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

Clinical Policy Committee (CPC)
Minutes

Wednesday 16th September 2015, 9.30 am to 12.30 pm

Committee Suite, County Hall, Exeter

Present:

Dr Alison Round*	GP Clinical Commissioner (Chair)	NEW Devon CCG
Dr Mick Braddick*	GP Clinical Commissioner	NEW Devon CCG
Jono Broad	Lay Member	
Rob Cowdry	Contracts Governance Manager	NEW Devon CCG
Dr Andrew Craig*	GP Clinical Commissioner	NEW Devon CCG
Richard Croker	Head of Medicines Optimisation Northern and Eastern Localities	NEW Devon CCG
Tracey Foss	Chief Pharmacist	RD&E NHS FT
Dr Andrew Gunatilleke	Consultant in Pain Management & Anaesthesia	SDHC NHS Foundation Trust
Andrew Kingsley**	Patient Safety and Quality	NEW Devon CCG
Dr Phil Melluish*	GP Clinical Commissioner	South Devon and Torbay CCG
Mac Merrett	Lay Member	
Samantha Morton*	Head of Contracting and Procurement	South Devon and Torbay CCG
Chris Roome*	Head of Clinical Effectiveness	NEW Devon CCG
Dr Ben Waterfall*	GP Clinical Commissioner	NEW Devon CCG
Dr Darunee Whiting*	GP Clinical Commissioner	NEW Devon CCG

Guests:

Alex Degan	GP	NEW Devon CCG
Emma Gitsham	Clinical Evidence Pharmacist	NEW Devon CCG
Dr Mansoor Hameed	Consultant in Respiratory & General Medicine	SDHC NHS Foundation Trust
Matt Howard	Clinical Evidence Manager	NEW Devon CCG
Hilary Pearce	Clinical Effectiveness Pharmacist	NEW Devon CCG
Miss Tahrina Salam	Consultant Ophthalmologist	SDHC NHS Foundation Trust
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
** Denotes attended meeting by teleconference

1. Welcome and introductions

Apologies

Mr Tawfique Daneshmend	Consultant Gastroenterologist and Hepatologist	Royal Devon & Exeter NHS FT
Miles Earl	Contract Accountant	NEW Devon CCG
Paul Foster	Chief Pharmacist	SDHC NHS FT
Mark Kealy	Consultant in Public Health	Devon County Council
Dr Peter Leman	GP Clinical Commissioner	NEW Devon CCG
Dr Jo Roberts	Clinical Member & Committee Chair	South Devon & Torbay CCG

Notification of Any Other Business

Members were asked if they had any items of AOB to discuss.

Confirmation of voting members and Declarations of Interest

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

The eight voting members present were identified.

Jo Roberts had deputised voting to Samantha Morton.

Peter Leman had deputised voting to Chris Roome

Tracey Foss attended the meeting as deputy for Paul Foster

DRUG/TECHNOLOGY TO BE CONSIDERED	PHARMACEUTICAL COMPANY / MANUFACTURER / SERVICE PROVIDER
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
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
Fluticasone furoate and vilanterol trifenatate (Relvar®, Ellipta®) **combination inhaler for asthma** Alternative treatments: **Fluticasone propionate/salmeterol** (Seretide® Accuhaler®, Seretide® Evohaler®, Sirdupla®) **Beclometasone dipropionate/formoterol** (Fostair®, Fostair® NEXThaler®) **Budesonide/formoterol** (Duoresp® Spiromax®, Symbicort® Turbohaler®)	**GlaxoSmithKline** **Allen & Hanburys, Mylan** **Chiesi Limited** **Teva Pharma, AstraZeneca**
Fluticasone furoate and vilanterol trifenatate (Relvar®, Ellipta®) **combination inhaler for chronic obstructive pulmonary disease** Alternative treatments: **Fluticasone propionate/salmeterol** (Seretide® Accuhaler®) **Beclometasone dipropionate/formoterol** (Fostair®) **Budesonide/formoterol** (Duoresp® Spiromax®, Symbicort® Turbohaler®)	**GlaxoSmithKline** **Allen & Hanburys** **Chiesi Limited** **Teva Pharma, AstraZeneca**
Assessment and removal of benign skin and subcutaneous lesions	As a provider of private treatments for patients with benign skin and subcutaneous lesions

NAME OF ATTENDEE	ROLE	
Jonathan Broad	Lay Member	Currently uses Fluticasone propionate/salmeterol (Seretide® Accuhaler®) and could possibly benefit from additional treatment.
Richard Croker	Head of Medicines Optimisation	Was previously paid for advice to Galan, Martindale, Menarini, Prostrakan, Galderma
Dr Alex Degan	GP/Eastern Locality Board Member	Owner of shares in various pharmaceutical companies via tracker funds. Wife owner of shares in various pharmaceutical companies through tracker funds and holds shares in Astra Zeneca
Matt Howard	Clinical Evidence Manager	In previous post attended a number of CPD events where refreshments etc were sponsored by a variety of pharmaceutical companies.

2. Minutes of the meeting held on 22nd July 2015 and matters/actions arising

The minutes of the meeting held on 10th June 2015 were approved.

Summary of actions		
	Action	**Lead**
15/13	*Recommendation and QEIA for the Assessment and removal of benign skin and subcutaneous lesions to be submitted to the CCGs' Executive Groups for approval.* *Further clarification of the referral pathway is required.* *The removal of benign skin and subcutaneous lesions is due to be discussed at the CPC meeting in September 2015.* This item was included on the agenda. Action complete	
15/17	*Specialist Management of Abdominal Wall Hernias in Adults: 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.* The policy and patient support information have been published. Action complete.	

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.	Rebecca Heayn
15/19	*Contracting teams at NEW Devon CCG and South Devon and Torbay CCG to review the setting in which administration of botulinum toxin 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.	Samantha Morton
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.	Rebecca Heayn
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.	Rebecca Heayn
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.	Samantha Morton
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.	Rebecca Heayn
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.*	Samantha Morton

3. Botulinum Toxin A for the management of Blepharospasm

As part of the work being undertaken on the use of botulinum toxin (BoNT) a review has been carried out with the aim of introducing a consistent commissioning policy for Devon regarding the use of BoNT A for the management of blepharospasm. Matt Howard, Clinical Evidence Manager, NEW Devon CCG presented a paper. Miss Tahrina Salam, Consultant Ophthalmologist, SDHC NHS Foundation Trust took part in the discussion of this item.

Blepharospasm is a dysfunction of the eyelids characterized by chronic intermittent or persistent involuntary eyelid closure. It is a focal dystonia whose prevalence is estimated to be 3.6 to 5 per 100,000 with the vast majority of cases being idiopathic. It usually begins in patients in their 50s or 60s and affects women more than men. Severity can range from repeated frequent blinking to persistent spasmodic closure of the eyelids leading to functional blindness with severe disability.

Local specialists have confirmed that BoNT A is the first line treatment of choice for the management of blepharospasm in Devon. It is an established treatment and if it were not to be commissioned there is currently no effective alternative intervention for blepharospasm.

CCGs are responsible for taking commissioning decisions related to the use of BoNT in ophthalmology. NHS England is responsible for patients treated in neurology. Any subsequent commissioning decision and related policies concern only patients whose blepharospasm is being managed by specialist ophthalmology services.

NICE have not produced any guidelines or recommendations for the diagnosis and management of blepharospasm or focal dystonias. Conclusions of systematic reviews from the Cochrane Collaboration, the European Federation of Neurological Societies and the American Academy of Neurology that botulinum toxin injections may be considered a safe and effective therapy for the management of blepharospasm are based on poorly reported uncontrolled studies and expert opinion. Three relevant RCTs have subsequently been published. The Xeomin® and Dysport® brands of BoNT have been shown to produce statistically significant improvements in symptoms and disabilities compared to placebo. A direct comparison found Xeomin® non-inferior to Botox® and changes from baseline were clinically meaningful for both products. Limited quality of life studies suggest a reduced health related quality of life (HRQoL) in patients with blepharospasm.

A cost-utility analysis with significant limitations suggests an ICER of between £3,750 and £18,606 per QALY gained when treatment is compared with placebo. However, the direct-costs in model assumed vial sharing, which is not currently practiced in Torbay Hospital. Scenario analyses by the Clinical Effectiveness Team resulted in ICERs of up to £76,778.

Further exploratory analyses were conducted by the Clinical Effectiveness team mapping quality of life scores from various studies to EQ5D health utility values. These found that a health state utility gain of less than half the value of the lowest obtained from mapping would be necessary for BoNT to be considered cost effective at a threshold of £30,000 per QALY gained. Annual per patient costs of treatment are estimated to be between £627.46 and £984.01, depending on brand of BoNT used, and whether vial sharing is practiced. Total annual expenditure on the management of blepharospasm with BoNT is crudely estimated to be approximately £90,000 in NEW Devon CCG and £42,500 in South Devon and Torbay CCG.

The committee were asked to make a policy recommendation to the executive groups of NEW Devon CCG and South Devon and Torbay CCG regarding the commissioning policy for the use of BoNT for the management of blepharospasm.

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

- All patients referred to ophthalmology are usually treated. Blepharospasm is a disabling condition and this is not a cosmetic treatment. The committee considered whether access criteria should be included in any positive commissioning policy. The Jankovic Rating Scale (JRS) was thought suitable.
- It was noted that NHS England would be the responsible commissioner if patients were treated in neurology. The specialist view was that blepharospasm should be treated in ophthalmology due to the importance of finding the right balance of muscles to be treated and the need to inject close to the eye. Neurology specialists will not inject close to the eye.

- Initial injections are given and patients are recalled in 2 weeks. Treatment is then given every 12 weeks, surgery is considered if BoNTA is or becomes ineffective. A few patients who have not responded to high dose BoNT A or surgery are treated with BoNT B. BoNT has been in use for many years.
- Patients rarely improve completely but usually stabilise. However, ongoing treatment is required.
- Vial sharing – there are medicolegal considerations and theoretical adverse consequences of vial sharing. However it is practised widely in the NHS and the options were discussed. Samantha Morton will raise the issue of vial sharing with the Medical Director at South Devon Healthcare NHS Trust.

ACTION: Samantha Morton to raise the issue of vial sharing with the Medical Director at South Devon Healthcare NHS Trust.

The committee voted unanimously in favour of the routine commissioning of botulinum toxin A for the management of blepharospasm.

The committee further voted 7-1 in favour of including access criteria based on the JRS within the policy recommendation.

ACTION: Matt Howard to work with the consultants to agree access criteria which capture the functional limitations consistent with the position the CCGs adopt in relation to other conditions.

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

4. Botulinum Toxin A for the management of hemifacial spasm

As part of the work being undertaken on the use of botulinum toxin (BoNT) a review has been carried out with the aim of introducing a consistent commissioning policy for Devon regarding the use of BoNT A for the management of hemifacial spasm. Matt Howard, Clinical Evidence Manager, NEW Devon CCG presented a paper. Miss Tahrina Salam, Consultant Ophthalmologist, SDHC NHS Foundation Trust took part in the discussion of this item.

Hemifacial spasm (HFS) is a condition characterized by involuntary paroxysmal contractions of muscles innervated by the facial nerve; bilateral involvement is rare. HFS is not dangerous but can cause significant cosmetic and functional disability; it is a chronic condition and recovery is rarely spontaneous.

BoNT A has become the established treatment of choice for hemifacial spasm; local specialists have confirmed that botulinum toxin is the first-line treatment of choice for the management of hemifacial spasm in Devon. Patients in Devon are currently treated by either ophthalmology or neurology services, depending on the nature and severity of symptoms. The responsibility for taking commissioning decisions related to the use of BoNT in ophthalmology rests with the CCG, whilst responsibility for neurology use rests with NHS England. Any subsequent commissioning decision and related policies concern only patients whose blepharospasm is being managed by specialist ophthalmology services.

Systematic reviews by the Cochrane Collaboration and the American Academy of Neurology (AAN) examined the safety and efficacy of BoNT in treating HFS. Patient numbers included in Randomised Controlled Trials were very small; the Cochrane authors also discussed open label studies which have shown improvements in between 76% - 100% of people. These studies, considered in a narrative review of open label case studies by Jost and Kohl, represented 2295 patients and indicated a mean duration of improvement of between 2.6 and 4 months. Cochrane concluded that all studies available strongly suggest that BoNT type A is safe and effective for treating HFS. The AAN review authors conceded that evidence supporting BoNT use in HFS is suboptimal, and that no studies have compared BoNT with other major treatment alternatives. However, they concluded that BoNT is possibly effective with minimal side effects for the treatment of HFS and recommended that BoNT injection may be considered as a treatment option for HFS. There are no high quality RCTs examining the efficacy of BoNT A in the treatment of HFS. BoNT

has been used in clinical practice for the treatment of HFS for many years. The large magnitude of beneficial effects in the initial open label studies has likely discouraged efforts to study BoNT in properly controlled clinical trials.

The Clinical Effectiveness team could not locate any published utility value or quality of life outcome changes that could be used to generate utility value changes associated with BoNT treatment of HFS. However, limited data were available that allowed estimation of baseline utilities from SF-36 scores compared to healthy controls. SF-36 scores were mapped to EQ-5D utility values; this produced baseline utilities of 0.73 for patients with hemifacial spasm and 0.83 for healthy controls. A threshold analysis suggests that a very small utility gain of 0.033 would need to be associated with treatment for BoNT to be cost-effective at a threshold of £30,000/QALY. The estimated annual cost of treatment per patient is between £469.56 and £984.01. Total current annual expenditure on the management of hemifacial spasm with botulinum toxin is crudely estimated to be approximately £65,000 in NEW Devon CCG and £10,500 in South Devon and Torbay CCG.

Local specialists have indicated that some patients with HFS may be suitable for microvascular decompression (MVD) of the facial nerve, which offers the prospect of a long term cure. They further suggest that there is no effective alternative intervention for HFS for patients in whom MVD is not suitable. The procedure cost for MVD of the facial nerve is currently £4,965. MVD is provided as part of specialist adult neurosurgery services; NHS England is the responsible commissioner for this procedure. MVD is a highly specialised procedure; ceasing to provide botulinum toxin may produce increased capacity pressures on neurosurgery services at Plymouth Hospitals NHS Trust.

The committee were asked to make a policy recommendation to the executive groups of NEW Devon CCG and South Devon and Torbay CCG regarding the commissioning policy for the use of BoNT for the management of HFS.

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

- The lack of high quality trial evidence.
- There are potentially serious risks associated with MVD including stroke and death, though these are rare. A few patients are currently referred to PHT, which is the only neurosurgery provider in Devon.
- Virtually all patients referred to ophthalmology with HFS receive treatment however a balance in the muscles treated is needed and in some cases only some areas of the face are treated. Side effects may be difficulty in eating and drooling of saliva.
- The disease does not spontaneously remit and may progress. Treatment does not slow progression but it gives patients function and control.

The committee considered whether access criteria should be included in any positive commissioning policy, and how comparability with other commissioning policies could be achieved. Discussion suggested that this may not be as straightforward as access criteria for blepharospasm but that Matt Howard would try to work with the consultants to agree criteria which capture functional limitations consistent with the position the CCG adopts in relation to other conditions.

The committee voted unanimously in favour of the routine commissioning of botulinum toxin A for the management of hemifacial spasm.

The committee further voted 7-1 in favour of including access criteria within the policy recommendation.

ACTION: Matt Howard to work with the consultants to try to agree access criteria which capture the functional limitations consistent with the position the CCGs adopt in relation to other conditions.

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

5. Fluticasone furoate and vilanterol trifenatate (Relvar® Ellipta®) combination inhaler for asthma

An application has been received requesting the inclusion of fluticasone furoate and vilanterol trifenatate combination inhaler into local formularies for the treatment of asthma. Emma Gitsham, Clinical Evidence Pharmacist, NEW Devon CCG presented an evidence review. Dr Mansoor Hameed, Consultant in Respiratory & General Medicine, SDHC NHS FT took part in the discussion.

Relvar® Ellipta® is a combination dry-powder inhaler containing two active ingredients: fluticasone furoate and vilanterol, an inhaled corticosteroid (ICS) and a long-acting beta$_2$-antagonist (LABA). The Ellipta® device is not currently listed in the Devon Joint Formularies. The inhaler has an in-use shelf-life of 6 weeks and is available as two different strengths: fluticasone furoate/vilanterol 100/25 and 200/25 micrograms.

The dose of fluticasone contained within Relvar® is not equipotent with existing fluticasone inhalers. The maximum dose for both strengths is one inhalation once daily. Both strengths are indicated for the regular treatment of asthma in adults and adolescents aged 12 years and older, who are not adequately controlled with an ICS and 'as needed' short acting beta2-agonist, and where use of a combination medicinal product is considered appropriate. The product is not licensed for switching between established ICS/LABA combination inhalers. Relvar® is indicated for patients moving from step 2 to 3 in the British Thoracic Society (BTS) and Scottish Intercollegiate Guidelines Network (SIGN) asthma management pathway. In the absence of marketed fluticasone furoate or vilanterol monotherapy inhalers, patients will require a change to their ICS or LABA when stepped up onto, or down from the combination inhaler.

The committee reviewed the clinical evidence. The effects observed on pulmonary function parameters and symptomatic endpoints with fluticasone furoate/vilanterol both strengths were considered clinically relevant by the European Medicines Agency (EMA) and consistent with other approved fixed dose combinations of ICS/LABA, although compared to monotherapy the differences in lung function measurements were not always significant and differences in symptomatic endpoints were small. The effects observed on severe exacerbations with fluticasone furoate/vilanterol 100/25 micrograms were considered to be clinically relevant by the EMA and in line with other approved ICS/LABA combinations, although the absolute risk reduction was small. The direct comparison of fluticasone furoate/vilanterol 100/25 micrograms, versus fluticasone propionate/salmeterol 250/50 micrograms, failed to detect a significant difference between treatments. Indirect comparisons suggest that efficacy on lung function measures and quality of life may be broadly comparable to a range of existing products, however superiority of inhaled fluticasone furoate/vilanterol compared other ICS/LABA combination inhalers has not been proven. Non-inferiority for exacerbations was not proven. The adverse reactions experienced by subjects taking fluticasone furoate/vilanterol were not dissimilar to other ICS/LABA combinations. It has been noted that the risk of pneumonia was not addressed in the asthma paper. Clinical trials noted that the incidence of pneumonia in patients with asthma was common at the higher dose and numerically higher compared with those receiving fluticasone furoate/vilanterol 100/25 micrograms or placebo; however pneumonia was more frequently, and commonly observed in patients with COPD compared to those with asthma.)

The cost for a 30 day supply of Relvar® used once daily is £27.80 for the 100/25 microgram strength. This is a lower cost compared to other ICS/LABA combination inhalers with dose equivalence, except Sirdupla®. The cost for the 200/25 microgram strength is £38.87, cheaper compared to all other ICS/LABA combination inhalers with dose equivalence. Twelve month usage costs per patient, assuming 100% compliance, are £338 and £473 for the 100/25 microgram and 200/25 microgram strength inhalers respectively. Glaxo Smith Kline has provided local budget impact model data since the paper was sent out to the committee members and specialists. For the combined CCGs, an estimated saving of £131,600 is predicted when using Relvar® for appropriate patients progressing from BTS/SIGN step 2 to 3 compared to ‘usual’ prescribing. This was based on patients using between 6-8 inhalers per year. If compliance improved, and more inhalers were issued, the estimated cost saving would be reduced. The model did not include ICS/LABA combination inhaler switching.

The committee were asked to make a policy recommendation to the executive groups of NEW Devon CCG and South Devon and Torbay CCG regarding the commissioning policy for fluticasone furoate/vilanterol trifenatate combination inhaler for the treatment of asthma.

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

- The possible advantages of this product are that, as a once daily treatment, patient compliance may be increased, although there is no current data to support increased adherence.
- It was also suggested that the treatment may cause less adrenal suppression than the proposed beclomethasone dipropionate equivalent strength.
- Concern was expressed with regard to the product's 6 week in-use shelf life with the potential for use of time expired medication or wastage.
- The lowest strength Relvar® products contain more steroid than is recommended at Step 3. Commencing this dose early in management prior to a trial of lower dose and LABA is not consistent with good practice.
- Patients who are stable on other combination products cannot be switched to Relvar® due to the restrictive licence.
- Relvar® Ellipta® combination inhaler is as effective as other products at equivalent doses but this needs to be weighed against limitations and potential clinical disadvantages to the patient.

The committee voted 7-1 against the routine commissioning of Relvar® Ellipta® combination inhaler for asthma.

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

6. Fluticasone furoate and vilanterol trifenatate (Relvar® Ellipta®) combination inhaler for chronic obstructive pulmonary disease

An application has been received requesting the inclusion of fluticasone furoate and vilanterol trifenatate combination inhaler into local formularies for the treatment of COPD. Emma Gitsham, Clinical Evidence Pharmacist, NEW Devon CCG presented an evidence review. Dr Mansoor Hameed, Consultant in Respiratory & General Medicine, SDHC NHS FT took part in the discussion.

Relvar® Ellipta® is a combination dry-powder inhaler with an in-use shelf-life of 6 weeks, containing two active ingredients: fluticasone furoate and vilanterol, an inhaled corticosteroid (ICS) and a long-acting beta2-agonist (LABA). The combination product is available as two different strengths. The lower strength Relvar® Ellipta® inhaler is indicated for the symptomatic treatment of adults with COPD and an FEV1<70% predicted normal, post-bronchodilator, with an exacerbation history despite regular bronchodilator therapy. The recommended dose in COPD is one inhalation of fluticasone furoate/vilanterol 100/25 micrograms once daily. There is no additional benefit of the 200/25 micrograms dose and there is a potential increased risk of pneumonia and systemic corticosteroid-related adverse reactions.

The committee reviewed the clinical evidence. Only one study compared fluticasone furoate/vilanterol 100/25 micrograms to the licensed strength of fluticasone propionate/salmeterol for COPD, 500/50 micrograms. Fluticasone furoate/vilanterol 100/25 micrograms inhaler has been shown to make improvements in lung function, symptom scores and exacerbation frequencies which are considered clinically relevant by the EMA. Fluticasone furoate/vilanterol 100/25 micrograms has been shown to be broadly comparable, to both fluticasone propionate/salmeterol 500/50 micrograms and budesonide/formoterol 400/12micrograms for changes in lung function and quality of life assessments.

A number of adverse effects are recognised for ICS and LABA treatments used in COPD patients, and those experienced by subjects taking fluticasone furoate/vilanterol were not dissimilar to other ICS and LABA combination treatments. The risk of pneumonia is increased in patients receiving treatment with fluticasone furoate/vilanterol however this is a class effect risk of ICS and was considered similar by the European Medicines Agency to other fixed dose combinations. During

clinical studies, pneumonia and also fractures were more frequently commonly observed in patients with COPD.

Fluticasone furoate/vilanterol 100/25 micrograms inhaler used once daily has a lower acquisition cost and lower 12 month cumulative spend per person in comparison to other ICS/LABA inhalers licensed for use in COPD. The acquisition cost for 30 days treatment is £27.80. If 75% of prescriptions for Seretide Accuhaler® 500/50 micrograms used twice daily are prescribed for COPD, a 100% switch to fluticasone furoate/vilanterol 100/25 micrograms used once daily, could save an estimated £671,800 over a 12 month period. This figure is not representative of total savings as switching between other products is also possible, however this suggests that a considerable cost saving is possible.

Glaxo Smith Kline has provided local budget impact model data since the paper was sent out to the committee members and specialists. Using Relvar® 100/25 micrograms for new incident COPD patients with an exacerbation history, instead of 'usual' ICS/LABA combination inhaler prescribing, a predicted saving of £73,500 for the combined CCGs has been estimated. This does not include Relvar® as part of triple therapy regimes and has not been calculated as part of a switch programme.

The committee were asked to make a policy recommendation to the executive groups of NEW Devon CCG and South Devon and Torbay CCG regarding the commissioning policy for fluticasone furoate/vilanterol combination inhaler for the treatment of COPD.

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

- Fluticasone furoate/vilanterol combination inhaler has been found to be equally as effective as other products for treating COPD.
- The product is a once a day treatment. This is easier for patients and can increase compliance although there are no current data to support increased compliance.
- The Ellipta device is relatively new but other treatment for COPD (LABA/LAMA) are available with this device.
- The product is licensed for switching in COPD patients.
- The increased risk of pneumonia associated with ICS use in COPD patients.
- Cost saving are potentially achievable however the amount of the cost saving is uncertain.

The committee voted 7-1 in favour of the routine commissioning of Relvar® Ellipta® combination inhaler for COPD. The committee member voting against commissioning of Relvar® Ellipta® combination inhaler for COPD noted that it had worked in trials however it was not known how effective it would be in practice for patients who were switched to the product.

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

7. Assessment and removal of benign skin and subcutaneous lesions

A policy for the removal of benign skin lesions was published by predecessor Primary Care Trusts in March 2012 and was adopted by NEW Devon CCG and South Devon and Torbay CCG in May 2013. NEW Devon CCG planned care lead GPs proposed an update to the policy which was discussed and recommended for approval by CPC in April 2015. This policy included circumstances in which removal of benign lesions would be routinely commissioned and provided information on referral of lesions suspicious of malignancy. The Planned Care Lead GPs knew that the new NICE clinical guideline on referral for suspected cancer was due to be published a few months later and it was intended that the policy would be updated at that time. The policy approved by CPC at the April meeting was not issued for two reasons.

The reasons for the non-publication of the policy approved by CPC in April 2015 were:

Firstly, shortly after the CPC meeting in April 2015 Dr Karen Davies, North Devon District Hospital dermatologist and Head of the South West Skin Cancer Network, contacted the Clinical Effectiveness Team. Dr Davies had been included in the consultation process for the policy.

Dr Davies' concern was over one of the referral routes for lesions suspicious of malignancy. This was a new route introduced to try to take some of the pressure off the two week referral system. Consequently, Planned Care Lead GPs, representatives from DRSS and the Clinical Effectiveness Team met with Dr Davies to discuss referral routes for lesions suspicious of malignancy across Devon. They concluded that due to geographical differences or service configurations it was very difficult to produce a single policy on referral routes in Devon for lesions where malignancy could not be confidently excluded.

Secondly, the new NICE clinical guideline for referral for suspected cancer (NG12) included extensive changes and meant that all the referral guidance for lesions suspicious of malignancy would have to be updated.

As a result the Planned Care Lead GPs concluded that all information on referral for suspected malignancy would be removed from the policy. The amended policy contains only the sections relating to benign lesions as approved by CPC in April and is an improvement on the original policy first published in March 2012.

Hilary Pearce Clinical Effectiveness Pharmacist, NEW Devon CCG presented an updated draft policy. Alex Degan, GP, NEW Devon CCG joined the meeting for the discussion of this item.

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

- Members agreed that it was sensible to remove reference to lesions suspicious of malignancy from the policy.
- The policy is not expected to impact on the two week wait referral system.
- A member of the committee reported that patients referred as being of 'diagnostic uncertainty' were being managed via the two week wait referral system. It was suggested that this may have been due to the way in which the referral letter had been written.
- Whether the policy would apply to specialists in secondary care to prevent non-malignant lesions being removed. It was noted that the policy does apply to secondary care and that an audit of what happens in secondary care is being planned.

The committee voted unanimously in favour of accepting the revised policy for the removal of benign skin and subcutaneous lesions.

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

8. Management of non-routinely commissioned drug treatments

This item was deferred to the next CPC meeting as two of the authors of the earlier letter regarding this were not present. Members were requested to submit any comments on the paper included in the meeting papers to Petrina Trueman, Joint Formularies Pharmacist, NEW Devon CCG.

ACTION: Comments on paper to be submitted to Petrina Trueman.

9. Update from NICE Planning, quality and Assurance Group (NPAG)

The committee received a summary of the NPAG meeting which had taken place on Tuesday 21 July 2015.

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

Public Health guidance on the impact on health of cold homes (NG6) and on weight management among adults and children (NG7) had also been considered. As had two pieces of Medical Technology Guidance, one piece of Interventional Procedure Guidance and two pieces of Diagnostic Guidance.

The group had also received a summary of the NICE Technology Appraisals Innovation Scorecard, the quarterly update of the National Audit Horizon Scanning Process and the Forward Planner of NICE guidance expected to be issued between June 2015 and September 2015.

10. Any other business

Shared Care

Dr Melluish had met with Dr Gunatilleke to discuss Shared Care; some new ideas had emerged. These may be of relevance to the Formulary Interface Groups. Dr Melluish asked that Chris Roome and Richard Croker attend a future meeting to explore these.

Date of next meeting

The meeting previously scheduled to take place on Wednesday 21 October had been cancelled. The next meeting will take place on Wednesday 2nd December in the Committee Suite, County Hall Exeter.

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.	Rebecca Heayn
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.	Samantha Morton
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.	Rebecca Heayn
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.	Rebecca Heayn
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	Samantha Morton
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.	Rebecca Heayn
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.*	Samantha Morton

15/25	Issue of vial sharing with regard to BoNT injections to be raised with the Medical Director at South Devon Healthcare NHS Trust	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.	Matt Howard
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.	Rebecca Heayn
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.	Matt Howard
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.	Rebecca Heayn
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.	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.	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.	Rebecca Heayn
15/33	Comments on paper for the management of non-routinely commissioned drug treatments to be forwarded to Petrina Trueman	Petrina Trueman