Northern, Eastern and Western Devon Clinical Commissioning Group

South Devon and Torbay Clinical Commissioning Group

Clinical Policy Committee (CPC)
Minutes

Wednesday 14th September 2016, 9.30 am to 12.30

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 Northern and Eastern Localities	NEW Devon CCG
Miles Earl	Contract Accountant	NEW Devon CCG
Mark Kealy	Consultant in Public Health	Devon County Council
Andrew Kingsley	Patient Safety and Quality	NEW Devon CCG
Dr Phil 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 Ben Waterfall*	GP Clinical Commissioner	NEW Devon CCG

Guests:

Louise Crathorne	Clinical Evidence Scientist	NEW Devon CCG
Dr Lucinda Harris	Clinical Lead	DRSS
Matt Howard	Clinical Evidence Manager	NEW Devon CCG
Dr Emily McGrath	Consultant Dermatologist	RD&E NHS Foundation Trust
Dr Nick Kennedy	Consultant Gastroenterologist	RD&E NHS Foundation Trust
Petrina Trueman	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 announcements

Attendees were welcomed to the meeting.

Apologies

Tawfique Daneshmend	Consultant Gastroenterologist & Hepatologist	RD&E NHS FT
Paul Foster	Chief Pharmacist	T&SD NHS FT
Barbara Jones	Head of Locality Contracting	NEW Devon CCG
Peter Leman	GP Clinical Commissioner	NEW Devon CCG
Samantha Morton	Head of Contracting and Procurement	South Devon & Torbay CCG
Darunee Whiting	GP Clinical Commissioner	NEW Devon CCG

Dr Peter Leman had deputised voting to Chris Roome.
Dr Darunee Whiting had deputised voting to Richard Croker.

Confirmation of voting members and Declarations of Interest

The eight voting members present were identified.

Declaration of Interest forms were collected and reviewed by the Chair. All Declarations of Interest are reported in the minutes.

DRUG/TECHNOLOGY TO BE CONSIDERED	PHARMACEUTICAL COMPANY / MANUFACTURER / SERVICE PROVIDER
Ivermectin (Soolantra®) for Rosacea	**Galderma UK Ltd**
Alternative treatments:	
Azelaic acid (Finacea®)	**Bayer Plc**
Metronidazole (Rozex®, Metrogel®, Metrosa® and generic)	**Galderma UK Ltd, Linderma Ltd and various**
Linaclotide (Constella®) **for the treatment of irritable bowel syndrome with constipation (IBS-C) in adults**	**Almirall**
Alternative treatments:	
Ispaghula husk (various brands)	**Various manufacturers**
Bisacodyl (various brands)	**Various manufacturers**
Macrogol 3350 (various brands)	**Various manufacturers**
Peppermint oil (Colpermin® IBS relief capsules, Mintec®, Apercap®)	**McNeil Products, Almirall, Auden McKenzie (Pharma Division) Ltd**
Hyoscine butylbromide (Buscopan®)	**Boehringer Ingelheim**
Mebeverine (various brands)	**Various manufacturers**
Dicycloverine (various brands)	**Various manufacturers**
Alverine (various brands)	**Various manufacturers**
Tricyclic antidepressants (various brands)	**Various manufacturers**
Selective Serotonin Re-uptake Inhibitors (SSRIs) (various brands)	**Various manufacturers**
Surgery for Ganglion Cyst	Would benefit from private provision of surgery for ganglion cyst

NAME OF ATTENDEE	ROLE	
Louise Crathorne	Clinical Evidence Scientist	In a previous post received fees for review of methods in review of economic evaluation from Almirall (NICE submission) different product to that being discussed today.

Richard Croker	Head of Medicines Optimisation	Worked as paid advisor on advisory boards for Galderma UK, Galen and Stirling Anglian (Macrogol), (Soolantra, Roxel)
Dr Lucinda Harris	GP	Spouse is an orthopaedic surgical trainee in the southwest. He does not undertake any private surgical procedures.
Matt Howard	Clinical Evidence Manager	In previous post attended a number of CPD events where refreshments, hospitality etc were sponsored by a variety of pharmaceutical companies.
Dr Mark Kealy	Consultant in Public Health Medicine	Prescribed Ivermectin on a number of occasions for disseminated scabies.
Dr Nick Kennedy	Consultant Gastroenterologist	Gave an invited talk on withdrawal of anti-TNF therapy to a regional meeting of gastroenterologists in February 2016 for which an honorarium was received from Actavis. Actavis has now rebranded as Allergan. Allergan has now also acquired the rights to linaclotide from Almirall. Have not had any commercial involvement with Almirall or with anything directly related to linaclotide.
Dr Emily McGrath	Consultant Dermatologist	Galderma have represented themselves and provided lunch at two dermalology meetings regionally in the past twelve months when Soolantra has been discussed.

Notification of Any other Business

Members were asked if they had any items of AOB to discuss. Jo Roberts reported that he had an item for discussion. No other members of the committee noted any item of AOB.

2. Minutes of the meeting held on 20th July 2016 and matter/actions arising

The minutes of the meeting held on 20th July were approved.

Summary of actions		
	Action	**Lead**
16/07	*Policy recommendation and QEIA for Dulaglutide (Trulicity®) for the treatment of type 2 diabetes to be prepared and subsequently progressed to final CCG approval and communication.* This has been considered by the Clinical Policy Engagement and Consultation Panel. The policy recommendation and QEIA were approved by NEW Devon CCG on 7th September 2016 and will be presented to South Devon and Torbay CCG on 15th September 2016.	Rebecca Heayn

16/08	*Policy recommendation and QEIA for Myringotomy/grommets with or without adjuvant adenoidectomy for the management of otitis media in children under 12 years to be prepared and subsequently progressed to final CCG approval and communication.* This has been considered by the Clinical Policy Engagement and Consultation Panel. The policy recommendation and QEIA were approved by NEW Devon CCG on 7th September 2016 and will be presented to South Devon and Torbay CCG on 15th September 2016.	Rebecca Heayn
16/09	*Policy recommendation and QEIA for Myringotomy with or without ventilation tubes (grommets) in adults and children aged 12 years and older to be prepared and subsequently progressed to final CCG approval and communication.* This has been considered by the Clinical Policy Engagement and Consultation Panel. The policy recommendation and QEIA were approved by NEW Devon CCG on 7th September 2016 and will be presented to South Devon and Torbay CCG on 15th September 2016.	Rebecca Heayn
16/10	*Policy recommendation and QEIA for Tonsillectomy to be prepared and subsequently progressed to final CCG approval and communication.* This has been considered by the Clinical Policy Engagement and Consultation Panel. The policy recommendation and QEIA were approved by NEW Devon CCG on 7th September 2016 and will be presented to South Devon and Torbay CCG on 15th September 2016.	Rebecca Heayn

3. Ivermectin (Soolantra®) for Rosacea

A formulary application has been received for the use of Ivermectin (Soolantra®) as a first line option for the treatment of Papulopustular Rosacea (PPR) as an alternative to topical metronidazole or azelaic acid. Petrina Trueman, Clinical Evidence Pharmacist, NEW Devon CCG presented an evidence review. Dr Emily McGrath, Consultant Dermatologist, RD&E NHS FT participated in the discussion of this item.

Soolantra® cream, which contains 1% ivermectin, is indicated for the topical treatment of inflammatory lesions of PPR and is applied once daily. A course of treatment lasts for four months and may be repeated but should be discontinued after three months if no improvement is seen.

The All Wales Medicines Strategy Group (AWMSG) and Scottish Medicines Consortium (SMC) have accepted Soolantra® for the treatment of inflammatory lesions of PPR in adults, although SMC restricts this to use in moderate to severe PPR only. There is no published NICE guideline on rosacea.

A literature search identified supportive clinical evidence in RCTs that compared Soolantra® with vehicle cream, and with metronidazole 0.75% cream. Two randomised controlled trials (RCTs) with identical designs compared the efficacy and safety of ivermectin versus vehicle over 12 weeks. Ivermectin was statistically significantly more effective than vehicle at reducing inflammatory lesion count and rosacea scores. Compared to metronidazole cream, ivermectin users showed both a statistically significantly greater level of treatment success and a greater reduction in inflammatory lesion count, over 16 weeks. Results from a 36-week extension phase of this trial showed a median relapse time of almost 4 months in the ivermectin group versus slightly less than 3 months in the metronidazole group. In addition, more subjects in the ivermectin group did not relapse during the whole extension period than in the metronidazole group. There are no published data reporting on the effectiveness of

initiating ivermectin cream in people with mild rosacea. No studies have looked at the efficacy and safety of ivermectin 1% cream when used beyond 12 months.

In the trials the incidence of adverse events (AEs) was similar between ivermectin, metronidazole and azelaic acid.

In cost utility analyses carried out by the manufacturers of Soolantra® for AWMSG ivermectin dominated metronidazole and azelaic acid over a 3 year time horizon. A range of sensitivity analyses was carried out in which ivermectin remained dominant. Although the model was sensitive to the daily amount of product used, the resulting incremental cost-effectiveness ratio (ICERS) remained less than £5,000 well below the accepted NHS willingness-to-pay threshold of £20,000 per quality adjusted life year (QALY) gained. Probabilistic sensitivity analyses confirmed the base case results. A course of treatment of Soolantra lasts 4 months and may be repeated. The frequency of repeats is not specified. One tube of Soolantra® costs £18.29 and should last between 30 and 42 days. In the cost utility model an annual acquisition cost of £152 was assumed for Ivermectin representing 8.3 tubes per year. Annual acquisition costs of individual brands of metronidazole range from £104 (Rozex®) to £268 (Metrogel®). If it is assumed that patients will apply the same amount of product per application and apply the product as frequently as recommended a 16 week course of Ivermectin cream would cost £68.28. The current average weighted cost of a course of metronidazole is £85.12 in NEW Devon and £94.08 in South Devon and Torbay. The weighting accounts for current prescribing variation across Devon.

In conclusion Ivermectin has shown greater clinical efficacy than both vehicle cream and metronidazole in RCTs, in the treatment of inflammatory lesions of moderate to severe PPR, with a similar adverse effect profiles to other topical agents. The use of Ivermectin in place of metronidazole is expected to be approximately cost neutral or to achieve a very small saving; a manufacturer-provided budget impact model estimates an annual cost saving of £800 in NEW Devon CCG and £500 in South Devon & Torbay CCGs based upon current volumes of metronidazole prescribing, and assuming a 100% switch to Soolantra®.

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

- Soolantra® is an alternative topical treatment for moderate to severe papulopustular Rosacea; the intended clinical use does not include mild rosacea.
- Soolantra® is slightly better tolerated than the alternatives. It is effective for patients with different skin types and a systemic antibiotic may not be needed.
- Specialist opinion was that Soolantra® would be a sensible first line treatment.
- The symptoms of rosacea - the specialist present reported that some patients experience pain, distress and other serious quality of life symptoms; rosacea is not just a cosmetic condition.
- Most patients will be treated in primary care rather than secondary care. Patients who are successfully treated may need fewer GP appointments.
- Commissioning Soolantra® should not change GP threshold for treatment. If Soolantra® is not commissioned an alternative treatment will be given.
- Using Soolantra® in place of metronidazole for moderate PPR is probably slightly cost saving overall.
- The Formulary Interface Groups will agree the formulary recommendation for place in therapy.

The committee voted unanimously in favour of the routine commissioning of Ivermectin (Soolantra®) for Rosacea.

ACTION: **Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.**

4. Linaclotide (Constella®) for the treatment of irritable bowel syndrome with constipation (IBS-C) in adults

Linaclotide was considered by the Clinical Policy Committee for this indication in November 2013. Although the evidence reviewed by the committee demonstrated that linaclotide improved symptoms in patients with IBS-C, it suggested that only 15-20% of patients obtained a benefit that could be attributed to the drug. In addition, the committee noted a number of limitations. These were that patients could take additional laxatives during the trials, the studies were of a short duration (considered a limitation as the condition is characterised by fluctuating severity over a long period of time) and that the acquisition cost of linaclotide is higher than other established options. Given these limitations, the committee considered that the cost of linaclotide was not justified by the effectiveness demonstrated.

A new formulary application has now been received for the routine commissioning of linaclotide (Constella®) for this indication in line with NICE CG61. The applicant indicated that since the original decision, additional evidence on efficacy and cost-effectiveness has been published; and that the context has changed in light of an update to this NICE clinical guideline. Matt Howard, Clinical Evidence Manager, NEW Devon CCG presented an evidence assessment. Dr Nick Kennedy, Consultant Gastroenterologist, RD&E NHS FT took part in the discussion of this item.

Linaclotide is licensed for the symptomatic treatment of moderate-to-severe IBS-C in adults; if patients have not improved after 4 weeks, the benefit and risks of continuing treatment should be reconsidered. The new NICE guidance now makes a weak recommendation that linaclotide may be considered for people with IBS only if optimal or maximum tolerated doses of previous laxatives from different classes have not helped; and they have had constipation for at least 12 months. In contrast to the 4-week follow up recommended in the Summary of Product Characteristics (SPC), NICE recommend following up people taking linaclotide after 3 months.

A literature search was conducted, and consideration was given to citations provided by the applicant. Since the original decision, there have been no new, relevant RCTs published. Subsequent meta-analyses provide further analysis of data from the RCTs which were available at the time of the original decision. As expected, these analyses also show that a higher proportion of patients reported relief with linaclotide than with placebo in terms of improvements in abdominal pain/discomfort; bowel movements; and quality of life. However, the limitations identified in the original application remain. There are still no long term efficacy data, the trials allowed use of concomitant laxatives, rescue laxatives and other medications; and there are no trials in the specific population. These meta-analyses reported placebo adjusted success rates of approximately 13% to 20%.

Since the original decision, a cost-utility analysis has been published which suggests that linaclotide would be considered cost effective compared to antidepressants at willingness-to-pay thresholds usually accepted by the NHS. The 5-year base case analysis produced an incremental cost-effectiveness ratio (ICER) of £7,370 per quality adjusted life year (QALY) gained. However, the model has a number of substantial limitations in terms of reliability of efficacy data and resource utilisation. The authors conducted a series of sensitivity and scenario analyses, producing ICERs which remained cost-effective compared to antidepressants at a willingness-to-pay threshold of £20,000 per QALY. This appears to have been the model previously accepted by Scottish Medicines Consortium (SMC) and subsequently modified for submission to the All Wales Medicines Strategy Group; who noted some of the limitations, but also accepted linaclotide for restricted use.

If linaclotide is effective, there may be health system wide savings from a reduction in GP/outpatient appointments; however these are notional savings, which may free up capacity but are unlikely to release cash for investment in other treatments or services. Due to the higher acquisition cost of linaclotide, it is likely that its use will result in additional

expenditure in comparison to other treatment options. A budget impact of £20,169 is estimated for year 1, rising to £201,692 by year 5.

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

- The specialist present reported that Linaclotide (Constella®) can be used in patients who are treatment refractory to alternatives. Other options are limited and not licenced.
- The specialist present reported that a new protocol was being developed at Royal Devon and Exeter NHS Foundation Trust based around CG61. CG61 recommends that Linaclotide (Constella®) is used in primary care.
- The specialist present had also reviewed the position taken by twenty other CCGs; two had not recommended use of Linaclotide (Constella®), others had stated that it should be used in secondary care and others that it should be used in primary care. The committee expressed some concern that GPs may prescribe Linaclotide (Constella®) in primary care to a wider range of patients than recommended by NICE.
- The committee noted that the group of patients for which this treatment is recommended is the group in which it has not been explicitly studied. The specialist present reported that use of Linaclotide (Constella®) is recommended in Scotland and that he had gained experience of its use there and had found it to be effective in the patient population for whom it was recommended. However, it is important that there is clear guidance in place for stopping the treatment if it is not working. It was also noted that no further evidence was expected to be produced as Linaclotide (Constella®) is widely used and has been approved by NICE.
- Placebo responses versus clinical responses. Concern was expressed that some patients may experience an improvement in their symptoms due to a placebo response and that this could increase costs. However it was noted that the group of patients for whom Linaclotide (Constella®) is recommended will have already had opportunities for a placebeo response with previous treatments.
- If patient numbers are small, Linaclotide (Constella®) could be suitable for request through the Trust Managed Individual Patients Process. If agreed, treatment would be initiated and subsequently the patient managed in secondary care for 6 months. If treatment was effective primary care take would then take over the management of the patient. There were no special requirements related to drug safety monitoring.

The committee voted 7 to 1 against recommending the routine commissioning of Linaclotide (Constella®) for the treatment of irritable bowel syndrome with constipation (IBS-C) in adults.

The committee voted 6 to 2 in favour of recommending that Linaclotide (Constella®) for the treatment of irritable bowel syndrome with constipation (IBS-C) in adults was suitable for access through the Trust Managed Individual Patients Process.

ACTION: Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.

5. Surgery for Ganglion Cyst

As part of the work being undertaken to align commissioning polices across Devon consideration has been given to surgery for ganglion cyst. NHS Devon Effective Practice Committee approved a policy for removal of wrist ganglia in 2010. NHS Plymouth Clinical Effectiveness Commissioning Group approved a policy for removal of wrist ganglia in 2011. This policy was based on the NHS Devon policy. The Healthcare Funding Request Group of Torbay Care Trust approved the NHS Devon policy in 2011. DRSS support staff and GP referral facilitators find that the existing policies require interpretation with respect to the position of the ganglion and the policies cover only ganglia of the wrist. There is also a need for clarity on which commissioning policy covers mucoid (myxoid) cysts. The wording proposed by the Planned Care Lead GPs for the Devon-wide policy is intended to overcome difficulties in applying the current policies as a result of the anatomical location of a ganglion cyst. The proposed policy covers ganglia of the hand and wrist and ganglia of the lower extremities. As mucoid (myxoid) cysts arise from connective tissue usually at the top of the

last segment of the finger, the policy for ganglion surgery is considered to be the appropriate place for commissioning criteria for mucoid cysts. The proposed policy was presented by Chris Roome, Head of Clinical Effectiveness, NEW Devon CCG. Dr Lucinda Harris, Clinical Lead, DRSS took part in the discussion of this item.

The proposed policy covers all anatomical sites. The consultation process included hand surgeons and plastic surgeons as well as foot and ankle surgeons. The specialists have no concerns over the commissioning criteria for surgery. However two lead foot and ankle surgeons expressed concern that the policy would be applied as criteria for referral. They highlighted the importance of ensuring that, if any doubt existed as to the diagnosis patients should be referred to a specialist as lumps can appear to be ganglia when they are in fact other benign or malignant growths.

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

- The suggested policy is an improvement on what presently exists.
- The policy together with the supporting clinical referral guidance (CRG) will support staff at DRSS to ensure safe and equitable referral for this group of patients, including for those patients who turn out to have other benign or malignant growths rather than a ganglion cyst.
- The importance of not overlooking quality of life issues for patients with ganglion cysts.

The seven voting committee members voted unanimously in favour of recommending the proposed policy on surgery for ganglion cyst.

Chris Roome abstained from voting as he had presented the policy to the committee.

ACTION: Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.

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

NPAG Meeting 28th June 2016

The committee received an update from the NPAG meeting that had taken place on 28th June 2016. At the meeting the group had considered six pieces of NICE Technology Appraisal guidance, seven NICE Guidelines, two pieces of Medical Technology Guidance and four pieces of Interventional Procedures Guidance. Much of the guidance considered at the meeting was commissioned by NHS England.

Future of NPAG

Previously it had been noted that attendance at NPAG had significantly diminished and that those who attended regularly were not able to deal with all the issues raised at meetings. Consideration had been given to the viability and value of the group. However it was felt that much of the work undertaken by the clinical effectiveness team in preparation for meetings produced a valuable resource for the CCGs detailing the position of local trusts and organisations with regard to NICE. As a result it was felt that the group should continue.

Agendas now identify the areas of work to which each item links. Senior CCG staff with responsibility for the areas of work relevant to each item are contacted to bring to their attention the publication of the guidance and the providers responses.

7. Update from Clinical Policy Engagement and Consultation Panel

The committee received the minutes of the Clinical Policy Engagement and Consultation Panel meeting which took place on Wednesday 17th August 2016.

It was reported that the group had considered four policy recommendations from the Clinical Policy Committee meeting held on 20th July 2016 and agreed that no further engagement or public consultation action was required.

8. Any Other Business

Resignations from the Clinical Policy Committee

The Chair reported that he had received two resignations from the Clinical Policy Committee.

The first was from Darunee Whiting, GP Clinical Commissioner. Darunee was not present at the meeting but was thanked in her absence for her input to the group.

The second was from Jono Broad, lay member of the group. The Chair expressed regret that Jono had resigned and thanked him for all the work he had done for the committee including for speaking his mind and asking difficult questions. Jono identified a change in his circumstances together with the increasing workload for lay members and lack of remuneration from the CCG as factors influencing his decision to resign. It was also noted that Jono had been a member of the group for two years as per his original contract.

It was noted that NEW Devon CCG was currently reviewing its policy for expenses and remuneration; his comments would be fed into this process. CPC is currently bound by the CCG position regarding remuneration of lay public and patient representatives to ensure consistency.

Summary of actions

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16/11	Policy recommendation and QEIA for Ivermectin (Soolantra®) for Rosacea to be prepared and subsequently progressed to final CCG approval and communication.	Rebecca Heayn
16/12	Policy recommendation and QEIA for Linaclotide (Constella®) for the treatment of irritable bowel syndrome with constipation (IBS-C) in adults to be prepared and subsequently progressed to final CCG approval and communication.	Rebecca Heayn
16/13	Policy recommendation and QEIA for surgery for Ganglion Cyst to be prepared and subsequently progressed to final CCG approval and communication.	Rebecca Heayn