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

Clinical Policy Committee (CPC)
Minutes

Wednesday 20th November 2013, 14.00-16.00

Stowford Room, The Watermark, Ivybridge

Present:

Dr Jo Roberts* (Chair)	GP Clinical Commissioner	South Devon & Torbay CCG
Dr Mick Braddick*	GP Clinical Commissioner	NEW Devon CCG
Dr Andrew Craig*	GP Clinical Commissioner	NEW Devon CCG
Richard Croker	Head of Medicines Optimisation	NEW Devon CCG
Paul Foster	Chief Pharmacist	South Devon Healthcare NHS FT
Dr Keith Gillespie*	GP Clinical Commissioner	NEW Devon CCG
Tina Henry	Consultant in Public Health	Devon County Council
Dr Stephen Hunt*	GP Clinical Commissioner	NEW Devon CCG
Andrew Kingsley	Patient Safety and Quality	NEW Devon CCG
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 Darunee Whiting*	GP Clinical Commissioner	NEW Devon CCG

Guests:

Hilary Pearce	Clinical Effectiveness Pharmacist	NEW Devon CCG
Sanjay Verma	Clinical Evidence Pharmacist	NEW Devon CCG

In attendance:

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 and the group introduced themselves.

Samantha Morton attended the meeting as contracting representative for the CCGs

Apologies

Stuart Kyle	Secondary Care Clinician	North Devon District Hospital
Andrew Gunatilleke	Secondary Care Clinician	South Devon Healthcare Trust
Tawfique Daneshmend	Secondary Care Clinician	Royal Devon & Exeter NHS Foundation Trust
Mike Finnegan	Secondary Care Clinician	Plymouth Hospital NHS Trust

Confirmation of voting members and Declarations of interest

The eight voting members present were noted.

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

DRUG/TECHNOLOGY TO BE CONSIDERED	PHARMACEUTICAL COMPANY / MANUFACTURER / SERVICE PROVIDER
Linaclotide (Constella®)	**Almirall**
Potential alternative treatments:	
Ispaghula husk (Fybogel®)	**Reckitt Benckiser, Forum Health Products**
Bisacodyl (Dulcolax®)	**Boehringer Ingelheim**
Macrogol 3350 (Klean-Prep®, Laxido®, Molaxole®, Movicol®, Moviprep®)	**Galen, Norgine, Meda Pharmaceuticals**
Peppermint oil (Colpermin® IBS relief capsules, Mintec®)	**McNeil Products, Almirall**
Hyoscine butylbromide (Buscopan®)	**Boehringer Ingelheim**
Mebeverine (Colofac®)	**Abbott Healthcare Products**
Amitriptyline	**Accord Healthcare, Wockhardt UK, Rosemont Pharmaceuticals, Actavis UK**
Citalopram	**Lundbeck, Accord Healthcare, Sandoz, Actavis UK, Kent Pharmaceuticals, Rosemont Pharmaceuticals, Aurobindo Pharma – Milpharm**
Dicycloverine	**Zentiva**

NAME OF ATTENDEE	ROLE	
Richard Croker	Head of Medicines Optimisation	Provided paid advice to Galan Pharmaceuticals regarding Laxido
Dr Jo Roberts	Chair/GP Clinical Commissioner	Meeting with Bayer Regional Manager applying for medical education grant circa £20,000 to support audit software implementation for CCG. Meeting with Abbot Healthcare Products representative.
Dr Alison Round	GP Clinical Commissioner	Attended a meeting at which a Bayer representative (contraception) was present but did not speak.

Notification of Any Other Business

The chair asked the committee if there were any items to be discussed under AOB.

2. Minutes of the meeting held on 9th October 2013 and matters/actions arising

The minutes of the meeting held on 9th October 2013 were approved.

13/28 Appeals procedure to be considered and report brought to November meeting.

This was included on the agenda.

Action complete.

13/35 Declaration of Interest Form to be amended to include space for voting members to record details of drug company rep contact.

Action complete.

13/36 Imiquimod 3.75% (Zyclara) for Actinic Keratosis commissioning policy to be published.

Action complete.

13/37 Proposed formal wording for accepting and deleting items into routine use to be e-mailed to members.

Action complete.

13/38 Policy on accepting and deleting items into routine use to be formalised in the governance arrangement for the CPC.

This was discussed as part of the review of the Terms of Reference

Action complete.

13/39 Insulin Degludec for use in type 1 and type 2 diabetes commissioning policy to be published.

Action complete.

13/40 Decision on revocation of existing policy on aflibercept for treatment of Wet Age Related Macular Degeneration to be communicated to Medical Directors and members of CPC distribution list.

Action complete.

13/41 Revocation of existing policy on aflibercept for the treatment of Wet Age Related Macular Degeneration in patients with a suboptimal response to treatment with ranibizumab to be reported to CCG Boards.

This had been taken to the Boards of NEW Devon and South Devon & Torbay CCGs. However Alison Round had been unable to attend the NEW Devon CCG Board meeting and will raise the issue again.

Action complete.

3. Review of Terms of Reference

The committee received an updated Terms of Reference; the changes were highlighted to the group. The revised document will be taken to the Governing Bodies of NEW Devon CCG and South Devon and Torbay CCG for noting.

ACTION: Revised Term of Reference to be taken to the Governing Bodies of NEW Devon CCG and South Devon and Torbay CCG for noting.

4. Appeals process

The committee received the draft appeals process which is currently under development. Key points identified included that:

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

The proposed process has been discussed with the Director of Public Health, Devon County Council and Non-executive Directors. The draft document will be submitted to the Governing Bodies of NEW Devon CCG and South Devon and Torbay CCG.

The committee discussed a number of issues pertinent to the appeals process including:

- who could make an appeal;
- that an appeal cannot be made against the decision; the appeal is against how the decision was made;
- that the outcome from an appeal may be to ask the CPC to look again at a topic
- that appeals must be made within two months of a decision being taken, however there is no timeframe in which a response must be provided;
- if situations change or new information becomes available issues can be considered again, however this is not part of the appeals process;
- GPs can prescribe what they consider to be appropriate;
- a patient can use the individual patient route to request specific treatments not generally available.

ACTION: Appeals process to be taken to the Governing Bodies of NEW Devon CCG and South Devon and Torbay CCG for noting.

ACTION: Jo Roberts to provide details of the identified South Devon and Torbay CCG appeals panel members.

5. Public Involvement

The committee were updated on the work being undertaken to secure additional public engagement on the committee. Progress includes:

- the role specification has been produced, this has been reviewed by the group's lay member;
- liaison with HR to secure media advertising;
- a press officer is writing a press release;
- engagement has taken place with Healthwatch;
- it is hoped that a network of public engagement can be developed.

6. Linaclotide for the treatment of Irritable Bowel Syndrome (IBS)

An application had been received requesting the inclusion of Linaclotide (Constella™) for the treatment of Irritable Bowel Syndrome with Constipation (IBS-C) onto local formularies.

The committee were asked to consider the evidence for commissioning Linaclotide for the treatment of IBS-C. Sanjay Verma, Clinical Evidence Pharmacist, NEW Devon CCG, presented an evidence review.

IBS-C is a common gastrointestinal disorder with a UK community-based prevalence of 2.5%. Linaclotide (Constella™) is a first-in-class, oral, once-daily, guanylate cyclase-C receptor agonist (GCCA) that causes decreased visceral pain, increased intestinal fluid secretion and accelerated intestinal transit. It was licensed in November 2012 for the symptomatic treatment of moderate-to-severe IBS-C in adults, and launched in the UK on 1 April 2013. The recommended dose is one capsule (290 micrograms) once daily at least 30 minutes before a meal. If patients have not experienced improvement in their symptoms after 4 weeks of treatment, the patient should be re-examined and the benefit and risks of continuing treatment reconsidered.

The product license does not stipulate whether Linaclotide (Constella™) is used as a first or second line treatment. The proposed use of Linaclotide outlined in the commissioning application states that it would be used when patients fail to gain an adequate response with a least 2 differing classes of laxatives and/or antispasmodics.

The committee reviewed the evidence for commissioning Linaclotide (Constella™) for the treatment of IBS-C. Clinical trial evidence on the efficacy of Linaclotide at the licensed dosage/indication is based on two placebo-controlled trials by Rao et al, 2012, and Chey et al 2012. Linaclotide was found to improve symptoms of patients with IBS-C. Although statistically significant, the difference in the proportion of patients who reported benefit was small compared to those who benefited from placebo. Furthermore a high placebo response rate in general was noted across a range of outcomes. The difference compared to placebo suggests that only 15-20% of patients obtained a benefit that could be attributed to the drug. No studies compared Linaclotide to other treatment options in IBS-C. The data available are limited to comparisons with placebo over short durations only. Patients could take additional laxatives during the trials and it is unclear how this influenced study outcomes. The short duration of study is considered a limitation in a condition which is characterised by fluctuating severity over a long period of time.

The direct acquisition cost of Linaclotide is higher than other established treatment options. Given the limitations in the research trial evidence it is considered that the cost of Linaclotide is not justified by the effectiveness demonstrated.

The committee discussed a range of issues pertinent to this therapy:

- the lack of evidence of long term efficacy, low success rates and the use of laxatives during clinical trials;
- the therapy was not felt to be cost effective for use in the general population.

The committee voted 5 to 3 against commissioning Linaclotide (Constella™) for the treatment of IBS-C. Members voting against commissioning Linaclotide for this indication cited lack of long term evidence and low rates of effectiveness.

ACTION: Commissioning policy to be published.

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

A meeting had taken place on Tuesday 22 October. The main item to be reported was the discussion regarding Clinical Guideline 168 on the diagnosis and management of varicose veins in the legs. This non mandatory guideline advises on a range of treatments one of which is slightly more cost effective. However, the eligible patient group has been widened which could have a

significant resource implication. This has been raised with leadership teams. Other recent non-mandatory guidelines which may require further consideration by the CCGs as to what extent these are implemented included Fertility (CG156) and Familial Breast Cancer (CG164). Committee members were asked for their view on how decisions on non-mandatory guidance such as these should be taken forward. The committee discussed a number of issues relevant to the commissioning of non-mandatory clinical guidance and noted the following:

- Capacity restrictions for clinical prioritisation decision making for services in both the CCGs.
- The strong desire to ensure consistency of access to treatments for patients with similar conditions across Devon. Currently no mechanism exists to take joint decisions on the possible expansion of service provision for procedures which may be considered of low priority.
- The perception of variability in the rigour of the development of NICE guidelines compared to technology appraisals. It was felt that some guidance was more authoritative and relevant than others and that not all of it should be implemented if resources are limited.
- The appropriateness of CPC as the right group to take decisions on the prioritisation of recommendations contained in NICE Clinical Guidelines. Some members felt that the committee's Terms of Reference would have to be changed and that additional lay public membership would be required as well as CCG leadership. It was also noted that if the functions of CPC was widened to accommodate this type of decision making it may result in intellectual tensions when making decisions regarding the benefits and value of individual treatment modalities.
- NEW Devon CCG is developing a Clinical Leadership Group comprising GPs from the Board and the lead nurse.
- Whether CPC should have a role in providing recommendations to the Clinical leadership group. The committee noted the need for complete transparency on the processes and timescale by which decisions would be taken and communicated once a recommendation has been made.
- Jo Roberts and Samantha Morton will raise the issues discussed with South Devon and Torbay CCG.

ACTION: Jo Roberts and Samantha Morton to raise issues discussed with South Devon and Torbay CCG.

8. Any Other Business

There was no other business to report.

Summary of actions

	Action	Lead
13/42	Revised Terms of Reference to be taken to CCGs' governing bodies for noting and agreement.	Rebecca Heayn
13/43	Appeals process to be taken to CCGs' governing bodies for noting and agreement.	Rebecca Heayn
13/44	Details of the identified South Devon and Torbay CCG appeals panel members to be provided.	Jo Roberts
13/45	Linaclotide for the treatment of Irritable Bowel Syndrome commissioning policy to be published.	Rebecca Heayn
13/46	Issues around CCG decision making capacity to be raised with South Devon and Torbay CCG.	Jo Roberts Samantha Morton