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

Clinical Policy Committee (CPC)
Minutes

Wednesday 18th March 2015, 10.00-12.00

Henlake Suite, The Watermark, Ivybridge, PL21 0SZ

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
Dr Tawfique Daneshmend	Consultant Gastroenterologist & Hepatologist	RD&E NHS FT
Dr Andrew Gunatilleke	Consultant in Pain Management & Anaesthesia	SDHC NHS Foundation Trust
Mark Kealy	Public Health Representative	Devon County Council
Andrew Kingsley	Patient Safety and Quality	NEW Devon CCG
Dr Peter Leman*	GP Clinical Commissioner	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 Alison Round*	GP Clinical Commissioner	NEW Devon CCG
Dr Ben Waterfall*	GP Clinical Commissioner	

Guests:

Matt Howard	Clinical Evidence Manager	NEW Devon CCG
Professor Ann Millward**	Consultant Diabetologist	Plymouth Hospitals NHS Trust
Hilary Pearce	Clinical Effectiveness Pharmacist	NEW Devon CCG
Bethan Rogers	Clinical Evidence Pharmacist	NEW Devon CCG
Petrina Trueman	Joint Formularies Pharmacist	NEW Devon CCG
Dr Rachel Tyler	GP/Clinical Lead Western Locality/DRSS GP Referral Facilitator	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 that participant joined the meeting via teleconference

1. Welcome and introductions

Attendees were welcomed to the meeting.

The need for longer meetings had been identified and discussed at the meeting which took place in February 2015. As a result members had been contacted regarding their preferences for the timing and venue of future CPC meetings. The responses had been considered. The majority of members had indicated that Exeter was suitable for them and that in order for afternoon commitments to be fulfilled there was a preference for meetings to start earlier. Therefore it had been decided that all future meetings would take place in the Committee Suite at County Hall, Exeter from 9.30 am to 12.30 pm.

Apologies

Darunee Whiting	GP Clinical Commissioner	NEW Devon CCG
Richard Croker	Head of Medicines Optimisation	NEW Devon CCG
Paul Foster	Secondary Care Chief Pharmacist	SDHC NHS FT

No secondary care pharmacist was able to attend the meeting.

Notification of Any Other Business

No items of AOB were identified.

Confirmation of voting members and Declarations of interest

The eight voting members present were identified.

Dr Darunee Whiting had deputised voting to Chris Roome.

Declaration of interest forms were collected. The chair informed the committee of declarations of interest received.

DRUG/TECHNOLOGY TO BE CONSIDERED	PHARMACEUTICAL COMPANY / MANUFACTURER / SERVICE PROVIDER
Referral for the Surgical Management of Heavy Menstrual Bleeding	**–**
Lixisenatide (Lyxumia®) Alternative treatments: **Exenatide** (Byetta®, Bydureon®) **Liraglutide** (Victoza®)	**Sanofi** **AstraZeneca** **Novo Nordisk**
Avanafil (Spedra®) Alternative treatments: **Sildenafil** (Viagra®, Nipatra® (branded generic) and Generic) **Tadalafil** (Cialis®) **Vardenafil** (Levitra®)	**Menarini** **Pfizer, AMCo** and **various manufacturers** (including: Zentiva, Hameln pharmaceuticals, Dr Reddy's, Accord, Actavis, Sandoz, Consilient Health) **Lilly** **Bayer**

NAME OF ATTENDEE	ROLE	
Andrew Gunatilleke	Consultant in Pain Management & Anaesthesia	*Received gifts, benefits or sponsorship of any kind, whether refused or accepted worth over £25 or several small gifts worth a total of over £100 from the above or closely related pharmaceutical manufacturing company/companies.* Pfizer paid for Dr Gunatilleke to go to the World Pain Congress in 2010.
Matt Howard	Clinical Evidence Pharmacist	In previous post had attended a number of CPD events where refreshments, hospitality etc were sponsored by a variety of pharmaceutical companies.
Dr Peter Leman	GP Clinical Commissioner	Attendance at training seminar sponsored by Grünethal Pharmaceuticals.
Professor Ann Millward	Consultant Diabetologist	Worked as paid adviser for Get Goal Study (Sanofi) Has taken part in clinical trials for Novo Nordisk, Sanofi Aventis, Merck (Oxford DTU), GSK, Astra Zeneca (Lilly) Takeda (Quintile), Pfizer (ICCH) In receipt of one lecture fee for talk for Sanofi Aventis.

2. Minutes of the meeting held on 4th February 2015 and matters/actions arising

The minutes of the meeting held on Wednesday 4th February 2015 were approved.

Summary of actions		
	Action	**Lead**
14/24	*Recommendation and summary of clinical discussion on Aspirin for the prophylaxis of Venous Thromboembolism following Elective Hip Replacement and Elective Knee Replacement to be taken to the CCGs' executive groups.* *This will be taken to the March meetings of the CCG Executive Groups.* The final recommendation has been submitted to the March meetings of the NEW Devon CCG and South Devon and Torbay CCG Executive Groups. Action complete	
15/01	*NICE CG164 familial breast cancer: Recommendation and summary of clinical discussion to be taken to the CCGs' executive groups.* It is planned that the final recommendations will be submitted to NEW Devon CCG and South Devon and Torbay CCG Executive Group meetings in April 2015.	Rebecca Heayn
15/02	Surgery for hallux valgus (bunions) to be published. Action complete	

15/03	Confirmation of funding of fitting of Jaydess® to be sought from Devon County Council. It was reported that all Local Authorities have the same system. Action complete	
15/04	Commissioning policy for the Jaydess® levonorgestrel 13.5 mg intrauterine systems to be published. The policy has been drafted and will be published once the formulary guidance had been agreed by the Formulary Interface Groups.	Rebecca Heayn
15/05	*Fertility policy: Assisted conception - recommendation and summary of discussion to be taken to CCGs' executive groups.* The final recommendation has been submitted to the March meetings of the NEW Devon CCG and South Devon and Torbay CCG Executive Groups. Action complete	
15/06	Fertility policy: Cryopreservation – recommendation and summary of discussion to be taken to CCGs' executive groups. The final recommendation has been submitted to the March meetings of the NEW Devon CCG and South Devon and Torbay CCG Executive Groups. Action complete	
15/07	Future meetings: timing and venue options to be circulated to the committee in order that members can state their preferences. Action complete	

Lipid modification: cardiovascular risk assessment and the modification of blood lipids for the primary and secondary prevention of cardiovascular disease.

This item had been due to be discussed at the meeting which took place on 4th February 2015 but had been deferred as it had not been considered an urgent priority and the meeting had overrun.

The committee received a verbal update with regard to Lipid modification.
NICE had produced a Clinical Guideline for Lipid modification: cardiovascular risk assessment and the modification of blood lipids for the primary and secondary prevention of cardiovascular disease. An earlier guideline recommended offering treatment to patients with a cardiovascular risk of 20% or more. The new guideline recommends that treatment for the primary prevention of cardiovascular disease is offered to people with a 10% or greater 10-year risk of developing cardiovascular disease.

The committee considered issues pertinent to this Clinical Guideline:

- NICE expects patients to be picked up via routine health checks. The committee noted that take up of health checks was low.
- The Clinical Guideline will be noted in the local formularies. GPs are aware of the guideline and the change in the threshold for treatment from 20% risk to 10% risk of cardiovascular disease.
- Information is in the public domain and decisions should be taken by GPs and their patients.
- NICE provide a useful patient decision aid which will be linked to from the formularies.

The majority of the committee felt that it was not necessary for this guideline to be discussed in detail by the Clinical Policy Committee at the current time. One member was in favour of further detailed discussion.

3. Referral for Surgical Management of Heavy Menstrual Bleeding (HMB)

As part of the work being undertaken to align commissioning policies across Devon consideration has been given to referral for the surgical management of HMB. Bethan Rogers, Clinical Evidence Pharmacist, NEW Devon CCG presented a paper. Dr Rachel Tyler, GP/Clinical Lead Western Locality, NEW Devon CCG and DRSS GP Referral Facilitator attended the meeting for the discussion and to answer clinical questions.

The proposed Devon-wide Commissioning Policy for the Surgical Management of HMB is based on the NICE Clinical Guideline (CG) 44 for HMB (2007) and is supported by the current Primary Care Referral; Guidance for Menorrhagia developed by Dr Tyler in use in the Plymouth area.

The proposed Devon-wide Commissioning Policy had been agreed by the 4 planned care GP leads in Devon and sent to all specialists across NEW Devon and South Devon and Torbay CCGs' for consultation. Comments from a Consultant Obstetrician and Gynaecologist at Plymouth Hospitals NHS Trust which indicated disagreement with the proposal that women would not be free to decline medical treatment prior to surgery were tabled at the meeting. A recent national audit has highlighted significant variation across Devon in the proportion of women who have received previous treatment in primary care for heavy menstrual bleeding; ranging from 10.6% in Plymouth Hospitals NHS Trust to 49.2% in South Devon Healthcare NHS Foundation Trust.

The committee were asked to make a recommendation to both CCGs on whether the proposed commissioning policy should be accepted for use across Devon. The policy states that referral for the surgical management of HMB will only be commissioned in women <u>without</u> significant fibroids or structural or histological abnormalities if they have failed appropriate pharmacological treatments. This is at variance to NICE, which recommends that (1) endometrial ablation may be offered as an initial treatment option for heavy menstrual bleeding and that (2) hysterectomy may be offered if other treatment options are declined.

NICE considered a range of hormonal and non-hormonal pharmacological treatment options and found that a number of them produced a clinically relevant reduction in blood loss. The levonorgestrel releasing intrauterine system was the most cost-effective treatment option compared to both surgical interventions and combined oral contraceptives. There is no evidence assessing the effectiveness of multiple pharmaceutical treatment options, however an RCT found that some women benefited from further pharmaceutical treatment and as a result did not require a hysterectomy. Although surgical treatment options were found to be both clinically and cost effective, they are more expensive for the CCGs to commission and therefore less affordable compared to pharmacological management.

The committee discussed issues pertinent to the proposed Devon wide policy for Referral for the Surgical Management of Heavy Menstrual bleeding:

- A Primary Care Clinical Referral Guideline for Menorrhagia will be available on the formulary and referral website providing detailed clinical advice to GPs on aspects such as:
  - Red flag features prioritise referral for consideration of other pathology
  - Pre-referral investigations which should be conducted by GPs.
  - Pharmaceutical management options.

Dr Rachel Tyler left the meeting and discussion continued.

- The significant variation in referral rates across Devon was noted. It was suggested that in the areas where referral rates are currently low, due to other options being explored prior to surgical management, there may be an increase over the next few years if other options were not effective.
- It is not uncommon for access policies to include requirements to have tried conservative or medical management before surgical treatment.
- The committee discussed the risks associated with surgical interventions and the magnitude of the decision to undergo surgery. It was felt that trial of more conservative pharmaceutical treatment options prior to referral was often appropriate.
- GPs discussed the interpretation of appropriate pharmacotherapy and understood that treatments which are contraindicated or medically inappropriate would not be required prior to referral.
- The committee noted that women would not be required to trial and fail all pharmaceutical treatment options prior to referral; although the primary care referral guideline encourages consideration of further pharmacological management unless drug choices were contraindicated or inappropriate.

The committee voted unanimously in favour of recommending that the Devon wide policy for referral for the Surgical Management of Heavy Menstrual Bleeding Commissioning Policy is adopted by the CCGs.

ACTION: The final recommendation to be submitted to the NEW Devon CCG and South Devon and Torbay CCG Executive Groups for approval.

4. Review of the commissioning decision on Lixisenatide for the treatment of type 2 diabetes

The CPC had considered an application for Lixisenatide as a treatment for adults with type II diabetes on 31st July 2013. At that time the Clinical Policy Committee voted against commissioning Lixisenatide for the treatment of type 2 diabetes. A review of the commissioning decision is now taking place. Petrina Trueman, Joint Formularies Pharmacist, NEW Devon CCG presented a paper. Professor Ann Millward, Consultant Diabetologist PH NHS Trust joined the discussion of this item via teleconference.

Lixisenatide (Lyxumia®▼) is a new glucagon-like peptide-1 (GLP-1) agonist indicated for the treatment of adults with type 2 diabetes mellitus in combination with oral hypoglycaemic agents and/or basal insulin when these, together with diet and exercise, fail to provide adequate glycaemic control. The drug is given once daily via a 60-dose prefilled pen, by subcutaneous injection, up to one hour before any meal of the day.

Since the decision not to commission lixisenatide was made, immediate concerns over the pancreatic safety of GLP-1 mimetic drugs as a class have been addressed in the EMA report published later in 2013 and results from the European Commission's SAFEGUARD project, published in April 2014. The clinical effectiveness of lixisenatide has been demonstrated, although there are limitations in comparative data with other GLP-1 mimetics. Lixisenatide has been approved for use in Wales and Scotland. The draft NICE clinical guideline on type II diabetes drugs recommends that, where a clear need for a particular GLP-1 mimetic is not demonstrated, the drug of lowest acquisition cost should be used, which is lixisenatide. NEW Devon CCG finds itself in a far more challenging financial position than was the case eighteen months ago; the potential for cost reductions that could be realised through the use of lixisenatide as an alternative once daily option to liraglutide in particular, could help release funds for other services. Lixisenatide costs 15% less per patient than exenatide 10mcg and 26% less than liraglutide 1.2mg. As an alternative to twice daily exenatide, there are further cost reductions to be achieved through the need for fewer needles.

The Clinical Policy Committee was asked to review the original commissioning decision on Lixisenatide for the treatment of type 2 diabetes in light of changes to factors that had been taken into account at the time of the original decision.

The committee discussed issues pertinent to this commissioning decision:

- Experience in use of Lixisenatide - lixisenatide has been used in Cornwall and good results have been achieved. Clinicians in Plymouth now have experience in the use of Lixisenatide and drug trial experience of the treatment.
- Trial Evidence - At the time lixisenatide was originally considered evidence from head to head trials was limited and there were concerns with regard to pancreatic risk of this class of drug. The EMA have addressed the safety concerns.
- Benefits of Lixisenatide – the efficacy of Lixisenatide compared to current treatments and the administration of the drugs are broadly similar. Lixisenatide is less expensive than the alternatives.
- Patient experience – Patients currently established and doing well on liraglutide or exenatide would not be switched. The benefits to patients of lixisenatide may be fewer side effects and ease of use. Specialists noted that there are differences between what is done in a clinical trial setting and in normal clinical practice. In clinical practice patients are seen to benefit from lixisenatide. Some members of the committee queried the benefit to the patient in terms of weight loss, reduction in HbA1c and long term cost effectiveness.
- NICE - NICE recommend that the treatment with the lowest acquisition costs should be used unless there is a clear reason why this is not appropriate.
- Stopping criteria – the committee agreed that stopping criteria, as described in the NICE guidelines, should be applied to all drugs in this class.

The committee voted 7 to 1 in favour of commissioning lixisenatide for the treatment of type 2 diabetes. The committee member voting against commissioning lixisenatide for this indication cited concerns about efficacy, the likelihood of treatment being discontinued if found to be ineffective and the potential for this to become a more expensive option in the long term.

ACTION: Commissioning policy for Lixisenatide for the treatment of type 2 diabetes to be published.

5. Avanafil for Erectile Dysfunction (ED)

An application has been received from Dr Kell, Consultant Physician, Torbay Sexual Medicine Service, requesting the inclusion of avanafil as an option for treating erectile dysfunction. The committee were asked to consider the evidence. Bethan Rogers, Clinical Effectiveness Pharmacist, NEW Devon CCG, presented an evidence assessment.

Avanafil (Spedra®) is a new, fourth in class, phosphodiesterase type 5 (PDE-5) inhibitor, licensed for the treatment of erectile dysfunction (ED) in adult men. It should be taken as required approximately 15 to 30 minutes before sexual activity, at a starting dose of 100mg.

There is currently no NICE clinical guideline for the diagnosis and management of ED and no published All Wales Medicines Strategy Group or Scottish Medicines Consortium drug appraisal for avanafil. Current European Association of Urology (EAU) guidelines discuss the use of PDE-5 inhibitors for the treatment of ED but do not consider avanafil. The applicant has proposed that avanafil should be considered for commissioning as per its licensed indication in patients who have previously failed treatment with generic sildenafil. Both Devon wide formularies list generic sildenafil as the first-line PDE-5 inhibitor of choice, with tadalafil and vardenafil considered as second line alternatives.

The committee reviewed the evidence for avanafil. Three phase III placebo controlled randomised control trials support the licensing of avanafil. Efficacy in men with mild to severe ED was considered in three discrete patient groups (general population, diabetic patients and patients with a history of bilateral prostatectomy). The Clinical Effectiveness Team considered a post-hoc subgroup

analysis of patients in the general population with a history of oral ED treatment use. However this analysis provides no evidence to specially support the use of avanafil in patients who have previously failed treatment with sildenafil. This is because the proportion of patients who reported 'failure' was particularly small at 7.5% and a specific analysis of this patient group was not reported. Patients with dose-limiting adverse effects or those who had experienced consistent failure with more than two PDE-5 inhibitors were also excluded from trials. Currently there is no robust evidence to support a preference for the use of any one of the other PDE-5 inhibitors over another. Pivotal RCTs consider the efficacy of avanafil compared to placebo and therefore provide no comparative data to support its efficacy and tolerability compared two other PDE-5 inhibitors. Both meta-analyses identified were limited by patient population and outcomes reported.

There is no published cost-effective analysis conducted for avanafil from the perspective of the NHS. Generic sildenafil is significantly cheaper, at all strengths, than avanafil, tadalafil and vardenafil and therefore should therefore be considered the first-line PDE-5 inhibitor of choice. The Clinical Effectiveness Team estimate an annual cost saving across both CCGs of up to £56k if avanafil is accepted as the second-line PDE-5 inhibitor of choice following treatment failure with sildenafil. With an additional £69k estimated per annum if 50% of patients currently prescribed tadalafil 10 mg or 20 mg or vardenafil 20 mg were actively switched to avanafil. However, tadalafil and vardenafil are due to lose their patents in 2017 and 2018 respectively, therefore any savings may be short lived. The clinical effectiveness team has estimate an ongoing additional cost of £470k per annum in 2017 if the cost of tadalafil falls to the current price of generic sildenafil.

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

- Cost savings may be short term. It was suggested that treatments can be removed from the formulary and that new patients would not be started on treatments that were less cost effective. It was noted that there is a lag between the formulary and GP prescribing. There will be costs to GPs associated with the complex discussions needed with patients.
- Patients may not be willing to switch from a treatment which works for them.
- The formulary provides a restricted list of drugs. This is helpful for safety.

The committee voted 5 to 3 against commissioning Avanafil for Erectile Dysfunction

ACTION: Commissioning policy for Avanafil for Erectile Dysfunction to be published.

6. Assessment and removal of benign skin and subcutaneous lesions

The Clinical Commissioning Groups are concerned that a large number of benign skin and subcutaneous lesions are being removed in secondary care. The committee discussed a number of issues pertinent to the assessment and removal of benign skin and subcutaneous lesions:

- It is intended that a policy for the assessment and removal of benign skin and subcutaneous lesions will be brought to the Clinical Policy Committee meeting in April 2015. There are a number of stakeholders including dermatologists and plastic surgeons and a mix of practice in primary care.
- Although GPs may remove benign skin lesions in primary care under services commissioned by NHS England the CCG cannot contractually alter this arrangement through policy. The CCGs wish to reduce the number of such lesions being removed in secondary care.
- There has been a year on year increase in referrals. Skin lesions have a number of potential diagnoses; accurate diagnosis can be difficult in primary care. GP referrals will be a key lever to reducing the removal of benign skin and subcutaneous lesions. Possible melanomas create difficulties. Clinicians do not want to take the clinical risk for a missed diagnosis. Fast track referrals are not filtered by DRSS.
- Clinicians provided examples of unexpected cancer diagnoses.
- In cancer services inappropriate referrals impact on diagnostic services. There has been no increase in funding and waiting times are at risk.

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

The committee received a summary of the NPAG meeting which had taken place on Tuesday 20th January 2015. In particular issues were noted with regard to NICE TA325: Nalmefene for reducing alcohol consumption in people with alcohol dependence and NICE IPG496: Radiofrequency ablation for Barrett's oesophagus with low-grade dysplasia or no dysplasia and NICE IPG497: Endoscopic radiofrequency ablation for squamous dysplasia or no dysplasia of oesophagus.

8. Proposed changes to the process of clinical policy formation via the Clinical Policy Committee

The committee received the proposed changes to the process for clinical policy formation via the Clinical Policy Committee (CPC).

These changes are in response to the challenges faced by organisations to commission sustainable healthcare within the financial resources available. They are intended to meet the needs of both CCGs with minimal disruption to existing decision making processes.

The effect of the proposed revision is that in future all output from the CPC will be policy recommendations rather than the current mix of decisions and recommendations. This will allow for a Quality and Equality Impact Assessment to be undertaken on the recommended policy. It is intended that these will be completed routinely and help the final decision making process. The changes will also allow for public consultation to be undertaken where appropriate prior to a final decision being taken by the CCGs. A separate Public Consultation Framework is currently being developed.

It is proposed that described changes be included in the CPC Terms of Reference and ratified by the Clinical Commissioning Groups to be operational from April 2015.

9. Any other business

There was no other business to report.

Summary of actions		
	Action	**Lead**
15/01	*NICE CG164 familial breast cancer: Recommendation and summary of clinical discussion to be taken to the CCGs' executive groups.* It is planned that the final recommendations will be submitted to NEW Devon CCG and South Devon and Torbay CCG Executive Group meetings in April 2015.	Rebecca Heayn
15/04	Commissioning policy for the Jaydess® levonorgestrel 13.5 mg intrauterine systems to be published. The policy has been drafted and will be published once the formulary guidance had been agreed by the Formulary Interface Groups	Rebecca Heayn
15/08	Final recommendation for referral for the surgical management of heavy menstrual bleeding to be submitted to the NEW Devon CCG and South Devon and Torbay CCG Executive Groups for approval.	Rebecca Heayn
15/09	Commissioning policy for Lixisenatide for the treatment of type 2 diabetes to be published.	Rebecca Heayn
15/10	Commissioning policy for Avanafil for Erectile Dysfunction to be published.	Rebecca Heayn