

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

**Clinical Policy Committee (CPC)  
Minutes**

**Wednesday 20 April 2016, 9.30 am to 12.30  
The Watermark, Ivybridge**

**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
Miles Earl	Contract Accountant	NEW Devon CCG
Dr Andrew Gunatilleke	Consultant in Pain Management & Anaesthesia	Torbay & S. Devon NHS FT
Mark Kealy	Consultant in Public Health	Devon County Council
Andrew Kingsley	Patient Safety and Quality	NEW Devon CCG
Dr Peter Leman*	GP Clinical Commissioner	NEW Devon CCG
Dr Phil Melliush*	GP Clinical Commissioner	South Devon and Torbay CCG
Mac Merrett	Lay Member	
Simon Mynes	Director of Pharmacy	Plymouth Hospitals Trust
Chris Roome	Head of Clinical Effectiveness	NEW Devon CCG
Dr Ben Waterfall*	GP Clinical Commissioner	NEW Devon CCG

**Guests:**

Dr Alex Degan	Planned Care Lead GP	NEW Devon CCG
Matt Howard	Clinical Evidence Manager	NEW Devon CCG
Dr Daniel Flanagan**	Consultant Physician	Plymouth Hospitals Trust
Hilary Pearce	Clinical Effectiveness Pharmacist	NEW Devon CCG
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

\*\* Denotes joined meeting by teleconference

## 1. Welcome and announcements

### Apologies

Richard Croker	Head of Medicines Optimisation	NEW Devon CCG
Dr Tawfique Daneshmend	Consultant Gastroenterologist & Hepatologist	RD&E NHS FT
Barbara Jones	Head of Locality Contracting	NEW Devon CCG
Paul Foster	Clinical Director – Pharmacy and Prescribing	Torbay & S. Devon NHS FT
Samantha Morton	Head of Contracting and Procurement	South Devon & Torbay CCG
Dr Alison Round	GP Clinical Commissioner	NEW Devon CCG
Dr Darunee Whiting	GP Clinical Commissioner	NEW Devon CCG

Dr Alison Round had deputised voting to Chris Roome

Simon Mynes attended the meeting as deputy for Paul Foster

### Confirmation of voting members and Declarations of Interest

The seven voting members present were identified.

Declarations of Interest forms were collected. The Chair reviewed the Declarations of Interest forms. All Declarations of Interest are reported in the minutes.

DRUG/TECHNOLOGY TO BE CONSIDERED	PHARMACEUTICAL COMPANY / MANUFACTURER / SERVICE PROVIDER
<b>Functional impairment as a criterion for access to treatment</b>	Would benefit from private provision of surgery or intermediate care for the following conditions: bunion, carpal tunnel syndrome, cataract, Dupuytren's contracture, ganglion cyst and hernia
<b>Insulin Degludec 100units/ml for use in patients with type 1 diabetes (Tresiba<sup>®</sup>)</b> Alternative treatments: <b>Insulin Glargine (Lantus<sup>®</sup>)</b> <b>Insulin Glargine biosimilar (Abasaglar<sup>®</sup>)</b> <b>Insulin Detemir (Levemir<sup>®</sup>)</b> <b>Insulin pump</b>	<b>Novo Nordisk</b>  <b>Sanofi</b> <b>Eli Lilly</b> <b>Novo Nordisk</b> various manufacturers
<b>Ulipristal acetate 5mg tablets for intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age (Esmya<sup>®</sup>)</b> Alternative treatments: <b>Surgical treatment</b> (myomectomy, uterine artery embolization, transcuteaneous resection of fibroid, endometrial ablation, hysterectomy)	<b>Gedeon Richter (UK) Ltd</b>  As a private provider of surgical treatments for patients with uterine fibroids

NAME OF ATTENDEE	ROLE	
Mick Braddick	GP Clinical Commissioner	<p><i>Although it does not fall within the official categories it was noted that:</i></p> <p>Mick Braddick hoped to have an active retirement and would be disappointed if the NHS could not provide support.</p>
Alex Degan	Planned Care GP Lead	<p><i>Any other family or business interest (including personal or family medical conditions) which could be seen as influencing views of the drug(s)/interventions/treatment under consideration.</i></p> <p>Brother is employed by Eli Lilly as Regional Digital Manager.</p> <p>Has shares in various pharmaceutical companies through tracker funds.</p> <p>Spouse has shares in Astra Zeneca and also has shares in various pharmaceutical companies through tracker funds.</p> <p>GP practice is a member of the federation of practices in Mid Devon called Mid Devon Healthcare – the federation is a potential provider of services in the future.</p>
Daniel Flanagan	Consultant Physician	<p><i>Advisory Board attendance for NovoNordisk, Novartis and MSD within past 3 years.</i></p> <p><i>Lecture fees from NovoNordisk, Sanofi and Lilly within the past 3 years.</i></p> <p><i>Payment for attendance at international conference by NovoNordisk within the past 3 years.</i></p>
Matt Howard	Clinical Evidence Manager	<p><i>Hospitality received where the drug(s) device(s) intervention(s) under consideration where discussed by a representative of a drug/manufacturing company/companies.</i></p> <p>In previous post, attended various CPD events where hospitality/refreshments etc may have been sponsored by various manufacturers.</p>
Simon Mynes	Director of Pharmacy, Plymouth Hospitals NHS Trust	<p><i>In receipt of payment/gift for transport and hospitality to attend national or international meeting or symposia.</i></p> <p>Support from Sanofi to attend EAHP conference in 2011.</p>

## Notification of Any Other Business

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

### **2. Minutes of the meeting held on 24<sup>th</sup> February 2016 and matters/actions arising**

Dr Alison Round had raised a point with regard to the draft minutes. This had been resolved and the minutes of the meeting held on 24<sup>th</sup> February 2016 were approved.

<b>Summary of actions</b>		
	<b>Action</b>	<b>Lead</b>
15/35	<p><i>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.</i></p> <p><i>Publication pending. Item due to be discussed at the South and West Formulary Interface Group meeting on 9<sup>th</sup> March 2016.</i></p> <p>The policy has been published. Action complete.</p>	
15/37	<p><i>Policy revision recommendation and QEIA for assisted conception to be prepared and subsequently progressed to final CCG approval and communication.</i></p> <p><i>Approval of QEIA awaited.</i></p> <p>The policy has been published. Action complete.</p>	
15/38	<p><i>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.</i></p> <p><i>In progress, an update will be provided at the next meeting.</i></p> <p><i>Item to be included on next meeting agenda.</i></p> <p>This item was included on the meeting agenda. Action complete.</p>	
15/39	<p><i>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.</i></p> <p><i>This had been raised at the Eastern locality Board meeting; it was suggested that a list of drugs is maintained.</i></p> <p><i>Paperwork for the management of non-routinely commissioned drug treatments has been provided to primary and secondary care.</i></p> <p>Action complete.</p>	

16/01	<p><i>Clinical Effectiveness Team to contact SW Cancer Network to explore options for next steps for Faecal occult blood testing for patients with clinical features associated with an increased risk of colorectal cancer.</i></p> <p>A meeting had been arranged for the following week. The CCG and the SW Cancer Network will work together to pilot an implementation site.</p> <p>Action complete</p>	
16/02	<p><i>Policy recommendation and QEIA for Tadalafil (Cialis®) 5mg tablets for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH) in adult males to be prepared and subsequently processed to final CCG approval and communication.</i></p> <p>The policy recommendation and QEIA have been submitted to the CCGs' executive groups of both South Devon and Torbay CCG and NEW Devon CCG for approval at their meetings in April and May respectively.</p>	Rebecca Heayn

### 3. Functional impairment as a criterion for access to treatment

Hilary Pearce, Clinical Effectiveness Pharmacist, NEW Devon CCG presented a paper. Dr Alex Degan, Planned Care Lead GP, NEW Devon CCG joined the meeting for the discussion.

With the restructuring of the NHS in 2013, the two CCGs in Devon inherited commissioning policies for surgical procedures from three predecessor Primary Care Trusts (PCT). These policies were for conditions which are common in the general population, may respond to conservative treatment, resolve spontaneously or where the substantial value of surgery is considered to be limited. It was agreed that these commissioning policies would be harmonised condition by condition to provide Devon-wide policies to ensure that access to surgery for patients with the same clinical circumstances is consistent throughout Devon regardless of where the patient lives. During the process of harmonising the commissioning policies it became apparent that the definition of functional impairment as a criterion for access varied between the three PCTs and between policies for individual PCTs. A benchmarking exercise of statements on functional impairment in policies issued by CCGs in England was undertaken to enable the CCGs in Devon to adopt a common position on functional impairment. A total of 165 policies issued by individual CCGs for a range of conditions included functional impairment as a criterion for access to treatment; 74 of these policies provided a definition of functional impairment. Review of the definitions included in the 74 policies found that the effect of a condition on occupation followed by acting as a carer, education and domestic activities were most frequently included in the definitions. The effect of a condition on hobbies was included as a criterion for access to treatment in 14 of the 75 policies but the CCGs who issued these policies did not consider the effect of a condition on domestic activities, education, self-care or acting as a carer to warrant access to treatment. The effect of a condition on recreational physical activity was considered a criterion for access to treatment in only 2 of the 74 policies.

The statement proposed for adoption had been discussed and agreed with GP clinical leads for the Devon Referral Support Service and the GP clinical lead for the Individual Funding Panel.

The committee were asked to recommend the use of two proposed statements. Firstly, the committee were asked to recommend the use of a proposed statement in all policies where functional impairment is a requirement for referral or access to treatment for conditions not affecting sensory organs. Secondly, the committee were asked to recommend the use of a proposed statement for use in policies for procedures involving the eye where the effect of visual impairment on daily life is a requirement for access to treatment.

The committee discussed a number of issues pertinent to the proposed statements:

- It was agreed that use of consistent statements was desirable.
- There was discussion of whether the proposal not to include hobbies and recreation was appropriate or challengeable.

Due to time constraints further discussion on these proposed statements was deferred to a future meeting.

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#### **4. Insulin Degludec 100units/ml (Tresiba®) for use in patients with type 1 diabetes**

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The Clinical Policy Committee first considered insulin degludec in October 2013. It was considered in two settings (a) patients with type 1 diabetes with poor control or recurrent hypoglycaemia and (b) patients with type 2 diabetes needing doses in excess of 100units. Insulin degludec was not routinely commissioned in either setting; whilst it was acknowledged that insulin degludec was an effective insulin, the target patient groups were excluded from clinical trials, insulin degludec was more expensive than other analogues, and it was felt that it did not represent good value for the local health economy. A reapplication has been received from Dr Daniel Flanagan, Consultant Diabetologist at Plymouth Hospitals NHS Trust for 100 unit/ml product for use only in patients with type 1 diabetes with poor control or recurrent hypoglycaemia, who would otherwise be considered for continuous subcutaneous insulin infusion (CSII) pump therapy. Matt Howard, Clinical Effectiveness Manager, NEW Devon CCG presented an evidence review. Dr Daniel Flanagan joined the meeting via teleconference. Petrina Trueman, Clinical Evidence Pharmacist, NEW Devon CCG took part in the discussion of this item having worked on the evidence review for this discussion and previously in 2013.

NICE NG17 recommends insulin degludec as an alternative to insulin glargine or insulin detemir where these treatments have failed. The full guideline notes insulin degludec is currently more expensive than both insulin detemir and insulin glargine and that there is no evidence of improved effectiveness. It also states that insulin degludec could be an option in patients who are currently receiving this treatment with satisfactory results or in patients for whom other insulins are not showing any effectiveness.

A literature search has been carried out. Three RCTs were found evaluating insulin degludec once daily in type 1 diabetes. Two of these comparing insulin degludec to insulin glargine were assessed in the previous application. The third trial, which was not previously available, compared insulin degludec to insulin detemir and was conducted in the same manner as the original trials involving insulin glargine. The results suggest that insulin degludec is non-inferior to insulin detemir in terms of Hba1c lowering, and demonstrated lower rates of nocturnal hypoglycaemia than insulin detemir, where nocturnal is defined as midnight to 6am. This would equate to approximately 1 or 2 fewer nocturnal hypoglycaemic events per patient per year. Overall rates of hypoglycaemic events were not significantly different between insulin degludec and insulin detemir. Insulin degludec is associated with a statistically significantly greater increase in body weight than insulin detemir. A meta-analysis provides a mixed picture for comparative risk of hypoglycaemic episodes between insulin degludec and insulin glargine depending on how hypoglycaemia and nocturnal are defined, and over what timescale data are assessed. The majority of analyses found no difference. However it is noted that patients with a history of recurrent hypoglycaemia were excluded from all clinical trials. No RCT data are available to provide evidence supporting efficacy in this patient group. No data are available evaluating the safety and efficacy of insulin degludec versus insulin pump therapy.

A cost-utility analysis comparing insulin degludec and Lantus brand glargine found insulin degludec to be cost effective at a willingness to pay threshold of £20,000, however efficacy data were extracted from trials which excluded patients with a history of recurrent hypoglycaemia, which may limit the applicability of results to the patient group under consideration. Additionally sensitivity analyses and the availability of the lower cost biosimilar, Abasaglar, suggest ICERs which may exceed this threshold. Insulin degludec is less costly than insulin pump therapy owing to the costs of the pump, the consumables and healthcare professional input required to maintain an insulin pump. However, if the use of insulin degludec extended beyond the group covered within the application, it

could represent a significant cost impact compared to other ultra-long-acting analogue insulins. As there are no efficacy data in patients who would otherwise receive a pump no estimate of cost effectiveness can be made.

Local specialist opinion indicates that the numbers of patients with persistently poor glycaemic control or recurrent hypoglycaemia, who might be considered for insulin degludec as an alternative to insulin pump therapy, are small. According to local specialist opinion the estimated number of patients who might be appropriate to be initiated on to insulin degludec and who might otherwise be initiated onto CSII therapy across both CCGs varies. The upper estimate is approximately 60 patients per year.

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

- It was noted that insulin degludec is already in limited use in most local trusts and that it may be useful as a treatment for a small group of patients with recurrent hypoglycaemia who had not been successful on other insulins. However there is a need to ensure that use is limited to those patients who benefit and in whom a pump would be the only alternative.
- Some concern was expressed that insulin degludec is being used despite the previous CPC decision not to recommend its use.
- The suggested benefits of insulin degludec in preference to an insulin pump are better quality of life for patients and that it is cheaper than an insulin pump.
- There are cheaper first line alternatives to which insulin degludec has been found to be non-inferior. Specialists agreed that insulin degludec was not a first line treatment.
- Daniel Flanagan commented that, although not included in the meeting papers, specialists had previously indicated that they supported use of insulin degludec. However the evidence review team confirmed that all specific comments elicited from specialists contacted during the evidence review had been included in the paper.
- Use of insulin degludec under the trust managed individual patients' process. Under this process treatment is funded by the acute trust in order to ascertain the clinical benefit and adverse effects of the treatment for an individual patient for a minimum of six months. Approval is required by the trust Drug and Therapeutics Committee (DTC) or equivalent on an individual basis. It is expected that individual patients would be prescribed insulin degludec by their specialist for at least six months. If insulin degludec was not successful alternatives such as insulin pump would be considered.

The committee voted 5 to 2 against recommending the routine commissioning of insulin degludec 100units/ml (Tresiba<sup>®</sup>) for use in patients with type 1 diabetes.

The committee voted 5 to 2 in favour of recommending that insulin degludec 100units/ml (Tresiba<sup>®</sup>) for use in patients with type 1 diabetes was suitable for access through trust managed individual patient routes.

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

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## **5. Ulipristal acetate 5mg tablets (Esmya<sup>®</sup>) for intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age**

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A formulary application has been received for Ulipristal acetate (UPA) 5mg tablets (Esmya<sup>®</sup>) for the intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. The applicant would like to use Esmya<sup>®</sup> as a second line therapy when currently recommended pharmacological therapy is unsuccessful, contraindicated or inappropriate. It would be used primarily as an alternative to invasive interventions such as hysterectomy, myomectomy, transcutaneous resection of fibroids, endometrial ablation or uterine artery embolism. The applicant indicated that he may use Esmya<sup>®</sup> first line in some cases. The applicant also stated that he intended to recommend Esmya<sup>®</sup> for 3 months, followed by a 3 month break, continuing in this intermittent way, he proposed that following initiation in secondary care, ongoing prescribing could be done by GPs. In addition the applicant suggested that the use of Esmya<sup>®</sup> could reduce the need for invasive procedures, thereby reducing the need for hospitalisation and associated risks and costs. Matt Howard, Clinical Evidence Manager, NEW Devon CCG presented an evidence review.

Esmya<sup>®</sup> contains 5 mg UPA, a selective progesterone receptor. It is taken once daily for 12 weeks. It was initially licenced for pre-operative use, to control bleeding and reduce fibroid size prior to invasive procedures, the licence was extended in 2015 to include intermittent treatment.

The NICE clinical guideline for heavy menstrual bleeding recommends a number of pharmacological interventions as first line options, followed by invasive procedures if medicines are unsuccessful or contraindicated. Esmya<sup>®</sup> is not discussed in the clinical guideline and there is no NICE Technology Appraisal. The All Wales Medicines Strategy Group (AWMSG) and Scottish Medicines Consortium (SMC) have accepted Esmya<sup>®</sup> as suitable for use.

Relevant controlled efficacy studies of Esmya<sup>®</sup> are limited to 13 weeks duration in a pre-operative setting. At 13 weeks the PEARL I RCT demonstrated that Esmya<sup>®</sup> was superior to placebo for controlling bleeding and reducing total fibroid volume in pre-operative women with uterine fibroids with menorrhagia and associated anaemia. The PEARL II RCT demonstrated non-inferiority of oral Esmya<sup>®</sup> once daily compared to intramuscular leuprolide acetate 3.75 once monthly for controlling bleeding associated with fibroids at week 13 in women planning surgery. Moderate to severe hot flashes were significantly less common with oral UPA 5mg once daily than with leuprolide acetate. All women enrolled in PEARL I and PEARL II were planning to undergo surgery. The open-label PEARL III and PEARL III extension studies investigated 10mg daily UPA and as such do not provide data which directly support the efficacy of Esmya<sup>®</sup>. The PEARL IV trial compared Esmya<sup>®</sup> with 10mg UPA once daily for four intermittent treatment courses of 84 days, followed by a treatment free period. It provides additional longer-term safety data for UPA 5mg taken orally once daily for up to 4 courses of up to 3 months' duration. The trial found that approximately 62% of women were in amenorrhoea at the end of both treatment courses 1 and 2; and that almost 49% of women reported amenorrhoea at the end of all four treatment courses. Esmya<sup>®</sup> was found to control bleeding at the end of both treatment courses 1 and 2 in 81% of women, and in 67% of women at the end of all four treatment courses. Pain and symptom severity scores improved during treatment courses and worsened during off-treatment periods. Whilst the proportion of women reported in PEARL IV to be in amenorrhoea after a single treatment course is broadly in line with that seen at 13 weeks in the placebo controlled PEARL I and active-controlled PEARL II studies, the lack of a relevant comparator after this time point limits longer term efficacy conclusions that may be drawn. Esmya has been positioned as an alternative to surgery however there is a lack of comparative data between Esmya and invasive procedures which limits conclusions that may be drawn in this regard.

No published cost-utility analysis is available, however the SMC and the AWMSG report on company provided analyses and additional information was sought from the health economist who prepared the submission. These report that Esmya<sup>®</sup> is cost effective at a threshold ICER of £20,000 per QALY by being cheaper but less effective than invasive procedures. A number of assumptions were made in the model and there is considerable uncertainty regarding these. Esmya<sup>®</sup> was no longer considered to be cost effective when: (a) utility values obtained from studies of surgical intervention are used, rather than those obtained from studies with drug therapy, when b) the time horizon was increased from three to four years, and when (c) the cost of hysterectomy was reduced by 20%. Currently the local cost of hysterectomy is approximately 35% lower than that quoted in the base case analysis. The cost effectiveness of Esmya<sup>®</sup> is uncertain, given the sensitivities of the model. Commissioning Esmya<sup>®</sup> is likely to reduce costs in the first year, and increase costs thereafter. Any savings from reduced surgery will only be possible if this activity can be extracted from secondary care contracts

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

- UPA 5mg tablets (Esmya<sup>®</sup>) appear to be cost effective compared to invasive procedures over some time frames but not others. Perimenopause is difficult to define/diagnose accurately. If Esmya<sup>®</sup> is approved based on an anticipated short duration of use there is a risk that prolonged treatment might ensue with considerable financial cost
- Relevant controlled evidence for this indication is lacking.
- Surgical procedures can have adverse effects which may require a further intervention at a later stage (such as incontinence risk following hysterectomy).
- Overall the longer term financial impact is likely to be higher costs to the CCGs.



The committee voted unanimously against recommending the routine commissioning of UPA 5mg tablets (Esmya®) for intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age.

The committee voted six to one against recommending that UPA 5mg tablets (Esmya®) for intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age was suitable for access through trust managed individual patient routes.

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

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## **6. Discussions of policy access criteria for Botulinum Toxin A for the management of blepharospasm and for the management of hemifacial spasm**

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The committee received a verbal update. During the discussions on Botulinum Toxin A for the management of blepharospasm and for the management of hemifacial spasm at the CPC meeting in December 2015 it had been agreed that further engagement with clinicians should take place to formally agree access criteria for treatment for these indications. A meeting has been arranged for early June with one consultant to progress this work.

It was reported that current practice is thought to be in line with the proposed policy.

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## **7. Commissioning policies for biological therapies for rheumatoid arthritis**

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Rebecca Heayn, Clinical Governance Manager, NEW Devon CCG presented a paper for the committee's information.

The committee were advised that mandatory recommendations in NICE TA375 (Adalimumab, etanercept, infliximab, certolizumab pegol, golimumab, tocilizumab and abatacept for rheumatoid arthritis not previously treated with DMARDs or after conventional DMARDs only have failed) published on 26 January 2016 have superseded three commissioning policies previously published by the Clinical Policy Committee.

NEW Devon CCG Executive Committee and South Devon and Torbay CCG Commissioning and Finance Committee have been formally notified and the superseded policies removed from the website. Local rheumatology specialists have been advised accordingly.

NICE TA375 was issued 2 years after the intended publication date. These policies provided cost saving treatment options when NICE technology appraisal guidance was delayed or not planned to enable use of less expensive and more convenient treatment options for patients locally.

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## **8. Annual Report 2015-16**

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The committee were asked to receive the third annual report of the Clinical Policy Committee. The report provided a comprehensive account of the work of the committee in 2015 to 2016 and the governance and operating arrangements underpinning the meetings.

Over the past year six meetings have been held. Some meeting rearrangement occurred as the scheduled dates coincided with junior doctor strike action.

In the year the Clinical Policy Committee has considered seventeen evidence assessments in respect of drugs and treatments in 2015-16 resulting in commissioning recommendations to the CCGs. Engagement has taken place with local clinical specialists as part of the assessment process, and they are invited to attend and contribute to discussions. This has increased with the widened remit and workload, and the complexity of the items for discussion.

In addition to the voting members, the committee is supported by advisory members. This includes two lay members, who ensure that the public interest of the local population is represented in discussion and decision making.

The clinical policy engagement and consultation panel has been established during the year to support the Clinical Policy Committee and the Clinical Commissioning Groups by providing a separate opportunity to reflect on the policy recommendations and consider the public interest issues. They meet approximately two weeks post Clinical Policy Committee to determine the need for any further engagement for formal consultation to be carried out prior to a final decision being taken by the Clinical Commissioning Groups. This process is lay-member led, supported by the Clinical Policy Committee lay members and the Clinical Commissioning Group Governing Body lay members for patients and public.

An output of this process is a recommendation for post-decision support communication to accompany publication of the policy. This follows a clear and consistent format that is useful for patients, the public and clinicians. The process ensures that Patient Advice/Experience and the communication teams of the Clinical Commissioning Groups are aware of intended policy publications and supporting information to enable them to be prepared and best able to respond to any patient or public queries. Four such publications have been produced. There were to support the hernia, haemorrhoid, cataract and benign skin lesion policies.

All policy recommendations have a Quality and Equality Impact Assessment undertaken as an integral step in the process following the recommendation of the committee. They are submitted to the Clinical Commissioning Groups along with the final policy recommendation for approval.

The secretariat has been mindful of the need to be cost conscious with meeting organisation and meetings have been held in facilities which are strategic partners of the NHS. Following a review last year, the regular meeting location has been County Hall, Exeter.

There has been on-going development and reflective practice throughout the year, including:

- Further committee development sessions, focussed on how the financial context frames committee decision making.
- A review of communications in light of the development of policy proposals that affect referral and activity management. The resulting Planned Care Control Centre communications and engagement plan aims to ensure a comprehensive and consistent approach. The Clinical Policy Committee Communication Framework has been refreshed in line with this.

The committee discussed issues pertinent to the annual report:

- It was noted that the Clinical Policy Engagement and Consultation Panel had not identified any additional public consultation required with regard to the policy recommendation of the Clinical Policy Committee.
- A minor amendment to the Terms of Reference was agreed to correct an inconsistency.
- Committee vice chair – the group agreed that the appointment of a permanent vice chair was not required and that group members would step into the role as necessary.

**ACTION: Report to be submitted to the appropriate bodies of the Clinical Commissioning Groups to be received and ratified.**

**ACTION: Once ratified the annual report will be published and made publically available via the CCG website.**

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## **9. Update from NICE Planning, Quality and Assurance Group (NPAG)**

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NICE produce a significant volume of guidelines and guidance. The majority of which is considered by NPAG. Technology appraisals are added to the local formularies within 90 days of publication. However other types of guidance and guidelines required more in depth consideration. It is noted that over time membership and attendance at NPAG meetings has changed and declined. It is therefore necessary for the CCGs to consider how to ensure appropriate consideration of all NICE guidance and guidelines. The NPAG annual report notes the changes that have taken place. The Clinical Effectiveness Team proposes discussions within the CCGs to enable discussion and agreement of changes required to the membership of NPAG and to ensure regular attendance of appropriate group members for both CCGs.

The committee received the minutes and a summary of the NPAG meeting which had taken place on Tuesday 1<sup>st</sup> March 2016.

NPAG had previously discussed CardioQ-ODM to guide IV fluid management in patients undergoing surgery (MTG03) however specialists from all the local acute trusts had expressed concern with regard to this technology. As a result the clinical effectiveness team has written to NICE (copied to NHS England) with regard to implementation of the guidance locally and to enquire whether NICE intend to reconsider this guidance.

NPAG had received thirteen technology appraisals and one piece of highly specialist technology guidance. These will be added to the local formularies within 90 days of publication. In addition two NICE public health guidelines, one clinical guideline and four pieces of interventional procedures guidance had been considered.

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## **10. Update from Clinical Policy Engagement and Consultation Panel**

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The committee received the minutes of the Clinical Policy Engagement and Consultation Panel meeting which took place on Wednesday 23 March 2016.

It was reported that:

- There was an aspiration to have further lay members on the panel to strengthen the membership.
- Rebecca Heayn, Clinical Effectiveness Governance Manager will prepare the panel's annual report.

The Committee discussed issues pertinent to the Clinical Policy Engagement and Consultation Panel. It was noted that the panel provides a robust, open and transparent process for lay engagement.

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## **11. Any other business**

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### Specialist engagement

A lay member raised the issue of lack of engagement by specialists with the Clinical Policy Committee.

The Clinical Effectiveness Team reported that specialists are invited to participate throughout the process of preparation of evidence reviews and to attend CPC meetings. The meetings are planned well in advance and specialists are given sufficient notice of meeting dates.

It was noted that one specialist had been due to participate in the discussion of Ulipristal acetate 5mg tablets (Esmya<sup>®</sup>) via teleconference. However the specialist had been on call and was unavailable at the time of the discussion.

<b>Summary of actions</b>		
	<b>Action</b>	<b>Lead</b>
16/02	<p><i>Policy recommendation and QEIA for Tadalafil (Cialis®) 5mg tablets for the treatment of the signs and symptoms of benign prostatic hyperplasia (BPH) in adult males to be prepared and subsequently processed to final CCG approval and communication</i></p> <p>The policy recommendation and QEIA have been submitted to the CCGs' executive groups of both South Devon and Torbay CCG and NEW Devon CCG for approval at their meetings in April and May respectively.</p>	Rebecca Heayn
16/03	Insulin Degludec 100units/ml (Tresiba®) for use in patients with type 1 diabetes. Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.	Rebecca Heayn
16/04	Ulipristal acetate 5mg tablets (Esmya®) for intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.	Rebecca Heayn
16/05	Clinical Policy Committee annual report to be submitted to the appropriate bodies of the Clinical Commissioning Groups to be received and ratified.	Rebecca Heayn
16/06	Ratified annual report to be published and made publically available via the CCG website.	Rebecca Heayn