Northern, Eastern and Western Devon Clinical Commissioning Group

South Devon and Torbay Clinical Commissioning Group

Clinical Policy Committee (CPC)

Minutes

Tuesday 11th June 2013, 14.00-16.00

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
Richard Croker	Head of Medicines Optimisation	NEW Devon CCG
Dr Tawfique Daneshmend	Consultant Gastroenterologist & Hepatologist	RD&E NHS FT
Paul Foster	Chief Pharmacist	SDHC NHS FT
Dr Keith Gillespie*	GP Clinical Commissioner	NEW Devon CCG
Barbara Jones	Head of Locality Contracting (N&E)	NEW Devon CCG
Dr Steven Hunt*	GP Clinical Commissioner	NEW Devon CCG
Andrew Kingsley	Patient Safety and Quality	NEW Devon CCG
Dr Philip Melluish*	GP Clinical Commissioner	South Devon & Torbay CCG
Mac Merrett	Lay Member	
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:

Dr Michael Gibbons	Consultant Respiratory Physician	RD&E NHS FT
Dr David Halpin	Consultant Physician & Honorary Associate Professor NHS Respiratory Clinical Lead (SW)	RD&E NHS FT
Dr Philip Hughes	Consultant Chest Physician	Plymouth Hospitals NHS Trust
Hilary Pearce	Clinical Effectiveness Pharmacist	NEW Devon CCG
Petrina Trueman	Joint Formularies 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.
Barbara Jones attended the meeting as Contracting/Finance Representative.
Andrew Kingsley attended the meeting as Patient Safety and Quality Representative.
Dr Philip Hughes joined the meeting via teleconference.
There was no public health representation at the meeting.

The order of the agenda had been changed to enable guests to contribute to the discussion on item 4 – Aclidinium and glycopyrronium inhaled therapy for treatment of COPD and item 5 Indacaterol for treatment of COPD.

2. Apologies

Dr Andrew Craig	GP Clinical Commissioner	NEW Devon CCG
Dr Mike Finnegan	Consultant in Acute Medicine	PH NHS Trust
Dr Andrew Gunatilleke	Consultant in Pain Management & Anaesthesia	SDHC NHS FT
Dr Stuart Kyle	Consultant Rheumatologist	NDHC NHS Trust
Tracey Polak	Assistant Director/Consultant in Public Health	Devon County Council
Mike Wade	Public Health Speciality Registrar	Devon County Council
Alison Wilkinson	Head of Contracting and Business Intelligence	NEW Devon CCG
Jenny Winslade	Chief Nursing Officer	NEW Devon CCG

3 Confirmation of voting members and declaration of interests

The seven voting members present were noted.

Declarations of interest forms were collected. The chair informed the committee that the respiratory specialists attending the meeting had declared interests in relation to the manufacturer of one or more products to be discussed. These would be detailed in the minutes. No person was excluded from the meeting.

Details of Declaration of Interest are detailed below.

DRUG/TECHNOLOGY TO BE CONSIDERED	PHARMACEUTICAL COMPANY / MANUFACTURER / SERVICE PROVIDER
aclidinium (Eklira®)	**Almirall**
glycopyrronium (Seebri®)	**Novartis**
indacaterol (OnBrez®)	**Novartis**
tiotropium (Spiriva®)	**Boehringer Ingelheim**
salmeterol (Serevent®)	**Allen & Handburys**

NAME OF ATTENDEE	ROLE	
Michael Gibbons	Consultant Respiratory Physician	Organised an educational meeting in October 2012 sponsored by Boehringer-Ingelheim. The meeting was an interstitial lung disease meeting not related to diseases or drugs discussed.
David Halpin	Consultant Respiratory Physician	In receipt of lecture fees in excess of £150 in the last year from pharmaceutical/manufacturing company/companies. In receipt of payment/gift for transport and hospitality to attend national or international meetings or symposia. Has interests with regard to a competitor of drug or device. Sponsorship received to attend international meetings and honoraria for lecturing, attending advisory boards and preparing educational material from Almirall, Astra Zeneca, Boehringer, Ingelheim, Chiesi, GlaxoSmithKline, Allen and Handburys, Intermune, Norvatis, Nycomed, MSD and Pfizer. Participated in trials of Aclidinium but not in last three years.
Phil Hughes	Consultant Respiratory Physician	Participated in drug trial for drug devices. In receipt of lecture fees in excess of £150 in the last year from pharmaceutical/manufacturing company/companies. Received hospitality where the drug(s)/ devices(s) under consideration were discussed by a representative of a drug/ manufacturing company/companies. Received payment/gift for transport and hospitality to attend national or international meetings or symposia. Has interests with regard to a competitor of drug or device. (Applies to Novartis, Boeringer Ingelheim, Allen and Handburys).
Alison Round	GP	Works as clinical advisor for a health/life assurance company one hour a week. Spouse is professor of Primary Care Diagnostics in University of Exeter, and receives grants to support his work. He does not receive any grants or fees from pharmaceutical companies.

4. Aclidinium and glycopyrronium inhaled therapy for treatment of Chronic Obstructive Pulmonary Disease (COPD)

The respiratory clinical specialist guests were welcomed to the meeting.

The committee were asked to consider the evidence for commissioning aclidinium and glycopyrronium as part of a range of treatments to be made available for COPD. The evidence assessment had been carried out by the Clinical Effectiveness Team, NEW Devon CCG. The following people had joined the meeting for this item: Petrina Trueman - Joint Formularies Pharmacist, NEW Devon CCG, Hilary Pearce - Clinical Effectiveness

Pharmacist - NEW Devon CCG, Dr Michael Gibbons - Consultant Respiratory Physician, Royal Devon and Exeter Foundation Trust, Dr David Halpin - Consultant Physician & Honorary Associate Professor NHS Respiratory Clinical Lead (SW) Royal Devon and Exeter Foundation Trust and Dr Philip Hughes - Consultant Chest Physician, Plymouth Hospitals NHS Trust for this discussion and for item 5 – Indacaterol for treatment of Chronic Obstructive Pulmonary Disease (COPD)

Aclidinium and glycopyrronium are two recently licenced long-acting muscarinic antagonists (LAMAs) indicated for maintenance bronchodilator treatment in patients with COPD. Prior to the licencing of these drugs tiotropium was the only LAMA available. No head to head trials have been undertaken comparing aclidinium and glycopyrronium. Each was thus considered separately.

The management of COPD in primary and secondary care is covered by NICE Clinical Guidelines 101 (issued in June 2010). NICE has no plans to produce technology appraisal guidelines for aclidinium or glycopyrronium.

Aclidinium

Aclidinium is a twice daily inhaled treatment. Three phase III trials investigating the efficacy of aclidinium at the dose licenced in the UK had been identified. The evidence for the efficacy of aclidinium is based on two short relatively small placebo-controlled randomised trials.

The committee reviewed the clinical evidence for aclidinium. It was noted that the primary outcome was FEV1 change from baseline. The safety profile of aclidinium is expected to be similar to tiotropium, however the lack of data prohibits making comparisons. £3.5 million is spent annually on tiotropium across Devon CCGs. Acclidinium costs about 15% less than tiotropium.

The committee then discussed a range of issues pertinent to this therapy.

- The importance of ensuring that patients were treated well in the most cost effective way was noted.
- Aclidinium is cheaper than tiotropium. While specialists would not generally advocate switching well controlled patients from other therapies it was considered suitable for new patients requiring a LAMA.
- Short term data is available, however longer term trial data is limited and the equivalence and safety of the drugs had not been demonstrated over the long term. The difficulties of collecting long term data for new drugs and that short studies are often undertaken for registration purposes was acknowledged. No additional data is expected over the next 12 months. Specialists considered data suggested that aclidinium was broadly equivalent to tiotropium.
- Reporting of exacerbation data is limited. However the twice daily dosing regimen is not expected to impact patient compliance or increase COPD admissions.
- The need to be aware of the potential combination of LAMAs with LABAs and the need to understand their individual effects was raised.
- The usefulness of having additional clinical options was discussed. Around thirty percent of patients do not benefit from tiotropium, and it was suggested that aclidinium could be used as an alternative. There is no trial evidence suggesting a benefit from treatment with aclidinium in patients who had not benefited from tiotropium.
- The potential for drug cost savings to be invested in other parts of the patient pathways was raised. It was confirmed that no agreement had been made for cost savings

resulting from prescribing alternative drugs to be used for funding other parts of a COPD pathway.

It was clarified that the decision to be taken was whether, given the evidence available, aclidinium was considered an appropriate use of CCG funds. Decisions on its place in therapy would be taken at local FIGs in consultation with local prescribers. Uptake may therefore vary across the localities but a decision that the drug was appropriate would lead to it being available to all patients across Devon at points in clinical pathways that local clinicians have agreed is appropriate for their local area.

Members voted five to two in favour of accepting the commissioning of aclidinium in Devon for the maintenance treatment of patients with Chronic Obstructive Pulmonary Disease (COPD) who require a long acting bronchodilator. Formulary Interface Groups should include this in locally defined treatment recommendations.

Those that voted against commissioning aclidinium identified no distinct advantage and lack of understanding with regard to exacerbation rates.

ACTION: Commissioning policy to be published

Glycopyrronium

Glycopyrronium is a once daily treatment. Evidence for Glycopyrronium is provided by two large scale phase III trials of six to twelve months duration, a smaller phase III cross over RCT to investigate the effect of glycopyrronium on exercise tolerance and a large RCT which included glycopyrronium and tiotropium as comparators.

The committee reviewed the clinical evidence. It was noted that the two large scale phase III trials were well conducted and that findings were largely consistent and comparable with tiotropium. The primary outcomes were of change in trough FEV1 from baseline, which in some cases were only marginally higher than the clinically significant level of 100mls but comparable with tiotropium. Both trials showed a showed a significant reduction in risk of moderate and severe exacerbations for patients receiving glycopyrronium compared to placebo.

Further data on exacerbation rates was available from a very large trial of patients at high risk of exacerbations which was not designed to compare glycopyrronium with tiotropium but in which these drugs were active controls. The rate of moderate and severe exacerbations was comparable for glycopyrronium and tiotropium (0.95 per patient per year vs 0.93). A higher rate of severe exacerbations only was reported for glycopyrronium compared to tiotropium (0.12 vs 0.08 per patient per year for tiotropium, RR=1.43, p=0.025).

The committee then discussed several issues pertinent to this therapy.

- Glycopyrronium is similarly priced to aclidinium. Glycopyrronium is cheaper than tiotropium. While specialists would not generally advocate switching well controlled patients from other therapies it was considered suitable for new patients requiring a LAMA.
- The availability of trial data suggesting comparability to tiotropium. The additional data on exacerbations should be considered in context with the high risk population recruited in the trial and with the unknown comparative efficacy of alternative

treatment options (LABA or LABA plus inhaled corticosteroid) for patients for whom tiotropium is not suitable.

- The possibility that the availability of a range of drugs would result in a reduction in the price of tiotropium was raised, however it was noted that although the licence for tiotropium expires in 2015 the device used to deliver the medication would be an issue. This had been the case for other drugs where devices were used by patients. It was agreed that Formulary Interface Groups (FIGs) be made aware.

ACTION: FIGs to be made aware of issues around devices affecting generic competition for respiratory products.

Members voted unanimously in favour of commissioning the drug as one of a range of drugs available for patients.

ACTION: Commissioning policy to be published

5. Indacaterol for treatment of Chronic Obstructive Pulmonary Disease (COPD)

The committee were asked to consider evidence for commissioning Indacaterol as part of a range of treatments for maintenance bronchodilator treatment of airflow obstruction in adult COPD patients. NEW Devon CCG Clinical Effectiveness Team provided an evidence assessment.

Indacaterol is licensed at UK doses of 150mcg and 300mcg, and has been available for a couple of years, use has been low. The place in therapy for LABAs is defined in NICE Clinical Guideline 101 (issued in June 2010). Indacaterol is a once a day long-acting $beta_2$ adregeneric agonist (LABA) delivered by a small inhaler device. NHS Devon considered Indacaterol in October 2010 at which time it was not recommended for routine use. At that time it had been shown it to be superior to placebo but no comparative studies with other LABAs had been available.

The committee reviewed recent clinical evidence for Indacaterol. At UK doses, data from short RCTs showed that at 12 weeks trough FEV_1 is greater in patients treated with indacaterol compared to either placebo or salmeterol. Non inferiority had been demonstrated for indacaterol compared to tiotropium. There are no published studies designed to compare the efficacy of indacaterol to formoterol. Additional indirect comparative evidence is available from a study and patient level meta-analysis of 22 RCTs evaluating indacaterol 75 mcg (half the UK Licenced dose) against tiotropium, salmeterol and formoterol.

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

- Comparative data are now available which suggest that indacaterol is at least as efficacious as the other commonly used options of salmeterol and tiotropium that could be used at this stage of COPD. The outcomes assessed include short term lung function measures and patient reported quality of life measures.
- Indacaterol would be no more expensive than salmeterol and cheaper than tiotropium. Should a patient later require the addition of an ICS this would be more expensive with indacaterol since indacaterol plus separate steroid is more costly than a combination salmeterol product.
- Specialists provided verbal and written support for including indacaterol in a range of treatment options for new patients requiring LABAs. Switching well controlled patients from other therapies was not generally advocated. Some specialists

considered that LABA combined with steroid was often used inappropriately in milder patients and such patients could be appropriately managed with indacaterol monotherapy.

- Potential risks and difficulties for patients associated with indacaterol included serious risks to asthma patients if this were used inappropriately and potential for confusing patients with additional devices. It was observed that the South Devon formulary uses a 'red' category for treatments that it considers have an associated serious risk which is best managed by limiting prescribing to hospitals only. Concerns about the use of LABAs alone in patients for whom there is some diagnostic uncertainty and an asthmatic reversible component to their respiratory pathology would apply to any of the existing LABA monocomponent products. The FIGs would need to determine where local clinicians consider would be the appropriate place in therapy of this drug if commissioning is accepted.

The committee voted four to three in favour of commissioning indacaterol as one of a range of treatments for airflow obstruction in adult COPD patients. Formulary Interface Groups should include this in locally defined treatment recommendations.

Those voting against commissioning indacaterol considered that there was no real need for or clinical advantage to this drug and more options would risk prescriber and patient confusion.

ACTION: Commissioning policy to be published

6. Minutes of the meeting held on 7th May 2013 and matters arising

The minutes of the meeting held on 7th May 2013 were approved.

Actions from previous meeting:

13/01 Review of ToR to be included on CPC agenda in six months

This has been included on the draft agenda for the meeting in November 2013

13/02 JR to write to Medical Directors to encourage clinician engagement with the CPC process

Complete.

13/03 Policy for dermatological treatments for focal hyperhidrosis to be taken to contracting meetings and issues resolved with PHT.

Barbara Jones to discuss with Alison Wilkinson.

13/04 Contracting and Business Intelligence to be involved at an early stage to consider costs for focal hyperhidrosis treatment and price.

Contracting will feedback if necessary.

13/05 Hyperhidrosis commissioning policy to be published

Complete.

13/06 Written details of Exogen ultrasound money back guarantee to be brought to next meeting.

Information was included in the meeting papers.

13/07 IFP to be asked to note the number of requests for treatment to be given before the nine month period for review by CPC in twelve months

Complete. This will be followed up and included on meeting agenda in 12 months' time.

13/08 Exogen Commissioning Policy to be published

Complete.

13/09 Dupuytren's commissioning policy to be published

Complete.

13/10 Policy variations to be resolved over the next twelve to eighteen months. Contact Local Authority Overview and Scrutiny Committee (OSC) leads to appraise them of this plan

CR is liaising with the communications team with regard to this.

13/11 Letter to be written to CCG governing bodies regarding alignment of access policies and request that the governing bodies inform the CPC if the proposal is not acceptable

Only one reply has been received. Outstanding action to be followed up.

13/12 Issues around the role, remit and membership of NPAG to be raised verbally with John Finn

Complete.

13/13 Dates and venue of future meetings to be finalised

Complete.

7. Dental Implants

Hilary Pearce - Clinical Effectiveness Pharmacist - NEW Devon CCG joined meeting for this item. The committee were asked to note that as part of the work being undertaken to align commissioning policies across Devon the commissioning policy statement and treatment criteria for dental implants approved by NHS Devon Effective Practice Committee in September 2011 and the dental implant policy approved by NHS Plymouth Clinical Effectiveness Commissioning group in December 2010 had been reviewed. Torbay Care Trust did not have a policy for dental implants. Some differences in patient access to treatment in the local policies on routine commissioning of dental implants have been identified. It was noted that in 2012 the Faculty of Dental Surgeons issued updated guidance on the selection of patients to receive dental implants which included several groups of patients not included in the local polices.

It is now the responsibility of NHS England to commission specialist services including for some of the patient groups identified in existing local policies. Not all patient groups identified in the latest Faculty of Dental Surgery guidance are covered by specialist services commissioned by NHS England however NHS England commission all other dental services through dental contacts. Advice from the contracting team at NEW Devon CCG is that NHS England is responsible for commissioning dental implants and there are no apparent financial considerations for the CCGs.

The local policies are no longer valid and have been removed from the NEW Devon CCG website. The website has been updated to indicate that the commissioning of dental implants is the responsibility of NHS England. Acute Trusts in Devon have also been notified.

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

Members of NPAG had expressed the view that GP input into the group would be helpful. AR has agreed to join NPAG. Any other GP Clinical Commissioners interested in supporting the NPAG process were requested to contact CR.

ACTION: GP Clinical Commissioners interested in supporting the NPAG process to contact CR.

NHS England is now responsible for a large proportion of commissioning. The majority of the guidance discussed at NPAG on 21 May 2013 is now the responsibility of NHS England. NICE's forward plan indicates that a number of recommendations will be issued over the coming months. These include three sets of public health guidance. Feedback on these will be required from the three local authorities in Devon. Previously it had been expected that NPAG would meet every other month, however the group had requested that, at least in the short term, meetings be held on a monthly basis.

9. Future meeting dates for information

Date	Time	Venue
Wednesday 31st July	10.00 – 12.00	Henlake Suite, The Watermark, Ivybridge PL21 0SZ
Wednesday 4th September	10.00 – 12.00	Castle Place Surgery, Tiverton EX16 6NP
Wednesday 9th October	10.00 – 12.00	Boardroom, Newcourt House, Old Rydon Lane, Exeter EX2 7JU
Wednesday 20th November	10.00 – 12.00	Henlake Suite, The Watermark, Ivybridge PL21 0SZ

In the event of not being available to attend a meeting all members were requested to inform the Clinical Effectiveness team as soon as possible. This is to ensure that sufficient members are present with the necessary range of skills to enable quoracy of the meeting to be monitored and avoid last minute cancellation.

Members noted that it could be difficult to identify a deputy and that sending a deputy may not be the right thing to do. It was noted that at least five of the eight GP Clinical Commissioners (voting members) must be present in order for the meeting to be quorate.

Members also noted the importance of members of the group being able to attend regularly and develop with the committee.

10. Any other business

Committee development

A discussion took place with regard to the complex nature of the material covered in the meeting papers and some members felt that additional direction from clinical evidence specialists would be helpful interpreting the evidence. However, the need to ensure that bias was not introduced was also noted.

The committee noted that during the meeting discussions three themes had appeared. These were with regard to clinical effectiveness; including the benefits and harms, what benefits patients would get and cost effectiveness. It would be helpful if these issues could be grouped in the discussion paper.

It was agreed that further refinement to the content and structure of evidence assessments would be undertaken, and that discussions were planned regarding public and patient involvement processes. The decision making process for the CPC will be developed and brought back to a future meeting of the group.

Freedom of Information Request

It was noted that a Freedom of Information request had been received asking for the names of the members of the group. It was also noted that when meeting minutes, which will contain this information, have been ratified they will be uploaded to the NEW Devon website. No members objected to his or her name being provided and the CCG will respond to the FOI request in line with regulations and policy.

Summary of actions		
	Action	**Lead**
13/03	*Policy for dermatological treatments for focal hyperhidrosis to be taken to contracting meetings and issues resolved with PHT.* Item to be raised with Alison Wilkinson	 Barbara Jones
13/10	*Policy variations to be resolved over the next twelve to eighteen months. Contact local authority Overview and Scrutiny Committee (OSC) leads to appraise them of this plan.* CR is liaising with the communications team with regard to this.	 Chris Roome
13/11	*Letter to be written to CCG governing bodies regarding alignment of access policies and request that the governing bodies inform the CPC if the proposal is not acceptable.* Only one reply has been received to date. Outstanding action to be followed up.	 Chris Roome
13/14	Aclidinium commissioning policy to be published.	Rebecca Heayn
13/15	FIGs to be made aware of issues around devices affecting generic competition for respiratory products.	Chris Roome
13/16	Glycopyrronium commissioning policy to be published.	Rebecca Heayn
13/17	Indacaterol commissioning policy to be published.	Rebecca Heayn
13/18	GP Clinical Commissioners interested in supporting the NPAG process to contact Chris Roome.	GP Clinical Commissioners
13/19	Decision making process to be developed for CPC and will be brought back to a future meeting of the group	Jo Roberts, Chris Roome