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

Clinical Policy Committee (CPC)

Minutes

Wednesday 2nd December 2015, 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
Paul Foster	Chief Pharmacist	T&SD NHS FT
Dr Andrew Gunatilleke	Consultant in Pain Management & Anaesthesia	T&SD NHS FT
Barbara Jones	Head of Locality Contracting	NEW Devon CCG
Tracey Kerslake	Contract Manager/Funding	South Devon & Torbay CCG
Dr Peter Leman*	GP Clinical Commissioner	NEW Devon CCG
Dr Phil Melluish*	GP Clinical Commissioner	South Devon & Torbay CCG
Mac Merrett	Lay Member	
Tracey Polak	Assistant Director/Consultant of Public Health	Devon County Council
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:

Emma Gitsham	Joint Formularies Pharmacist	NEW Devon CCG
Matt Howard	Clinical Evidence Manager	NEW Devon CCG
Hilary Pearce	Clinical Effectiveness Pharmacist	NEW Devon CCG
Petrina Trueman	Clinical Evidence Pharmacist	NEW Devon CCG
Bethan Rogers	Medicines Information & Formulary Support Pharmacist	RD&E NHS FT
Carol Webb	Joint Formularies Technician	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
** Denotes attended via teleconferencing facilities

Note: From the 1st October 2015 South Devon Healthcare NHS Foundation Trust and Torbay and Southern Devon Health and Care Trust merged to become Torbay and South Devon NHS Foundation Trust.

1. Welcome and announcements

Apologies

Andrew Kingsley	Lead Nurse Healthcare Acquired Infections	NEW Devon CCG
Tawfique Daneshmend	Consultant Gastroenterologist	RD&E NHS FT

No representative from Patient Safety and Quality was available to attend the meeting.

Confirmation of voting members and Declarations of Interest

Declaration of Interest Forms were collected. The chair reviewed the Declaration of Interest forms. Declarations of Interest are reported in the minutes.

The eight voting members present were identified.

Tracey Kerslake attended the meeting as deputy for Samantha Morton.

DRUG/TECHNOLOGY TO BE CONSIDERED	PHARMACEUTICAL COMPANY / MANUFACTURER / SERVICE PROVIDER
Budesonide prolonged release tablets (Cortiment®) **for ulcerative colitis**	**Ferring Pharmaceuticals Ltd**
Alternative treatments:	
Beclometasone dipropionate tablets (Clipper®)	**Chiesi Ltd**
Rectal corticosteroids (Budenofalk® rectal foam, Endocort® enema, Colifoam® foam enema, Predsol® enema and generic)	**Dr Falk Pharma UK Ltd, AstraZeneca UK Ltd, Meda Pharmaceuticals Ltd, Focus Pharmaceuticals Ltd, various manufacturers**
Oral Budesonide (Budenofalk® capsules and granules)	**Dr Falk Pharma UK Ltd**
Oral Prednisolone	**Various manufacturers**
Clindamyicn 1%/Tretinoin 0.025% w/w gel (Treclin® ®) **for the topical treatment of acne vulgaris**	**Meda Pharmaceuticals Ltd**
Alternative treatments:	
Benzoyl peroxide with Clindamycin (Duac®)	**Stiefel Laboratories (UK) Ltd**
Adapalene with Benzoyl peroxide (Epiduo®)	**Galderma (UK) Ltd**
Isotretinoin with erythromycin (Isotrexin®)	**Stiefel Laboratories (UK) Ltd**
Tretinoin with erythromycin (Aknemycin Plus®)	**Almirall Ltd**
Other topical preparations for acne containing one or more of Benzoyl peroxide, retinoid and/or antibiotic	**Various manufacturers**
Oral Isotretinoin (Roaccutane® or generic)	**Roche Products Ltd, various manufacturers**
Oral antibiotics or combined oral contraceptives	**Various manufacturers**
Alogliptin (Vipidia®) **for type 2 diabetes**	**Takeda UK Ltd**
Alternative treatments:	
Linagliptin (Trajenta®)	**Boehringer Ingelheim Ltd**
Saxagliptin (Onglyza®)	**AstraZeneca UK Ltd**
Sitagliptin (Januvia®)	**Merck Sharp and Dohme Ltd**
Vildagliptin (Galvus®)	**Novartis Pharmaceuticals UK Ltd**
Other oral antidiabetic medication	**Various manufacturers**
Assisted conception	**Providers of assisted conception services**
Botulinum toxin A for the management of blepharospasm (Botox®, Dysport®, Xeomin®)	**Allergan, Ipsen, Merz Pharma UK** As a provider of private botulinum toxin treatment for patients with blepharospasm

DRUG/TECHNOLOGY TO BE CONSIDERED	PHARMACEUTICAL COMPANY / MANUFACTURER / SERVICE PROVIDER
Botulinum toxin A for the management of hemifacial spasm (Botox®, Dysport®) Alternative treatments: **Microvascular decompression**	**Allergan, Ipsen** **Specialist neurosurgery providers** As a provider of private treatments for patients with hemifacial spasm

NAME OF ATTENDEE	ROLE	
Richard Croker	Head of Medicines Optimisation	*Work as paid advisor to pharmaceutical/manufacturing company/companies* Undertook advisory board for Galderma (UK) Ltd
Matt Howard	Clinical Evidence Manager	In previous post attended a number of CPD events etc where refreshments may have been sponsored by a variety of pharmaceutical companies
Ben Waterfall	GP Clinical Commissioner	Has 3 children via IVF Contact with most of the dermatology drug companies as sponsors of clinical meetings attended over the last 12-24 months but no specific interests in companies listed above

2. Minutes of the meeting held on 16th September 2015 and matters/actions arising

The minutes of the meeting held on 16th September 2015 were approved.

Summary of actions		
	Action	**Lead**
15/18	*Cataract Surgery: Policy Recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.* *The lay-member panel discussed the committee's recommendation and considered that no formal public consultation was required. The policy and QEIA have subsequently been signed off by both CCGs' Executives Groups.* *Patient support information to be produced to accompany publication of the policy.* *Pending publication, patient information is being produced.* The policy and accompanying support information has now been published. Action complete.	

15/19	*Contracting teams at NEW Devon CCG and South Devon and Torbay CCG to review the setting in which administration of BoNT for the management of urinary incontinence due to detrusor activity takes place with the aim of working towards a standardised and cost-effective practice.* *Meetings will take place at NEW Devon CCG and South Devon and Torbay CCG. The outcomes of these will be reported to the next CPC meeting.* Discussions have taken place. Work will progress in line with other priorities. Action complete.	
15/20	*Policy recommendation and QEIA for the routine commissioning of botulinum toxin for the management of urinary incontinence due to detrusor activity to be prepared and subsequently progressed to final CCG approval and communication.* *Final policy recommendation and QEIA has been submitted to CCGs' executive groups for approval at their meetings in September.* The policy has now been published. Action complete.	
15/21	*Policy recommendation and QEIA for the routine commissioning of BoNT for the treatment of chronic anal fissure to be prepared and subsequently progressed to final CCG approval and communication*. Final policy recommendation and QEIA has been submitted to CCGs' executive groups for approval at their meetings in September. The policy has now been published. Action complete.	
15/22	*Contracting meeting regarding audit of the use of botulinum toxin for the treatment of chronic anal fissure to be set up.* *Meetings will take place at NEW Devon CCG and South Devon and Torbay CCG. The outcomes of these will be reported to the next CPC meeting.* Discussions have taken place. Work will progress in line with other priorities. Action complete.	
15/23	*Policy recommendation and QEIA for the referral and specialist management of haemorrhoids in adults to be prepared and subsequently progressed to final CCG approval and communication.* Final policy recommendation and QEIA has been submitted to *CCGs' executive groups for approval at their meetings in September.* *Patient support information to be produced to accompany publication of the policy.* The policy and accompanying support information has now been published. Action complete.	

15/24	*Local contracting process for the treatment of minor anal procedures as an outpatient to be agreed by the contracting teams of NEW Devon and South Devon and Torbay CCGs.* Discussions have taken place. Work will progress in line with other priorities. Action complete.	
15/25	*Issue of vial sharing with regard to BoNT injections to be raised with the Medical Director at South Devon Healthcare NHS Trust.* Action complete.	Samantha Morton
15/26	Access criteria for BoNT A for the management of blepharospasm to be agreed with consultants which capture the functional limitations consistent with the position the CCGs adopt in relation to other conditions. Item included on meeting agenda. Action complete.	
15/27	*Policy recommendation and QEIA for BoNT for the management of blepharospasm to be prepared and subsequently progressed to final CCG approval and communication.* Item included on meeting agenda. Action complete.	
15/28	*Seek to agree access criteria with consultants for BoNT A for the management of hemifacial spasm which capture the functional limitations consistent with the position the CCGs adopt in relation to other conditions.* Item included on meeting agenda. Action complete.	
15/29	*Policy recommendation and QEIA for BoNT for the management of hemifacial spasm to be prepared and subsequently progressed to final CCG approval and communication.* Item included on meeting agenda. Action complete.	
15/30	*Policy recommendation and QEIA for fluticasone furoate and vilanterol trifenatate (Relvar® Ellipta®) combination inhaler for asthma to be prepared and subsequently progressed to final CCG approval and communication.* The recommendation has been approved by the CCGs' Executive Groups. The policy will be published following discussion at the forthcoming FIGs.	Rebecca Heayn
15/31	*Policy recommendation and QEIA for Fluticasone furoate and vilanterol trifenatate (Relvar® Ellipta®) combination inhaler for chronic obstructive pulmonary disease to be prepared and subsequently progressed to final CCG approval and communication.* The recommendation has been approved by the CCGs' Executive Groups. The policy will be published following discussion at the forthcoming FIGs.	Rebecca Heayn

15/32	*Policy recommendation and QEIA for the assessment and removal of benign skin and subcutaneous lesions to be prepared and subsequently progressed to final CCG approval and communication.* The recommendation has been approved by the CCGs' Executive Groups and accompanying support information prepared. This will be published once an implementation date has been agreed by DRSS and Planned Care.	Rebecca Heayn
15/33	Comments on paper for the management of non-routinely commissioned drug treatments to be forwarded to Petrina Trueman Item included on the meeting agenda. Action complete.	Petrina Trueman

3. Budesonide prolonged release tablets (Cortiment®) for ulcerative colitis

A formulary application has been submitted by a Consultant Gastroenterologist based at Torbay and South Devon NHS Foundation Trust requesting the inclusion of budesonide 9mg prolonged release multi-matrix tablets (MMX® Cortiment®) for the treatment of ulcerative colitis. Emma Gitsham, Joint Formularies Pharmacist, NEW Devon CCG presented an evidence review. Written comments received from Dr T Daneshmend, Consultant Gastroenterologist, RD&E NHS FT, Dr M Metzner-Hosi, Consultant Gastroenterologist, Plymouth Hospital NHS Trust and Dr R Johnston, Consultant Gastroenterologist, Torbay and South Devon NHS FT were included in the meeting papers

Budesonide prolonged release tablets (Cortiment®) are licenced for use in adults for the induction of remission of mild to moderate active ulcerative colitis where 5-aminosalicylic acid (5-ASA) treatment is not sufficient. The rationale for the applications was that the multi-matrix system offers targeted release for topical effect at the site of inflammation in the colon, and there is limited systemic availability of budesonide following single administration suggesting that reduced adverse events may be experienced.

The committee reviewed the clinical evidence. Two eight week randomised controlled trials demonstrated the efficacy of budesonide 9mg tablets compared to placebo, in active mild-to-moderate disease. The rate of combined clinical endoscopic remission was between 17-18% for budesonide tablets in both trials, resulting in a small absolute effect size difference between budesonide and placebo, of 10-13%. Although the absolute effect size was small it was clinically significant. Remission rates were lower for patients with extensive disease and moderate disease severity. The observed differences between budesonide and placebo, for the secondary endpoint rate of clinical and endoscopic improvement were less than or equal to 10%. There was no significant difference between budesonide and placebo for clinical improvement. One trial compared budesonide 9mg tables with placebo as add-on therapy to oral aminosalicylate in people with active, mild or moderate disease. Adding budesonide was significantly more effective than placebo at inducing combined clinical and endoscopic remission, histological healing and endoscopic remission assessed independently. Clinical remission assessed separately was not statistically significant for budesonide verses placebo. No direct head-to-head evidence versus currently recommended treatments when aminosalicylates are considered insufficient was identified during the review. The incidence of adverse events for budesonide tablets was comparable to placebo, during the pre-licensing clinical trials. The most common adverse effects are nausea, upper abdominal pain, headache, insomnia, altered mood, decreased blood cortisol, influenza and viral upper respiratory tract infection. There was an absence of data to enable the safety of budesonide tablets to be directly compared to prednisolone.

Due to a lack of data, it was not possible to draw any meaningful conclusions on the cost-effectiveness of budesonide multi-matrix tablets compared to other treatments. The cost of an 8 week course of budesonide 9mg multi-matrix tablets is £140. There is a cost difference of £129 per patient/flare between an 8 week course of prednisolone weaning down daily by 5mg by day once weekly from 40mg daily, and budesonide 9mg daily. There is uncertainty on the potential uptake of this treatment and the resulting budget impact. The manufacturer provided a budget impact model which was felt to potentially underestimate the total number of courses of budesonide that may be prescribed and resulting cost. Calculations conducted by the Clinical Effectiveness Team suggest that the cost of treatment could result in an increased spend of over £40,000 per year if prescribing of budesonide 9mg prolonged release multi-matrix tablets replaced all other use of corticosteroids for the management of active disease.

The committee considered the written comments submitted by hospital consultants.

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

- Side effects: Suppression of the HPA axis is a problem associated with corticosteroids. Budesonide 9mg tablets may have reduced adrenal side effects although no direct head to head safety evidence was identified.
- Effectiveness: The drug had been shown to be effective when the manufacturer carried out limited work. However budesonide 9mg tablets have not been compared to other commonly used drug regimens in the licensed indication – there is no head to head comparator data on efficacy.
- Treatment options: A specialist at the RD&E has commented verbally that currently there are some gaps in treatment options and budesonide 9mg tablets may be useful for some patients where prednisolone tablets cause specific problems. If not routinely commissioned, budesonide 9mg tablets could be available for appropriate patients via individual funding routes.
- Cost: This treatment is more costly than available oral alternatives.

The committee voted unanimously against recommending the routine commissioning of Budesonide prolonged release multi-matrix 9mg tablets (Cortiment®) for ulcerative colitis.

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

4. Clindamycin 1%/Tretinoin 0.025% w/w gel (Treclin®) for the topical treatment of acne vulgaris

A formulary application has been received from a consultant dermatologist requesting the inclusion of Treclin® into local formularies for the topical treatment of acne vulgaris in adults and children over twelve years of age. The applicant has indicated that Treclin® is better tolerated and that it provides faster onset of action than relevant comparators resulting in improved likelihood of patient adherence and therefore better results. Matt Howard, Clinical Evidence Manager, NEW Devon CCG presented an evidence review.

Treclin® is a combination gel containing the antibiotic, clindamycin; and the retinoid tretinoin, for once daily application. NICE have not published either a clinical guideline for the diagnosis and management of acne vulgaris, or a NICE Technology Appraisal for Treclin®. The NICE Clinical Knowledge Summary for acne vulgaris suggests a combined topical treatment (antibiotic *plus* benzoyl peroxide; or antibiotic *plus* topical retinoid) is the preferred regimen for the treatment of moderate acne.

The committee reviewed the clinical evidence. Three almost identical randomised, controlled trials were pooled to show that Treclin® produces a statistically significant reduction in acne lesions compared to individual component monotherapies or vehicle gel. The trials also demonstrated statistically significantly higher success rate in an evaluators global severity score. However, the active comparators in the trial are not those recommended as alternatives for moderate acne, where Treclin® might be considered; the dosage of clindamycin used was less frequent than the current licensed UK clindamycin monotherapy product. These efficacy studies found no differences in tolerability or irritancy between the comparators, all of which produced low irritability.

A small limited trial comparing Treclin® and Duac® found that Duac® may be more effective at reducing antibiotic resistant *P.acnes* bacteria than Treclin®, but did not demonstrate any significant differences in clinical efficacy, or tolerability between the products. There are no direct head to head clinical efficacy studies of Treclin® versus other combination topical treatments. Additional small trials suggest that Treclin® may produce statistically significantly lower irritation than monotherapy with a higher strength tretinoin gel; and that Treclin® may produce statistically significantly less burning/stinging than Epiduo (although irritancy of both products was low); there was no difference in tolerability or irritancy when compared to adapalene gel.

The assertion that Treclin® has a faster onset of action than its component monotherapies, or other products has not been definitively demonstrated. In the pivotal efficacy trials, adverse event rates were low and of mild to moderate severity; and broadly in line with those expected of the individual active ingredients.

A lack of published utility values or suitable quality of life data has meant that cost-utility analyses have not been possible. It is noted that Treclin® is cheaper per gram than Duac® and Epiduo®, but higher in cost than Isotrexin® gel. Duac® and Epiduo® currently make up the majority of prescribed combination topical treatments for acne in Devon. Use of Treclin® in place of these two products would be slightly cost saving (up to almost £12,000 across Devon annually).

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

- Some bacteria have high levels of antibiotic resistance. The 12 week restriction on use of Treclin® is an attempt to prevent antibiotic resistance. After 12 weeks of treatment the condition is usually controlled and can be treated with benzoyl peroxide. Subsequent flare ups can be treated with Treclin®.
- There is only limited evidence comparing Treclin® to current treatments.
- None of the combination acne treatments are available for patients to buy over the counter.
- Treclin® is being promoted as being cheaper than other options however there are cheaper alternatives on the formulary.
- Treclin® should be commissioned and its place in the formulary discussed at Formulary Interface Group meetings.
- This is an additional option which may reduce referral to secondary care and/or use of oral isotretinoin.

The committee voted 7 to1 in favour of recommending routine commissioning of Clindamycin 1%/Tretinoin 0.025% w/w gel (Treclin®) for the topical treatment of acne vulgaris.

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

5. Alogliptin (Vipidia®) for type 2 diabetes mellitus

A formulary application has been received from the medicines optimisation team, NEW Devon CCG requesting consideration of commissioning the DPP-4 inhibitor (or "gliptin"), Alogliptin (Vipidia®) for use in patients with type 2 diabetes mellitus. Petrina Trueman, Clinical Evidence Pharmacist, NEW Devon CCG presented an evidence review.

Alogliptin (Vipidia®) is a once daily tablet; the usual daily dose is 25mg. It is licensed for add-on dual therapy with metformin, a sulphonylurea, pioglitazone, or insulin, or triple therapy with metformin and either pioglitazone or insulin. Other gliptins on the local joint formularies include sitagliptin, saxagliptin and linagliptin. Sitagliptin is the most widely used. NICE updated its guideline on 2nd December 2015 and recommends gliptins as one of a range of intensification options after metformin which also include sulphonylureas, pioglitazone or SGLT-2 inhibitors, or instead of metformin if metformin is not tolerated. The Scottish Medicines Consortuim and All Wales Medicines Group have approved alogliptin for use in dual therapy with metformin and a sulphonylurea.

The committee reviewed the clinical evidence. Evidence for licensing of Alogliptin (Vipidia®) for type 2 diabetes mellitus was based on 5 placebo controlled trials, where statistically

significant reductions in HbA1c at 26 weeks were seen with the drug as monotherapy and as an add-on to metformin, sulphonylurea, pioglitazone, and insulin, and also when used in triple therapy with metformin and pioglitazone. A greater percentage of subjects in the placebo-controlled trials also achieved HbA1c levels of 7% or less in the alogliptin groups than in the placebo groups, the majority were statistically significant. Alogliptin (Vipidia®) was found to be non-inferior to glipizide when used in dual therapy with metformin, with respect to reduction in HbA1c at 52 and 104 weeks but this study used a lower dose of glipizide than would be seen in clinical practice. A systematic review and mixed treatment comparison incorporated patients with type 2 diabetes receiving any gliptin, GLP-1 agonist, SGLT-2 inhibitor as mono-, dual or triple therapy with metformin or sulphonylurea. It found that alogliptin was non-inferior to other gliptins with respect to reductions in HbA1c at 26 weeks, when added to metformin or sulphonylurea. The incidence of side effects was low overall. The European Medicines Agency concluded in their European Public Assessment Report that the safety profile is similar to that of other gliptins. A review of cardiovascular safety concluded that Alogliptin (Vipidia®) is not associated with an increased cardiovascular risk and post hoc analyses indicated that alogliptin (Vipidia®) does not have an adverse effect upon composite outcomes of cardiovascular death, or hospital admission for heart failure. (Heart failure was investigated specifically following a finding in trials investigating the cardiovascular safety of saxagliptin, that it was associated with an increase in hospitalisations for heart failure).

Cost projections are based upon actual spend across the two CCGs for the twelve months to July 2015. Total expenditure on gliptins in NEW Devon CCG and South Devon & Torbay CCGs was £932,731 and £417,843 respectively. The potential cost reduction associated with 25% or 75% of gliptin prescribing by volume being alogliptin (Vipidia®) would be approximately £75,000 and £227,000 respectively. Figures provided by the manufacturers of alogliptin (Vipidia®) predict a growth in the use of gliptins of up to 46 percent over the next three years, based upon trends seen over the past three years. This growth may alter depending on the impact of the new NICE guideline.

In conclusion, alogliptin (Vipidia®) is a gliptin with a lower acquisition cost than other gliptins. Direct comparative evidence is lacking but indirect evidence shows that alogliptin (Vipidia®) is non-inferior to other gliptins with respect to changes in HbA1c and has a similar safety profile. This application has been identified as an opportunity to reduce the rate of growth in prescribing costs in this area as it has a 16-20% lower acquisition cost than other gliptins without adversely affecting patient care. However this opportunity must be balanced against limitations in evidence. The application has received support from secondary care clinicians in Plymouth Hospitals Trust and the Royal Devon and Exeter NHS Foundation Trust.

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

- Alogliptin (Vipidia®) is cost saving compared to other gliptins; there are no anticipated changes to the cost of other gliptins.
- There are a number of gliptins available; consideration was given as to how to manage the number and position of gliptins on the formulary. It was noted that NICE generally produce guidelines when a number of similar drugs become available.

The committee voted unanimously in favour of the routine commissioning of Alogliptin (Vipidia®) for use in patients with type 2 diabetes mellitus.

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

6. Assisted conception – policy wording amendments for clarification

The committee agreed a policy for assisted conception earlier in 2015. Following publication of the policy, a DRSS GP referral facilitator has developed Clinical Referral Guidance (CRG) for fertility to support GPs in general practice when discussing potential referrals with their patients. This process has identified sections of the policy which would benefit from greater clarity. The proposed changes are not considered to represent a change in current practice. Clinical Effectiveness Team pharmacists, NEW Devon CCG, presented the policy amendments for clarification.

The layout of the first page of the policy has been amended to bring together information on the circumstances in which assessment and investigations for fertility are commissioned for heterosexual and same-sex couples. Two subheadings have been added to the eligibility criteria: 'Eligibility criteria for NHS-funded fertility assessment' and 'Eligibility criteria for NHS-funded assisted reproduction techniques'. The eligibility criteria for fertility assessment and investigation exclude couples including a partner who has been sterilised and couples who have undergone previous NHS-funded assisted reproduction techniques by virtue of the fact that a couple must be investigated before undergoing fertility treatments. In order to receive NHS-funded assisted reproduction techniques, both individuals must meet the criteria outlined under 'Eligibility criteria for NHS-funded assisted reproduction techniques'. The proposed clarification to the eligibility criteria for treatment allows for the fact that NICE guidance has introduced a change in the recommended treatment for the majority of patients from intrauterine insemination to IVF.

The committee considered issues pertinent to the policy wording clarification.

- In addition it was noted a proposed clarification to the policy for cryopreservation will be brought to a future meeting of CPC.

The committee voted unanimously in favour of accepting the policy revisions.

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

7. Consideration of discussions of policy access criteria for Botulinum Toxin A for the management of blepharospasm and for the management of hemifacial spasm

At the meeting of the Clinical Policy Committee on Wednesday 16th September 2015, the committee voted unanimously in favour of commissioning botulinum toxin (BoNT) A for two indications: the management of blepharospasm, and the management of hemifacial spasm. The committee also voted 7-1 in favour of adopting access criteria within both policy recommendations. For blepharospasm, it was suggested that these access criteria could be based on the Jankovic Rating Scale (JRS). For hemifacial spasm, it was not clear whether JRS would be an appropriate tool, or whether a different, more suitable scale existed. It was agreed that Matt Howard, Clinical Evidence Manager, NEW Devon CCG would engage local consultants to agree access criteria which capture the functional limitations consistent with the position the CCG adopts in relation to other conditions. Matt Howard presented details of the subsequent engagement.

During the engagement process, several concerns were raised regarding the adoption of access criteria and a consensus had not been reached regarding suitable criteria. Specialists had expressed some concern as to the usefulness of access criteria and the possibility of an inappropriate reduction in referrals or conversely an increase in referrals.

In light of the comments received and the difficulty in reaching a consensus with specialists, the committee was asked to decide whether it wished to reconsider the commissioning decision (including the specifics of access criteria, if necessary) relating to BoNT A for blepharospasm and for hemifacial spasm, at the January 2016 meeting.

The committee discussed a number of issues pertinent to access criteria for BoNT A for the management of blepharospasm and for the management of hemifacial spasm. The points raised included:

- that the specialists appeared genuinely concerned that the introduction of access criteria might stop appropriate referrals,
- that not all patients want the treatment; the committee suggested that patient engagement take place in order to gain patient views,
- that a global quality of life measure which can apply a functional basis to all indications was required; it was suggested that it would useful to formally consider functional criteria at a future meeting,

- it was proposed that a face to face meeting be arranged to include Jo Roberts, Mac Merrett (as lay representative), Andrew Gunatilleke, Matt Howard and specialists to agree access criteria for BoNT A for management of blepharospasm and for the management of hemifacial spasm.

The committee were asked to make a decision on whether to do nothing and leave the decision on whether to treat a patient to the consultants' clinical judgement or to engage with consultants to agree suitable access criteria for referral.

The committee voted 7 to 1 in favour of further engagement with clinicians to produce access criteria. One committee member voted in favour of accepting the policies as they are without criteria.

ACTION: Matt Howard to set up a meeting with clinicians regarding access criteria for treatment with BoNT A for the management of blepharospasm and for the management of hemifacial spasm

8. Management of non-routinely commissioned drug treatments

Petrina Trueman, Clinical Evidence Pharmacist, NEW Devon CCG presented a paper outlining a process for the management of non-routinely commissioned drug treatments. Drug treatments that are submitted to the clinical policy committee for consideration are subject to a robust review process by the clinical effectiveness team, whereby all relevant evidence is evaluated for clinical benefit and value for money to the health community and presented to the committee for consideration. However, from time to time there will be individual patients for whom a non-commissioned drug treatment will be the only option.

Currently the route to gain approval for the use of non-commissioned drug treatments is through the Individual Funding Request Panel (IFRP). However, this is a burdensome administrative process and disproportionate for relatively simple treatments that are within tariff, used for conditions that would routinely be managed in primary care and for which there are no particular drug-specific monitoring requirements or financial arrangements necessary to enable the future transfer of care if the medication is continued. There are recurrent anecdotal reports that such prescribing occurs and that because there is no process the communications between secondary and primary care regarding initiation and ongoing care are not always optimal. Therefore a less burdensome, clinically more appropriate, clear and transparent process is required whereby specialists in secondary care apply for individual approval for non-commissioned treatments that have these general characteristics. Such treatment would be for a limited trial period (initially six months), in order to establish the drugs' on-going effectiveness for the patient. After this time the secondary care specialist will contact the patient's GP to suggest that they continue to prescribe the treatment. This would help ensure that inappropriate requests for primary care initiation or continuation where the drug concerned is clearly of a specialist nature do not take place and to stop similarly inappropriate requests for routine use made in an attempt to circumvent formulary rejections.

If the proposal is accepted CPC will determine if a non-commissioned treatment is suitable for individual approval for limited use via Trusts' individual Drugs and Therapeutics Committees (or equivalent) or if IFRP applications are required.

The committee discussed a number of issues pertinent to the management of non-routinely commissioned drug treatments.

- The proposed process had been developed at a meeting that included the chairs of the four acute trust Drugs and Therapeutics Committees (or equivalent), Trust pharmacists, medicines optimisation team, and clinical effectiveness.
- The proposed process would deliver a number of benefits including providing secondary and primary care with a transparent and robust procedure for the management of a few specific non-commissioned drug treatments which the CPC would judge to be appropriate for limited individual use without recourse to panel. It is relatively onerous, but clinically appropriate for secondary care being responsible for the prescribing, monitoring the effectiveness of treatment and for the budget for the first six months. Trusts could use this

time to collect and audit cohort data. However it was noted that CPC does not reconsider a previously rejected treatment unless new trial evidence becomes available.

- Potential areas of concern were considered by the committee. In particular these related to the introduction of a two facets to a decision not to routinely commission a drug, the potential increase in costs, the equity of the process and providers making decisions based on what they wanted to provide.
- This process was only suitable for relatively low cost in–tariff medications.
- Other issues considered included:
  - that the process will apply only to drugs considered by CPC in the future and not to those that have already been considered,
  - clarity will be needed on the formulary website.
  - a slight change to the CPC Terms of Reference will be needed,
  - the trusts' Drugs and Therapeutics committee (or equivalent) will be the approval committee where drugs are considered appropriate for this.

The committee voted 7 to 1 in favour of a one year's trial of the proposed management process (following minor amendments) for non-routinely commissioned drug treatment with a six month review.

ACTION: Agreed minor amendments to be incorporated into the paperwork and communication to primary and secondary care to be planned.

9. Joint Formularies Interim Report 2015

Carol Webb, Joint Formularies Technician, NEW Devon CCG presented the Interim Annual Report of the Devon Formulary Interface Groups. The aim of the report was to highlight the work undertaken by the North and East Devon Formulary Interface Group and the South and West Devon Formulary Interface Group for 2015 – 2016 up to and including September 2015. A full annual report will be produced for the June 2016 meeting.

The Devon Formularies promote safe, clinically appropriate, cost effective prescribing in both primary and secondary care. Operationally both of the Devon Formularies are managed and co-ordinated by one team of Pharmacists and a Pharmacy Technician within the Clinical Effectiveness Team of NEW Devon CCG.

Between April and September 2015 three formulary chapters have been reviewed, the formularies have supported the timely and planned implementation of 22 pieces of NICE guidance and guidelines, one commissioning decision made by CPC on drug treatments has been added to the formulary and its position on the formulary agreed by the Formulary Interface Groups (FIGs), the formulary received applications for six drugs and made changes to the preferred brands of nine drugs.

Both the Devon formularies have a geographically tailored website to reflect the decisions of the FIG, both are available on a single app that is available on both android and Apple® devices. Updates are received immediately by users without the need for manual updates. A survey of users took place at the end of September 2015; 161 users completed the survey. Another survey will be undertaken in the future.

The website and app was recently a finalist for the HSJ 'Using Technology to Improve Efficiency' award.

The committee discussed issues pertinent to the report and to the formulary. The committee

- stated that the team should be proud of the formulary.
- asked what the challenges were; it was reported that the main challenges were around decommissioning of treatments and also having to work within tighter and tighter budgets.
- asked about the difference between the two formularies; it was noted that there may be small differences for example between first and second line treatments.
- asked if the two formularies could be merged into one. It was noted that the same team work on both the formularies, which is bringing them closer together.

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

The committee received a summary of the NPAG meeting which had taken place on 10th September 2015. The minutes and a summary had been included in the meeting papers.

NPAG had considered three NICE Technology Appraisals. These will be added to the Local Formularies within 90 days of publication.

In addition one clinical guideline, one medical technology guideline, one piece of diagnostic guidance and eight pieces of interventional procedures guidance had been considered.

CPC also received a verbal update of the NPAG meeting held on 10th November. A copy of the minutes and a summary will be included in the meeting papers for the CPC meeting due to take place on Wednesday 27th January 2016.

11. Any Other Business

The Clinical Policy Engagement & Consultation Panel

The lay members noted that CPC did not currently routinely receive feedback from the recently established Clinical Policy Engagement and Consultation Panel. The committee agreed that feedback from lay members following such meetings should be a standing item on future CPC agendas. Jono Board and Rebecca Heayn to liaise.

ACTION: Jono Broad and Rebecca Heayn to liaise with regard to feedback to CPC following meetings of the Clinical Policy Engagement and Consultation Panel meeting.

Summary of actions		
	Action	**Lead**
15/30	Policy recommendation and QEIA for fluticasone furoate and vilanterol trifenatate (Relvar® Ellipta®) combination inhaler for asthma to be prepared and subsequently progressed to final CCG approval and communication. The recommendation has been approved by the CCGs' Executive Groups. The policy will be published following discussion at the forthcoming FIGs.	Rebecca Heayn
15/31	Policy recommendation and QEIA for Fluticasone furoate and vilanterol trifenatate (Relvar® Ellipta®) combination inhaler for chronic obstructive pulmonary disease to be prepared and subsequently progressed to final CCG approval and communication. The recommendation has been approved by the CCGs' Executive Groups. The policy will be published following discussion at the forthcoming FIGs.	Rebecca Heayn
15/32	Policy recommendation and QEIA for the assessment and removal of benign skin and subcutaneous lesions to be prepared and subsequently progressed to final CCG approval and communication. The recommendation has been approved by the CCGs' Executive Groups and accompanying support information prepared. This will be published once an implementation date has been agreed by DRSS and Planned Care.	Rebecca Heayn
15/34	Policy recommendation and QEIA for the routine commissioning of Budesonide prolonged release tablets (Cortiment®) for ulcerative colitis to be prepared and subsequently progressed to final CCG approval and communication.	Rebecca Heayn
15/35	Policy recommendation and QEIA for the routine commissioning of Clindamycin 1%/Tretinoin 0.025% w/w gel (Treclin®) for the topical treatment of acne vulgaris to be prepared and subsequently progressed to final CCG approval and communication.	Rebecca Heayn
15/36	Policy recommendation and QEIA for the routine commissioning of Alogliptin (Vipidia®) for type 2 diabetes mellitus to be prepared and subsequently progressed to final CCG approval and communication.	Rebecca Heayn
15/37	Policy revision recommendation and QEIA for assisted conception to be prepared and subsequently progressed to final CCG approval and communication.	Rebecca Heayn
15/38	Meeting to be set up with clinicians regarding access criteria for treatment with BoNT A for the management of blepharospasm and for the management of hemifacial spasm.	Matt Howard
15/39	Agreed minor amendments to be incorporated into the paperwork for the management of non-routinely commissioned drug treatments. Communication to primary and secondary care to be planned.	Petrina Trueman
15/40	Aspects of feedback to CPC following meetings of the Clinical Policy Engagement and Consultation Panel meeting to be agreed.	Jono Broad & Rebecca Heayn