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

Clinical Policy Committee (CPC)

Minutes

Wednesday 29th April 2015, 9.30 to 12.30 pm

Committee Suite, County Hall, Exeter

Present:

Dr Jo Roberts* (Chair)	GP Clinical Commissioner	South Devon & Torbay CCG
Dr Mick Braddick*	GP Clinical Commissioner	NEW Devon CCG
Jono Broad	Lay Member	
Dr Andrew Craig*	GP Clinical Commissioner	NEW Devon CCG
Richard Croker	Head of Medicines Optimisation	NEW Devon CCG
Dr Tawfique Daneshmend	Consultant Gastroenterologist & Hepatologist	RD&E NHS FT
Miles Earl	Contract Accountant	NEW Devon CCG
Mark Kealy	Public Health Representative	Devon County Council
Dr Phil Melluish*	GP Clinical Commissioner	South Devon and Torbay CCG
Mac Merrett	Lay Member	
Samantha Morton	Head of Contracting and Procurement	South Devon and Torbay CCG
Chris Roome*	Head of Clinical Effectiveness	NEW Devon CCG
Dr Alison Round*	GP Clinical Commissioner	NEW Devon CCG
Dr Ben Waterfall*	GP Clinical Commissioner	NEW Devon CCG
Dr Darunee Whiting*	GP Clinical Commissioner	NEW Devon CCG

Guests:

Tamsin Sleep	Consultant Ophthalmologist	South Devon Healthcare NHS FT
Matt Howard	Clinical Evidence Manager	NEW Devon CCG
Rob Turner	GP	NEW Devon CCG
Karl Whittaker	Consultant Ophthalmologist	North Devon District Hospital
Anthony Quinn	Consultant Ophthalmologist	Royal Devon & Exeter NHS FT
Nabil Habib	Hon. Professor and Consultant Ophthalmic Surgeon	Plymouth Hospitals NHS Trust
Charles Bill	Director Optometrist	Bill Opticians/The Medical Eye Clinic/South Devon Healthcare NHS FT
Emily McGrath	Consultant Physician	Royal Devon & Exeter NHS Trust
Hilary Pearce	Clinical Effectiveness Pharmacist	NEW Devon CCG
Emma Hewitt	Clinical Evidence Pharmacist	NEW Devon CCG

In attendance:

Rob Cowdry	Contracts Governance Manager, Commissioning	NEW Devon CCG
Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NEW Devon CCG
Rebecca Heayn	Clinical Effectiveness Governance Manager	NEW Devon CCG

* Denotes voting members

1. Welcome and introductions

Attendees were welcomed to the meeting.

Miles Earl had joined the group as the permanent pan-CCG finance advisory member.
Rob Cowdry was in attendance from NEW Devon CCGs contracting department.

Apologies

Andrew Gunatilleke	Consultant in Pain Management & Anaesthesia	South Devon Healthcare
Paul Foster	Secondary Care Chief Pharmacist	South Devon Healthcare
Andrew Kingsley	Patient Safety and Quality	NEW Devon CCG
Dr Peter Leman	GP Clinical Commissioner	NEW Devon CCG

No secondary care pharmacist was able to attend the meeting.
No representative from patient safety and quality was able to attend the meeting.

Notification of Any Other Business
Members were asked if they had any items of AOB to discuss.

Confirmation of voting members and Declarations of Interest
The eight voting members present were identified.

Dr Peter Leman had deputised voting to Chris Roome.

Declaration of interest forms were collected. The chair informed the committee of declarations of interest received.

The group discussed the process for DoI reporting and agreed that the chair of the group would review the forms prior to the meeting and read only those that he felt may impact on the discussion. DoIs will be recorded in full in the meeting minutes.

DRUG/TECHNOLOGY TO BE CONSIDERED	PHARMACEUTICAL COMPANY / MANUFACTURER / SERVICE PROVIDER
Cataract surgery	As a provider of private treatments for patients with cataracts
Brimonidine tartrate 0.5% gel (Mirvaso®) Alternative treatments: **Azelaic acid 15% gel** (Finacea®) **Metronidazole 0.75% gel or cream**	**Galderma UK Ltd** **Bayer Plc** **Various manufacturers**
Assessment and removal of benign skin and subcutaneous lesions	As a provider of private treatments for patients with benign skin and subcutaneous lesions

NAME OF ATTENDEE	ROLE	
Mick Braddick	GP Clinical Commissioner	Hospitality received where the drug(s)/devices(s) intervention(s)/treatment(s) under consideration were discussed by a representative from the drug/manufacturing company/companies. Galderma UK Ltd
Charles Bill	Director, Optometrist	Director of Bill Opticians and Director of the Medial Eye Clinic. Works at Torbay Hospital eye department. Also Chairman of the Devon Local Optical Committee (LOC) and a Board Member of Local Optical Committee Support Unit (LOCSU). Bill Opticians are a group of opticians that refer patients into the NHS system. The Medical Eye Clinic is a surgical facility that performs cataract operations. The LOC represents all optometrists in Devon. LOCSU is a national board that represent all LOCs

NAME OF ATTENDEE	ROLE	
Richard Croker	Head of Medicines Optimisation	Worked as paid adviser to above pharmaceutical/manufacturing company/companies. Attended advisory board on the marketing of Mirvaso
Fiona Dyroff	Clinical Effectiveness Governance Support Officer	Any family member or business interests (including personal or family medical conditions) which could be seen as influencing views of the drug(s) /intervention/treatment under consideration. Family member awaiting referral for cataract surgery.
Nabil Habib	Hon. Professor and Consultant Ophthalmic Surgeon	Operates privately at Plymouth Nuffield Health.
Rebecca Heayn	Clinical Effectiveness Governance Manager	Family member has had a cataract operation within the past 3 years and has been referred for a second for the other eye.
Matt Howard	Clinical Evidence Manager	In previous post had attended a number of CPD events where refreshments, hospitality etc were sponsored by a variety of pharmaceutical companies.
Emily McGrath	Consultant Physician	Has been paid honoraria of £200 for 2 teaching sessions for Galderma in the past 12 months. Neither of these related to rosacea or the product in question, but have been in general education in dermatology.
Ben Waterfall	GP Clinical Commissioner	Attended five South West Dermatology meetings where Galderma co-sponsor lunch.
Karl Whittaker	Consultant Ophthalmologist	Stated that if cataract surgery is 'rationed' by the NHS, likely to benefit financially by offering private treatment.
Anthony Quinn	Consultant Ophthalmologist	Chair of Consultant Eye Surgeons Partnership (South West) LLP Partner of Exeter Laser Eye Surgeons LLP

2. Minutes of the meeting held on 18th March 2015 and matters/actions arising

The minutes of the meeting held on Wednesday 18th March 2015 were approved.

Summary of actions		
	Action	**Lead**
15/01	*NICE CG164 familial breast cancer: Recommendation and summary of clinical discussion to be taken to the CCGs' executive groups.* *It is planned that the final recommendations will be submitted to NEW Devon CCG and South Devon and Torbay CCG Executive Group meetings in April 2015.* This had been delayed pending a subsequent response from NICE to the earlier queries raised. Nothing further has been received. Final recommendation to be submitted to the CCG Executive Groups next meeting (May/June 2015) for approval.	Rebecca Heayn
15/04	*Commissioning policy for the Jaydess® levonorgestrel 13.5 mg intrauterine systems to be published.* *The policy has been drafted and will be published once the formulary guidance had been agreed by the Formulary Interface Groups* This policy has been published. Action complete.	
15/08	*Final recommendation for referral for the surgical management of heavy menstrual bleeding to be submitted to the NEW Devon CCG and South Devon and Torbay CCG Executive Groups for approval.* *The policy has been published*. Action complete	
15/09	*Commissioning policy for Lixisenatide for the treatment of type 2 diabetes to be published.* The decision has been taken to the North and East Formulary Interface Group and is due to be taken to the South and West Formulary Interface Group. Once formulary discussions are complete, the policy will be published.	Rebecca Heayn
15/10	*Commissioning policy for Avanafil for Erectile Dysfunction to be published.* The policy has been published. Action complete.	

3. Cataract surgery

It is anticipated that the requirement for cataract surgery will increase with increasing life expectancy and associated population numbers. NEW Devon CCG and South Devon and Torbay CCG decided independently to develop a policy for cataract surgery. A member of the Clinical Effectiveness team presented the draft policy. Tamsin Sleep, Consultant Ophthalmologist at SDHC, Karl Whitaker, Consultant Ophthalmologist at NDDH, Anthony Quinn, Consultant Ophthalmologist at RDE, Nabil Habib, Hon. Professor and Consultant Ophthalmologist Surgeon at PHT and Charles Bill, Director Optometrist at Bill Opticians, The Medical Eye Clinic and SDHC joined the meeting for the discussion.

There are two reasons for developing the policy. First, the adjusted rate of cataract surgery is higher than the national rate for NEW Devon CCG. Second, there is variation in the rate of cataract surgery across Devon. The draft policy has been developed in line with the Royal College of Ophthalmologist's commissioning guide on cataract surgery. Consultation on the proposed policy has been held with ophthalmologists from each of the acute trusts in Devon and with two high-street practising optometrists. The financial impact of the policy is difficult to determine because of the current variation in cataract surgery rates across Devon. A reduction in the cataract surgery rate in NEW Devon CCG to the national rate would result in cost savings of approximately £660,000 per year. A Devon-wide commissioning policy would ensure consistency in the provision of cataract surgery across Devon. It is anticipated that the policy will result in cost savings and free up capacity in some ophthalmology departments across Devon.

The committee were asked to make a recommendation to the executive groups of NEW Devon CCG and South Devon and Torbay CCG regarding the commissioning policy for cataract surgery.

The committee discussed a number of issues pertinent to this policy:

- The committee generally felt that the policy would reduce variation in treatment provision across Devon.
- Some members felt that cost savings in the longer term would be limited as cataract is a progressive condition and ultimately patients would meet the criteria for cataract surgery.
- Two points were discussed which were raised during the consultation process:
    - It was suggested that wording be included around rapid progressive myopia as this group of patients are replacing glasses very frequently in an attempt to maintain their vision.
    - Reduce contrast sensitivity was added to the criteria for referral.
- It was felt that a small amendment to the proposed wording with regard to occupational requirement was needed to indicate that patients in recognised occupations require better than 6/12 eyesight.
- There was also a discussion as to whether further groups of patients at risk of complications during cataract surgery should be considered. This was not raised during the consultation process therefore it was agreed that the ophthalmologists should submit evidence for discussion at a future meeting on this point.
- The role of DRSS: there was a discussion on how DRSS apply commissioning policies to referrals. It was noted that criteria for referral need to be specific. Currently DRSS only return referrals for cataract surgery when documentation is incomplete. Education of Optometrists in making referrals may be needed.

Following discussion at the meeting it was agreed that the proposed policy would be revised and shared with specialists prior to subsequent recommendation by the committee.

ACTION: Policy to be revised and shared with specialists prior to its return to Clinical Policy Committee for a recommendation to the CCGs' Executive Groups.

4. Brimonidine for the symptomatic treatment of facial erythema of rosacea in adult patients

A formulary application has been received from a local consultant dermatologist requesting the addition of brimonidine tartrate gel (Mirvaso®) to the local formulary for the treatment of symptomatic facial erythema for rosacea in adult patients. The application is for GPs and secondary care specialists to initiate and prescribe ongoing treatment, however it is recognised that the majority of patients will be managed in primary care. Emma Hewitt, Clinical Evidence Pharmacist, NEW Devon CCG presented an evidence assessment. Dr Emily McGrath, Consultant Physician took part in the discussion of this item.

The committee reviewed the evidence for Brimonidine. Rosacea is a chronic relapsing disease of facial skin. Brimonidine 0.5% gel is the only licenced product in the UK that directly targets the persistent facial erythema of rosacea.

Efficacy evidence is based upon two short term phase 3 trials comparing brimonidine gel to vehicle gel. No robust head to head trials with active comparator treatment were identified. A 1-grade improvement is considered to represent an effect that is noticeable by both clinicians and patients and is therefore clinically relevant. A 2-grade improvement is a more stringent criterion for success. The percentage of subjects with severe erythema at baseline achieving a 2-grade composite success ranged from 9% to 27% in the active group versus 0% to 11% in the vehicle group. The percentage of patients with moderate to severe erythema, achieving 1-grade composite success ranged from 47% to 71% for subjects treated with brimonidine gel and 17% to 43% for those using vehicle gel. An evaluation of 'number needed to treat' for day 29, hour 6 of treatment suggests that for every 3 to 5 patients treated with brimonidine 0.5% gel, 1 would achieve a 1-grade composite success for erythema who would not have responded with placebo. The most frequently reported adverse events in the trials included worsening of erythema and/or flushing, pruritus, skin irritation and worsening of rosacea.

The cost of one 30g container of brimonidine 0.5% gel is £33.69. The costs of azelaic acid gel and metronidazole gel and cream preparations range from £6 to £23. No papers reporting cost effectiveness of brimonidine from a UK or NHS perspective were found. The cost effectiveness model submitted to the Scottish Medicines Consortium (SMC) was very sensitive to a number of parameters with ICER in excess of £60k/QALY in some scenarios. The company revised their model and the SMC considered the economic case was demonstrated. However the Clinical Effectiveness Team identified that the amendments were not based on robust evidence gathered in relation to treating patients with rosacea. There is also uncertainty over potential uptake of brimonidine gel and resulting budget impact. The manufacturer provided a budget impact model which appeared to contain several design/computational errors in uptake calculations. A revised local budget impact model estimates year 5 costs varying from £54,000 to £379,000 for brimonidine gel depending on the prevalence rates for rosacea and associated erythema.

The committee discussed a number of issues pertinent to this commissioning recommendation including:

- There are 2 types of rosacea: some patients experience spots and respond well to other treatments however those without spots do not. Brimonidine is the only specific licensed treatment for this group. Patient numbers are expected to be small.
- The effect of brimonidine is short lived and ongoing daily application is required.
- Uncertainties of the evidence and the unintended consequences of treatment.
- The length of time for which brimonidine could be used.
- Some members felt that there was a place in therapy for brimonidine however concern was expressed with regard to the possible unwarranted increase in prescribing for rosacea generally. Clear criteria would be needed in the formulary.
- Quality of life (QoL): no improvement in QoL was found in the studies. It was suggested that rosacea was a cosmetic problem and that camouflage treatments may provide a safer option.

The committee voted 6 to 2 against recommending that Brimonidine for the symptomatic treatment of facial erythema of rosacea in adult patients is commissioned by the CCGs.

ACTION: Recommendation and QEIA to be submitted to CCGs executive groups for approval.

5. Assessment and removal of benign skin and subcutaneous lesions

A policy for the removal of benign skin lesions was published by predecessor Primary Care Trusts in March 2012 and was adopted by NEW Devon CCG and South Devon and Torbay CCG in May 2013. The policy outlines circumstances in which the removal of a benign skin lesion is routinely commissioned and provides information on the referral of lesions suspicious of malignancy. NEW Devon CCG planned care lead GPs have proposed an update to the policy. Hilary Pearce Clinical Effectiveness Pharmacist, NEW Devon CCG presented the draft policy. Rob Turner, GP, NEW Devon CCG and Emily McGrath, Consultant Physician, Royal Devon and Exeter NHS Foundation Trust took part in the discussion.

The proposed new policy contains two key changes. The first change relates to referral for diagnostic confirmation of lesions which are not suspicious of malignancy. The second change relates to referral routes for lesions which do not fall under the two week wait criteria. A consultation had taken place with dermatologists and plastic surgeons from the four acute trusts in Devon and included GPs with a special interest (GPwSI) in dermatology.

The committee were asked to make a recommendation to the executive group of NEW Devon CCG and to the executive group of South Devon and Torbay CCG regarding the commissioning policy for removal of benign skin and subcutaneous lesions.

The committee discussed a number of issues pertinent to the development of this policy:

- The criteria for the removal of benign skin lesions are;
  - recurrent infections, *or*
  - diagnostic uncertainty (This should mean possible skin cancer, however there is a suspicion that other patients are referred in this way and that some clinicians in secondary care may be removing known benign skin lesions. This is unaffordable).
- Diagnostic uncertainty accounts for about 80% of practice. If GPs are certain that a patient has a low risk Basal Cell Carcinoma (BCC) they can be referred to a GPwSI. Any other skin lesion suspicious of malignancy must be referred to a skin clinic.
- The role of DRSS: In cases where a melanoma or squamous cell carcinoma has been referred through the non-urgent route, DRSS has upgraded these referrals to the two week wait pathway. There was some concern that the change to the policy may enable DRSS to send other referrals for suspected skin malignancies to a GPwSI instead of referral to a skin clinic.
- A very clearly worded policy is needed with regard to the pathway for:
  - melanoma and non-melanoma referrals; and.
  - in cases where uncertainty exists with regard to whether a lesion is malignant.
- Primary Care: the policy should support primary care in making referral decisions and managing the expectations of patients with benign skin lesions.
- It is national policy that GPwSIs keep records on their patient outcomes.
- It was suggested that the route and outcomes of referrals for patients with an uncertain diagnosis is audited.
- The role of imaging in helping to make diagnostic decisions.

The committee voted unanimously to recommend the proposed policy.

ACTION: Recommendation and QEIA to be submitted to the CCGs' executive Groups for approval.

6. Annual Report 2014 – 15

The committee were asked to receive the second annual report of the Clinical Policy Committee. The report provided a comprehensive account of the work of the committee in 2014 – 15 and the governance and operating arrangements underpinning the meetings.

Over the past year the committee met 7 times at approximately 6 weekly intervals. Two new voting members were welcomed to the committee. These were Dr Peter Leman and Dr Ben Waterfall who replaced Dr Keith Gillespie and Dr Stephen Hunt respectively. The number of specialists attending meetings to contribute to discussions has increased with the widened remit and workload of the committee, and the complexity of the items for discussion.

In the year the Terms of Reference were revised to allow CPC to additionally provide a forum for cross-CCG clinical discussion and formulation of recommendations to the CCGs for final decision making, (Part 1 and Part 2 business). A total of 19 commissioning policy decisions and recommendations have been taken by the committee. These comprised 13 commissioning policy decisions (part 1 business) which led to 9 commissioning policies being put in place and 4 decisions being taken to not routinely commission a treatment. Six commissioning policy recommendations were made (part 2 business). In addition, the committee also agreed that one old commissioning policy in one of the former PCTs should be removed as this was now almost obsolete from clinical practice. Further changes to the TORs have been agreed for 2015-16 onwards for all CPC output to be a commissioning recommendation to be approved by the CCGs executive groups.

The clinical effectiveness team have always routinely undertaken an equality impact assessment on all policy decisions; these are published online alongside the policies. This has been brought into a Quality and Equality Impact Assessment tool to assess the impact of the proposal or recommendation on safety, effectiveness, experience and equality and diversity.

Reflective practice and on-going development have included changes to the terms of reference to provide a forum for clinical discussion and recommendations to be made to the CCGs. A committee development session to consider factors pertinent to assessing the value for money of a health care intervention was provided. The committee's lay members have clarified their role and a description of this has been added to the TORs. The timings and venue of future meetings were reviewed. The committee also reviewed its expectations with regard to member attendance and deputies. The clinical effectiveness team have again been mindful of the need to be cost conscious when organising meetings. In order to keep costs to a minimum meetings take place in facilities belonging to strategic partners of the NHS.

The Governing Bodies of NEW Devon CCG and South Devon & Torbay CCG will be asked to accept and ratify the annual report and endorse the role of the committee.

ACTION: Governing Bodies of NEW Devon CCG and South Devon and Torbay CCG to be asked to ratify and endorse the annual report of the Clinical Policy Committee.

ACTION: Annual report to be published following ratification.

The committee noted that no vice chair had been appointed.

Subsequent to the meeting clarification was sought as to whether a lay member of the committee could chair the meeting in the event of the Chair of the committee not being available. This was discussed at the meeting on 10th June 2015 and it was agreed that any permanent member of the committee who was available for a pre meeting and easily contactable could act as chair.

7. Update from NICE Planning, Quality and Assurance Group (NPAG)

The committee received a summary of the NPAG meeting which had taken place on Tuesday 18th March 2015. In particular it was noted that several NICE TAs had been discussed including NICE TA329: Infliximab, adalimumab and golimumab for treating severely active ulcerative colitis after the failure of conventional therapy. Infliximab is now available as three biosimilars. The CCGs had discussed the implementation of the use of these biosimilars with clinicians from the acute trusts in Devon.

It was noted that a number of treatment areas have complex joint CCG/NHS England commissioning arrangements. The NEW Devon CCG Business Intelligence Team has been asked to undertake work to identify whether the CCGs are being charged for any aspects of treatments which are NHS England commissioned.

8. Any other business

Clinical input into the development of commissioning decisions and policy

Clinicians are routinely asked for comments on proposed commissioning and policy development. However it had been noted that there are times when new information which had not been provided to the clinical effectiveness team during the development stage is raised by clinicians at CPC meetings.

It was agreed that the CPC chair would write to trust clinical and medical directors to explain the process for clinician engagement with the CCGs Clinical Effectiveness Team during the development of policies and with the Clinical Policy Committee.

ACTION: Chair of the Clinical Policy Committee to write to the Clinical and Medical Directors of local trusts with regard clinician engagement in the process of policy development and at CPC meetings.

Summary of actions		
	Action	**Lead**
15/01	NICE CG164 familial breast cancer: Recommendation and summary of clinical discussion to be taken to the CCGs' executive groups. It is planned that the final recommendations will be submitted to NEW Devon CCG and South Devon and Torbay CCG Executive Group meetings in April 2015. This had been delayed pending a subsequent response from NICE to the earlier queries raised. Nothing further has been received. Final recommendation to be submitted to the CCG Executive Groups next meeting (May/June 2015) for approval.	Rebecca Heayn
15/09	Commissioning policy for Lixisenatide for the treatment of type 2 diabetes to be published. The decision has been taken to the North and East Formulary Interface Group and is due to be taken to the South and West Formulary Interface Group. Once formulary discussions are complete, the policy will be published.	Rebecca Heayn
15/11	Policy for Cataract surgery to be revised and shared with specialists prior to its return to Clinical Policy Committee for a recommendation to the CCG's Executive Committee.	Hilary Pearce
15/12	Recommendation and QEIA for Brimonidine for the symptomatic treatment of facial erythema of rosacea in adult patients to be submitted to CCGs executive groups for approval.	Rebecca Heayn
15/13	Recommendation and QEIA for the Assessment and removal of benign skin and subcutaneous lesions to be submitted to the CCGs' Executive Groups for approval.	Rebecca Heayn
15/14	Governing bodies of NEW Devon CCG and South Devon and Torbay CCG to be asked to ratify and endorse the annual report of the Clinical Policy Committee.	Rebecca Heayn
15/15	Annual report to be published following ratification.	Rebecca Heayn
15/16	Letter to be written to Clinical and Medical Directors of local trusts with regard clinician engagement in the process of policy development and at CPC meetings.	Jo Roberts