 4

DECLARATIONS OF INTEREST REGISTER (APRIL 2014 – MARCH 2015)

Declarations of interest made by committee members

Name of attendee	Role	Meeting Date	Declared interest
Dr Peter Leman VOTING MEMBER	GP Clinical Commissioner	22 October 2014	Self: • Partner in PMS Practice Mannamead Surgery Plymouth. • Shareholder Sentinel CiC • Surgery is a member of the Drake Medical Alliance – a federation of 6 practices in Plymouth. Partner: • None
		18 March 2015	Attendance at training seminar sponsored by Grünethal Pharmaceuticals
Larissa Sullivan	Interface Pharmacist	22 October 2014	Married to a member of Devon Partnership Trust Medicines Team.
Dr Ben Waterfall VOTING MEMBER	GP Clinical Commissioner	4 February 2015	*Any other family or business interests (including personal or family medical conditions) which could be seen as influencing views of the drug(s) /intervention/treatment under consideration.* Has 3 children through assisted conception (Derriford).
Dr Andrew Gunatilleke	Consultant in Pain Management & Anaesthesia	18 March 2015	*Received gifts, benefits or sponsorship of any kind, whether refused or accepted worth over £25 or several small gifts worth a total of over £100.* Attended world pain congress – sponsored by Pfizer in 2010.

Additional Declarations of Interest (Experts, Guests and Secretariat)

Name of attendee	Role	Meeting Date	Declared interest
Dr James Greig	Consultant Medical Microbiologist	16 July 2014	In last 3 years – no conflicts regarding Astellas. (In relation to discussion on fidaxomicin [Dificlir®] Astellas)
Dr Ray Sheridan	Consultant Physician	16 July 2014	On-going local researcher for MODIFY – monoclonal antibody multi-centre trial for C.Difficile. Actively recruits for the trial but receives no direct financial benefit from being involved in this trial. (In relation to discussion on fidaxomicin [Dificlir®] Astellas)
Dr Philip Kell	Consultant Physician	16 July 2014	Has worked as paid adviser to above pharmaceutical / manufacturing company / companies. Is in receipt of lecture feeds in excess of £150 in the last year from above pharmaceutical manufacturing company/companies. (In relation to discussion on dapoxetine [Priligy®] Menarini Farmaceutica Internazionale SLR).
Mr Richard Pearcy	Consultant Urologist	16 July 2014	Worked as paid lecturer at a meeting of other medical practitioners Received a meal at a meeting which was part sponsored. (In relation to discussion on dapoxetine [Priligy®] Menarini Farmaceutica Internazionale SLR).
Mr Simon Ashley	Consultant Vascular Surgeon	10 September 2014	Treats varicose veins in private practice. Has contributed data to STD Pharmaceuticals Ltd., the manufacturers of STS a drug used for Foam and liquid Sclerotherapy. These data were used within their application to obtain European licensing of STS for air-based Foam Sclerotherapy treatment of varicose veins. STD Pharmaceuticals have provided some financial sponsorship for Mr Ashley and trainees to attend scientific meetings in the past. Mr Ashley has not received any direct payments

Name of attendee	Role	Meeting Date	Declared interest
Steve Cooke	Chief Pharmacist Plymouth Community Healthcare	22 October 2014	In relation to discussion on depot Second Generation Antipsychotics Hospitality received where the drug(s)/devices(s)/intervention(s)/treatment(s) under consideration were discussed by a representative of a drug/manufacturing company/companies. Feb 2014: Included a presentation on Abilify Maintena; meeting sponsored by Lundbeck Feb 2012: Included a presentation on Xeplion; meeting sponsored by Janssen
Dr Mike Cooper	Consultant Psychiatrist	22 October 2014	In relation to discussion on depot Second Generation Antipsychotics In receipt of payment/gist for transport and hospitality to attend national or international meeting of symposia. – Conference assistance.
Dr Keith Gilhooly	Consultant Psychiatrist	22 October 2014	In relation to discussion on depot Second Generation Antipsychotics 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. Sandwiches provided at a free 1 day conference on ZypAdhere sponsored by the company.
Dr Tom Beech	ENT Consultant	3 December 2014	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. During one of the regular hospital meetings (which is likely to have taken place within the last 2 to 3 years) at a previous trust, a Meda representative gave a talk on Dymista®. Lunch may have been provided.

Name of attendee	Role	Meeting Date	Declared interest
Mr Jonathan Keenan	Orthopaedic Surgeon	3 December 2014	Personal: BAYER THROMBOSIS ADVISORY GROUP: Birmingham, February 2007 Birmingham, February 2008 Birmingham, February 2009 Transport and hospitality to attend EFORT, Vienna. June 2009. Bayer Orthopaedic Surgery Advisory Board Meeting 28th March 2014, London (VTE in cast immobilised patients). Non Personal: Thrombosis Publications funded by Sanofi Aventis (? Thrombosis nurse funding Sanofi)
Jonathan Lord	Consultant in Obstetrics and Gynaecology	3 December 2014	Employee of the provider of fertility services in Cornwall (Royal Cornwall Hospitals Trust, RCHT); person responsible under the HFEA Act at RCHT for assisted conception. Director of Cornwall IVF who administers the satellite service for NHS and self-funded IVF in Cornwall in partnership with RCHT and the IVF units. Partner of GAIA Health (not trading, but established to facilitate community gynaecology services in an interface-type service). Complete DoI available on file at RCHT, but nil else directly relevant to fertility (e.g. sponsored study leave for gynae, but not fertility; employee of Peninsula Medical School).
Jacqueline Ruell	Consultant Haematologist	3 December 2014	In receipt of payment/gift for transport and hospitality to attend national or international meetings or symposia. Bayer pharmaceutical company meeting – expenses paid only.

Name of attendee	Role	Meeting Date	Declared interest
Nichola Rymes	Consultant Haematologist	3 December 2014	*In receipt of lecture fees in excess of £150 in the last year from above pharmaceutical / manufacturing company / companies.* 2014: Pfizer (Fragmin) provided light refreshments for a nurse – led 'VTE Ambassadors'' meeting in Torbay Hospital. 2012: presented a talk on anticoagulation at SW VTE materclass. Event sponsored by Bayer (Rivaroxaban). 2013: presented a talk to local GP's on NOACs. Event sponsored by Bayer (Rivaroxaban). Fees for the last 2 events donated to charity.
Mr Andrew Temple	Consultant Surgeon	3 December 2014	Received lecture fees from Smith and Nephew (Orthopaedic Implant Company). Delivered lectures on hip and knee replacement course in 2013 and 2014.
Dr Jane Bush	Associate Specialist	4 February 2015	*Received gifts, benefits or sponsorship of any kind, whether refused or accepted worth over £25 or several small gifts worth a total of over £100 from the above or closely related pharmaceutical / manufacturing company*. Had received sponsorship from Bayer for a training day for GPs. They provided lunch. *In receipt of lecture fees in excess of £150 in the last year from above pharmaceutical/manufacturing company/companies.* Has been paid for giving a contraception update lecture at a Women's Health update afternoon by Bayer.
Matt Howard	Clinical Evidence Manager	4 February 2015 & 18 March 2015	In previous position attended a number of LPC organised training/CPD events – refreshments may have been sponsored by pharmaceutical company.
Margaret Jenkin	Advanced Practitioner Radiographer	4 February 2015	*Have taken part in drug trial for the above drug/s devices/intervention/treatment.* Research Tomosynthesis study for Siemens equipment on research log.
Professor Ann Millward	Consultant Diabetologist	18 March 2015	Worked as paid adviser for Get Goal Study (Sanofi) Has taken part in clinical trials for Novo Nordisk, Sanofi Aventis, Merck (Oxford DTU), GSK, Astra Zeneca (Lilly) Takeda (Quintile), Pfizer (ICCH) In receipt of one lecture fee for talk for Sanofi Aventis.

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	Board Member for the Academic Health Sciences Network (AHSN). Recent presentation to Industry Engagement Event. Sits on Phama Industry Sector Board	June 2014
		MSD telehealth project for heart failure - ongoing	June 2014
		Hearst Health corporation – development work on Smart carepathways - ongoing	June 2014
		Pfizer, Boerhringer-Ingelheim, Bayer, MSD, daichii-sankyo provision of medical education grants to support implementatioin project of NICE atrial fibrillation guidance	Nov 2014
		Meeting INR star	June 2014
		Ascribe and CPC evaluation of tenders for eprescribing system	June 2014
		Meeting with Pfizer regional manager	July 2014
		Meeting with bayer regional manager	July 2014
		Meeting with Teva regional manager	July 2014
		Meeting account manager boehringer Ingelheim	Aug 2014
		Meeting with national manager apple healthkit and Emis	Sept 2014
		Meeting regional manager daichi sankyo	Sept 2014
		Trip to Boston to Intersystems to liaise re clinical portal	Sept 2014
		Presentation on Integrated care to Wellards forum with numerous companies represented	Sept 2014
		Meeting with apple healthkit and emis	Oct 2014
		Meeting Teva local rep and regional manager	Oct 2014
		Meeting regional manager Astra Zeneca	Nov 2014
		Meeting with Plessey semiconductors re single lead ECG device will be ongoing project	Nov 2014

Name of attendee	Role	Details of contact	Date recorded
		Through role with SW AHSN we are engaging with each of the pharma companies that are either manufacturing or marketing NOACs to provide medical education grants in the region of £20k to fund implementation of the NICE CG 180 initially in South Devon and Torbay but to hopefully role out across the whole of the AHSN footprint.	Dec 2014
		Meeting with GSK regarding rebates scheme for seretide and some new product information	Jan 21015
Keith Gilhooly	Consultant Psychiatrist	Has spoken on the phone and in person to reps from Lilly, Jansen and Bristol Myers Squibb	Oct 2014
Dr Peter Leman VOTING MEMBER	GP Clinical Commissioner	In house produce meeting supported with sandwiches provided by representative of Napp pharmaceuticals and Nova Nordisk pharmaceuticals	Dec 2014

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 decision, 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 decision was taken.

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 decision**

  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 commissioning 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 decision 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 decision 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 Clinical Policy Committee decision.

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 decision of the Clinical Policy Committee 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 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.

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 by standard distribution list to include primary care practices
- Primary care relevant intervention requiring further consideration through Formulary Interface Groups (FIGs) – communicated after FIG discussions
- Primary care relevant 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 (FIGs) prompting local treatment pathway development incorporating the commissioning decisions
- Engagement with Devon Referral Support Services (DRSS) [Devon Access and Referral Team (DART)/ Tamar Referral and Appointments Centre (TRAC)] for articulation of commissioning decision into effective referral criteria