NHS
Devon
Clinical Commissioning Group

Clinical Policy Engagement & Consultation Panel

MINUTES

Thursday 4 June 2020, 14.00-15.30

Via teleconference

Present:

Charlotte Burrows*	Governing Body Lay Member for patient & public involvement
Rebecca Heayn	Clinical Effectiveness Governance Manager
Carol McCormack-Hole*	Lay Member from the Patient Engagement Forum
Mac Merrett*	Lay Public Member, Clinical Policy Committee
Chris Roome	Head of Clinical Effectiveness
Jon Taylor	Strategy Manager
Mark Taylor*	Lay Public Member, Clinical Policy Committee

* Denotes voting members

1. Welcome and Introductions

The group were welcomed and thanked for joining the meeting via teleconference in order to conduct discussions whilst maintaining social distancing during the COVID-19 pandemic.

Apologies were noted from Nicola Bonas, Deputy Head of Communications.

2. Declaration of Interests

Chris Roome advised that he had declared an interest at the Clinical Policy Committee meeting and had absented himself from the discussions relating to Sativex for multiple sclerosis. This was a professional interest; he co-authored a paper on the cost effectiveness of Sativex on which the National Institute for Health and Care Excellence (NICE) had based their 2014 recommendations.

The panel noted this and agreed that this did not preclude Chris from the panel meeting discussions of this item; he was not part of the decision making process that led to the recommendation at the Clinical Policy Committee meeting, and his knowledge of the topic was considered to be helpful to the panel in enhancing their understanding and in addressing any questions arising.

3. Minutes from the meeting 10 December 2019

The panel considered the minutes from the meeting held on 10 December 2019 and agreed them to be an accurate record.

The action log was updated as follows:

Action no.	Description and update
19/07	Follow up on the pledge made in the NHS Long Term Plan that all pregnant women with type 1 diabetes will be offered continuous glucose monitoring by 2020/21 to query how this will be enacted. **Chris Roome advised that recent events and the shift to focus on responding to the COVID-19 pandemic had overtaken delivery of this action, which was originally intended to be delivered from April 2020. When NHS England publishes further information on how this commitment will be taken forward, this will be picked up and reviewed by the Clinical Effectiveness team.**

4. Discussion and recommendation on the Clinical Policy Committee decisions from 11 March 2020

Sativex® for the treatment of spasticity in multiple sclerosis

An overview of the Clinical Policy Committee recommendation and the background to this treatment was noted by the panel. The CCG has an existing policy position which has been in place since 2010; this states that Sativex is not routinely commissioned in Devon. This decision was reached on the basis that, although evidence supported the efficacy of Sativex, it was not found to be cost effective. This policy position has been reconsidered following the publication of NICE guideline NG144 on cannabis-based medicinal products in November 2019. NICE has changed their position on Sativex as the result of a new cost effectiveness model.

The Clinical Policy Committee has subsequently recommended the use of Sativex in Devon for the treatment of moderate to severe spasticity in adults with multiple sclerosis who meet specified criteria.

The panel considered the public interest themes in relation to this policy:

1. <u>Is the reason for introducing the policy plausible? and 2. Does the policy output address this intent?</u>

   It was acknowledged that the current CCG policy position has been reconsidered in light of NICE guideline NG144 on cannabis-based medicinal products, and a new CCG policy has been proposed as a result.

3. <u>Have the effects of the policy on individual patients and carers been considered?</u>

   It was considered that the policy recommendation is positive for patients. Sativex is a non-invasive treatment sprayed into the mouth which can be administered by the patient themselves, giving them greater control over their treatment. If patients show a sufficient improvement in their spasticity related symptoms following an initial trial of Sativex and continue on treatment, this may reduce the need for them to progress to more invasive treatments.

   From their experience with private use of Sativex, local specialists consider it a beneficial treatment and are keen for its use in Devon. They suggest that there may be quality of life improvements for those who respond to treatment with Sativex,

such as an increase in the time patients can avoid needing a wheelchair, reductions in spasticity, bedsores and fatigue.

4. Have the wider consequences on society been considered?

   It was felt that there were no wider consequences of the proposed policy beyond the individuals involved.

5. Has the opportunity cost been considered?

   It was noted that NICE concluded Sativex is a cost effective use of resources where patients continue treatment if they achieve a 20% reduction in spasticity related symptoms following a four-week trial. The manufacturer has maintained their responder scheme which provides a four-week trial of Sativex at no cost to the NHS.

   NICE suggests that savings may be made in social care by a reduction in the need for home care visits, although the costs will fall in the health sector. Locally the cost impact is estimated to be in the region of £180,000 and it was considered that the use of Sativex would seem highly suitable for funding from the Better Care Fund, which spans both NHS and local government and seeks to join-up health and care services. Given the potential cost impact of implementing this proposed policy, it was queried whether the Better Care Fund was a realistic prospect. It was discussed that, given the potential cost impact resulting from a decision to implement the NICE recommendations, the CCG executive team had already been advised of the considerations and implications of review of this policy area. The Director of Finance had been made aware of the potential resource impact and had supported this.

   Local specialists have suggested that, over time, spasticity is anticipated to be less of a problem. This is as a result of the management of multiple sclerosis having changed over the last 10-15 years; patients are now receiving treatment earlier than previously.

6. Is there knowledge of public concern in relation to a) the disease and b) the specific intervention?

   The panel were not aware of any specific public concern in respect of spasticity symptoms in patients with multiple sclerosis. However it was acknowledged that the NICE guideline on cannabis based medicinal products was a high profile area and had attracted media attention. This had largely been focused on the use of cannabis based treatments for severe treatment-resistant epilepsy; recommendations on the treatment of spasticity were not themselves considered to be a prominent issue.

7. What information on the treatment and condition is available to patients via nhs.uk (formerly NHS Choices)?

   nhs.uk gives information on the treatment of specific multiple sclerosis symptoms. It states that muscle spasms and stiffness (spasticity) can be improved with physiotherapy. If symptoms are more severe, patients may be prescribed a medicine to relax their muscles, usually either baclofen or gabapentin, although there are alternative medicines such as tizanidine, diazepam, clonazepam and dantrolene. It states that if these medicines are not effective, patients may be offered a four-week trial of Sativex, which is a cannabis-based medicine sprayed into the mouth.

   nhs.uk also includes more general information on medical cannabis. This includes information on whether medical cannabis is safe, the side effects and under what circumstances it may be prescribed.

Considering all these factors together the panel recommended that no further engagement or formal consultation was required at this point.

Pitolisant hydrochloride for the treatment of narcolepsy with or without cataplexy in adults

An overview of the Clinical Policy Committee recommendation and the background to this condition was noted by the panel. Narcolepsy is a rare sleep disorder. Up to 75% of people with narcolepsy are also affected by cataplexy, which is a sudden muscular weakness triggered by emotional stimuli. Commissioning responsibilities in this area are split, with NHS England responsible for children and CCGs for adults.

It was advised that the split commissioning responsibilities had influenced the existing CCG policy for sodium oxybate for the treatment of narcolepsy with cataplexy which has been in place since 2017. NHS England agreed to fund sodium oxybate for the treatment of narcolepsy with cataplexy in children in specific circumstances. Most children treated are likely to require lifelong treatment and the responsibility for funding this treatment passes to CCGs when the patient reaches 19 years old. The CCG therefore took the decision to accept the use of sodium oxybate to enable continuation of care for patients successfully treated in line with NHS England criteria, and in the interests of equity, in adults who meet the same criteria.

Pitolisant is another treatment licensed for the treatment of narcolepsy with or without cataplexy in adults. It had been considered by the Clinical Policy Committee following an application from a consultant neurologist.

The panel considered the public interest themes in relation to this revised policy:

1. Is the reason for introducing the policy plausible? and 2. Does the policy output address this intent?

   It was noted that an application had been received for the use of pitolisant to be supported in Devon for the treatment of adults with narcolepsy with or without cataplexy. After consideration, the Clinical Policy Committee has recommended the routine commissioning of pitolisant in Devon for the treatment of narcolepsy with cataplexy in adults who would otherwise be eligible for treatment with sodium oxybate, in line with the existing CCG policy. Pitolisant is not recommended for commissioning for the treatment of patients with narcolepsy without cataplexy.

3. Have the effects of the policy on individual patients and carers been considered?

   It was acknowledged that pitolisant represents another drug treatment option, the side effects of which are similar to other stimulant medications. Stimulants and anti-depressant medicines are the first line treatment options for narcolepsy and cataplexy. Pitolisant is recommended for use when patients might otherwise be eligible for sodium oxybate, i.e. where attempts to control symptoms have failed despite a trial of first and second line medications.

   It may be easier and more manageable for patients to take pitolisant than sodium oxybate. Pitolisant is taken as tablets in a single dose in the morning. In contrast, sodium oxybate is take as a liquid at night in two doses, the first when going to bed and the second 2.5 to 4 hours later. Patients may therefore need to use an alarm clock to ensure that the medicine is taken at the appropriate time.

4. Have the wider consequences on society been considered?

   It was felt that there were no wider consequences of the proposed policy beyond the individuals involved.

5. Has the opportunity cost been considered?

   It was noted that pitolisant is not recommended in place of other medications routinely used for the treatment of narcolepsy; it is significantly more costly and

there is no evidence to suggest that patients respond better to pitolisant that to standard medications.

However it offers an alternative treatment for patients who would otherwise be eligible for treatment with sodium oxybate, which is more expensive. The Clinical Policy Committee had concluded that pitolisant offers value for money for the NHS if it successfully manages a patient's symptoms without the need to escalate to more costly treatment with sodium oxybate.

6. Is there knowledge of public concern in relation to a) the disease and b) the specific intervention?

   The panel were not aware of any specific public concern in respect of narcolepsy with or without cataplexy. This is a rare condition which affects a very small number of people.

7. What information on the treatment and condition is available to patients via nhs.uk (formerly NHS Choices)?

   nhs.uk gives information on the treatment of narcolepsy. It notes that there is no specific cure, but symptoms can be managed to minimise their impact on daily life. Details are given of good sleeping habits, talking to others and sources of advice, and medicines that can be used to treat the symptoms of narcolepsy.

   It is stated that a patient may be prescribed a stimulant, such as modafinil, dexamphetamine, methylphenidate or pitolisant. These medicines stimulate the central nervous system, which can help keep someone awake during the day. These medicines are usually taken as tablets every morning.

   Sodium oxybate, which is not funded by the NHS in many areas, can improve sudden loss of muscle control and help someone sleep at night. This can also reduce their daytime sleepiness. It is a liquid medicine taken at night in 2 doses.

   nhs.uk also states that antidepressants are sometimes used to treat symptoms like sudden loss of muscle control, hallucinations and sleep paralysis. These include selective serotonin reuptake inhibitors (SSRIs) such as femoxetine, fluoxetine and citalopram; serotonin noradrenaline reuptake inhibitors (SNRIs) such as venlafaxine; and tricyclic antidepressants (TCAs) such as imipramine and clomipramine.

Considering all these factors together the panel recommended that no further engagement or formal consultation was required at this point.

Invicorp® for erectile dysfunction

An overview of the Clinical Policy Committee recommendation and the background to this treatment was noted by the panel.

The use of Invicorp for erectile dysfunction had been considered by the Clinical Policy Committee following an application from a local consultant urologist. Currently the first line treatment option for patients with erectile dysfunction is phosphodiesterase type 5 (PED-5) inhibitors. If patients do not respond to these, and decline or do not respond to vacuum pumps, they are offered alprostadil. Alprostadil is available in three forms - topical, intraurethral and intracavernosal (injection into the base of the penis). However topical and intraurethral formulations are less effective.

Invicorp is another intracavernosal treatment for erectile dysfunction. Its use is proposed as an alternative treatment option to alprostadil for patients who have failed to response to PED-5 inhibitors.

The panel considered the public interest themes in relation to this policy:

1. Is the reason for introducing the policy plausible? and 2. Does the policy output address this intent?

   It was noted that an application had been received for the use of Invicorp to be supported in Devon for the treatment of erectile dysfunction. After consideration, the Clinical Policy Committee has recommended the routine commissioning of Invicorp in Devon for the treatment of erectile dysfunction when a patient has failed to respond to eight doses at the maximum tolerated dose with sexual stimulation of two different PED-5 inhibitors, or is unable to take PDE-5 inhibitors due to a contraindication, and meets the NHS Drug Tariff Selected List Scheme criteria.

3. Have the effects of the policy on individual patients and carers been considered?

   It was discussed that Invicorp offers an alternative treatment option for patients with erectile dysfunction requiring injection treatment, which may be less painful for some patients than alprostadil. Invicorp is also available in one strength, whereas alprostadil requires titration and may require more outpatient appointments. If treatment is successful this has benefits for patients, and may avoid consideration for penile prosthesis, which is an invasive surgical procedure.

4. Have the wider consequences on society been considered?

   It was felt that there were no wider consequences of the proposed policy beyond the individuals involved.

5. Has the opportunity cost been considered?

   It was noted that Invicorp offers an alternative treatment option for patients which, on average, is a little cheaper than alprostadil. Successful treatment may avoid patients being considered for a penile prosthesis, which is an expensive and invasive surgical procedure, although it was acknowledged this is commissioned by NHS England rather than CCGs.

   Invicorp is available in one strength and does not require titration. It was discussed whether there was potential for expansion of the patient group as this offers an additional treatment, but the local specialists present at the Clinical Policy Committee felt this was unlikely. The Clinical Policy Committee had concluded that Invicorp offers good value to the local health economy.

6. Is there knowledge of public concern in relation to a) the disease and b) the specific intervention?

   The panel were not aware of any specific public concern in respect of erectile dysfunction, although it was acknowledged that this is a potentially sensitive topic.

7. What information on the treatment and condition is available to patients via nhs.uk (formerly NHS Choices)?

   nhs.uk states that erectile dysfunction is very common, particularly in men over 40. Treatment for erection problems depends on the cause and can include medicines to lower blood pressure and cholesterol, hormone replacement and changes to medicine where erectile dysfunction is a side effect of prescribed medication.

   Sildenafil (Viagra) is often used to treat erectile dysfunction and is available from chemists. There are other similar medicines called tadalafil, vardenafil and avanafil that work in a similar way.

   nhs.uk advises that the Sexual Advice Association has factsheets on medicines and other treatments, including injections, implants and creams. These give further information on injection treatment. It is stated that alprostadil has been used as an injection for the treatment of erection problems since 1994. It relaxes the penile

muscles and blood vessels. Alprostadil injections work in more than 80% of men who do not respond to tablets. Possible side effects include occasional pain, a burning sensation, or a small nodule in the shaft of the penis which disappears if you change the injection site.

Invicorp is another type of injection therapy which may work well for men who have found little success with other treatments and some may find it less uncomfortable to use than alprostadil injections.

Considering all these factors together the panel recommended that no further engagement or formal consultation was required at this point.

Minimally invasive treatments for low back pain with and without sciatica

An overview of the background to this condition was noted by the panel. The CCG had adopted a policy for injections for non-specific low back pain without sciatica in March 2019 as a result of the recommendations in the Evidence Based Interventions (EBI) guidance to CCGs.

In parallel there has been a commissioner-provider workstream assessing spinal services. The need for a suite of policies was identified from this work to give some structure and provide clarity as to what treatments are routinely commissioned in Devon for low back pain with and without sciatica.

As a result, three policy proposals were considered and recommended by the Clinical Policy Committee; an update to the existing policy for injections for non-specific low back pain without sciatica to clarify the inclusion and exclusion criteria, a policy for radiofrequency denervation for patients with chronic or non-specific low back pain, and a policy for spinal injections for sciatica.

The panel considered the public interest themes in relation to these policies:

1. <u>Is the reason for introducing the policies plausible? and 2. Does the policy output address this intent?</u>

   It was acknowledged that the proposed policies had resulted from commissioner-provider assessment of the CCG's spinal pathway. The policies comprise clarifications to an existing policy and two new policies for which there is not currently an established position. The policies aim to clarify good existing practice and set clear expectations.

3. <u>Have the effects of the policies on individual patients and carers been considered?</u>

   There was discussion of how these interventions may impact on a person's quality of life, particularly the likely success of treatment. It was explained that a test injection would usually be undertaken. If the patient experiences immediate relief, they are likely to be a good candidate for denervation. It was clarified that all interventions are undertaken in a hospital setting.

   It was queried whether there is likely to be a reduced cohort of patients as a result of these polices, i.e. whether a service will be withdrawn for some patients. It was discussed that although there was not anticipated to be an overall change in numbers, it may be harder for repeat injections to be undertaken. A question was asked as to whether clinicians would be comfortable explaining the policies to patients. It was noted that they aim to ensure a commonality of approach and were considered to be clinically credible; local specialists had been involved in their development.

It was acknowledged however that there is tension with the demand on spinal surgery. An approach drawing on NICE guideline NG59 on low back pain and sciatica and the National Back Pain Pathway was therefore considered most appropriate for these policies, with clinicians responsible for managing this for patients. It was noted that these treatments are very individually specific and as such, it was felt it would be difficult to meaningfully conduct any engagement in this area without resulting in confusion.

4. Have the wider consequences on society been considered?

   It was felt that there were no wider consequences of the proposed policy beyond the individuals involved.

5. Has the opportunity cost been considered?

   The policies aim to ensure appropriate interventions are provided consistently across Devon; overall there is not anticipated to be a change in activity.

   It was advised that subsequent to the Clinical Policy Committee meeting, sentences relating to providers being required to seek CCG approval for equipment purchase had been removed from the proposed radiofrequency denervation policy. On reflection it had been felt that this was not appropriate within the CCG policy as it relates to equipment purchase which was routine provider business.

6. Is there knowledge of public concern in relation to a) the disease and b) the specific intervention?

   The panel were not aware of any specific public concern in respect of back pain and sciatica, although it was noted to be a common condition. The policies were not felt to be controversial and it was noted they draw on NICE guideline NG59 on low back pain and sciatica, the National Back Pain Pathway and the Getting It Right First Time (GIRFT) spinal services report.

7. What information on the treatment and condition is available to patients via nhs.uk (formerly NHS Choices)?

   nhs.uk gives information on back pain and its treatment. It is stated that it is often not possible to identify the cause of back pain; this is called non-specific back pain. Back pain will usually improve within a few weeks or months and there are several things that people can try themselves to help reduce their pain. These include back exercises and stretches, painkillers, hot and cold packs, relaxing and staying positive. However there are some specialist treatments that may be recommended if simple measures are not likely to be effective on their own. These include exercise classes, manual therapy, psychological support and surgery and procedures.

   It is stated that surgery for back pain is usually only recommended if there is a specific medical reason for the pain, such as sciatica or a slipped disc, and other treatments have not helped.

   Radiofrequency denervation may sometimes be used if a person has had back pain for a long time, the pain is moderate or severe, and the pain is thought to originate from the joints in the spine. The procedure involves inserted needles into the nerves that supply the affected joints. Radio waves are sent through the needles to heat the nerves, which stops them sending pain signals. It is stated that, as with all procedures, it carries the risk of complications, including bleeding, bruising, infection and accidental nerve damage. These would be discussed with the specialist prior to agreeing to treatment.

   nhs.uk also notes that a number of other treatments are not recommended by NICE because of a lack of evidence. These include belts, corsets and foot orthotics,

traction, acupuncture, therapeutic ultrasound, transcutaneous and percutaneous electrical nerve stimulation, interferential therapy, and painkilling spinal injections (although these can help if you have sciatica).

Considering all these factors together the panel recommended that no further engagement or formal consultation was required at this point.

5. Annual Report 2019-2020

The panel received an Annual Report setting out its activity, governance and operational arrangements in 2019-20.

It was highlighted that there had been some membership changes in the past year. Charlotte Burrows and Carol McCormack-Hole were welcomed as new members of the panel in July 2019, replacing Chris Peach and Jennie Willmott who stepped down from their Governing Body roles when the CCGs merged to become NHS Devon CCG in April 2019. Jenny McNeill had also now left the panel following her retirement from the CCG, but the panel continued to be supported by Jon Taylor who had previously shared this role with Jenny.

Four meetings were held last year, considering and making recommendations to the CCGs' executive group on a total of 17 clinical policy recommendations.

On discussion of these recommendations, the panel had been satisfied that the public interest issues had been fully considered and that further engagement or formal public consultation activity would not yield additional insights. However they made some recommendations in relation to specific policy proposals to support the communication and implementation of these across Devon. These were all taken forward as described below:

Breast reduction surgery

Following review with regard to NHS England Evidence Based Interventions Guidance for CCGs, the panel noted that it was proposed to maintain the existing commissioning position that breast reduction surgery is not routinely commissioned in Devon.

Although it was considered that this was a long-standing position, there was discussion that some patients may be unhappy that the CCG has not adopted the NHS England criteria for breast reduction, under which they may have qualified for surgery. It was recommended that information should be produced to accompany and support publication of the commissioning policy, for the benefit of patients, clinicians in discussion with patients seeking treatment, and CCG colleagues responding to queries. This would explain how and why decisions are made and what this means for patients with breast hyperplasia (enlargement).

Surgery for carpal tunnel syndrome

The panel acknowledged that referral should not be delayed for patients with symptoms indicating a risk of damage to nerves. There was discussion of how feedback from specialists that patients are sometimes referred at a late stage when surgery may be less effective is best communicated to GPs to reinforce appropriate referral messages.

It was considered that this would be best clarified in the clinical referral guidance for GPs which is published on the Devon Formulary and Referral. It should also be reiterated in policy communications that a single corticosteroid injection should be administered, rather than repeated injections, and that referrers should avoid any delay in referring patients with risk of nerve damage.

Continuous glucose monitoring

The panel noted that type 1 diabetes is a well-recognised condition and there was patient interest in technologies which could support them with their glucose monitoring. The CCG had received a significant number of queries in relation to the FreeStyle Libre device and also enquiries regarding the availability of continuous glucose monitors. However, there is commonly confusion about the difference between FreeStyle Libre (frequently referred to as flash glucose monitoring) and continuous glucose monitors.

Given the confusion between the different types of technology, it was considered important to try to clarify this when the policy for continuous glucose monitoring was published on the CCG website, alongside the existing policy for FreeStyle Libre.

It was recommended that it would be helpful to produce an explanatory leaflet about technology available for patients encountering different types of problems with the management of their diabetes and the routes of access to these.

The current Terms of Reference were included in the annual report. It was noted that these are reviewed annually to ensure they remain up-to-date. However any necessary revisions to these are usually proactively identified and suggested. No changes have been identified as being required as this time.

The annual report will be submitted to the CCG as usual for acceptance and assurance of the function fulfilled by the panel in supporting the CCG's clinical policy processes.

Action: Annual report to be reported to the CCG for information and assurance

6. Any Other Business

It was queried whether there were any plans to broaden the scope of the Clinical Policy Committee to include consideration of digital innovations and apps. It was advised that the clinical effectiveness team had been involved in discussions on this topic, however it had been concluded that the Clinical Policy Committee was not necessarily the best or most appropriate route for this.

7. Next meeting date

The next meeting is due to be held on Thursday 23 July 2020 from 2.00pm.

It was discussed that the meeting had been held acceptably via teleconference, particularly as a hard copy of the papers had been send to the lay members beforehand and these are clear and easy to follow. However members of the panel felt that they would benefit from being about to see each other during their discussions.

It was noted that NHS staff are currently working from home for the foreseeable future, and although the aim is to return to face-to-face meetings, this can only occur when it is safe to do so. In the meantime, Rebecca and Chris will explore options to enhance future virtual meetings through the use of video functionality to enable those able to join in this way to do so. It was advised that the NHS does not support the use of Zoom; however NHS staff all have access to Microsoft Teams so this will be explored.

ACTION LOG

Action no.	Meeting date	Action description	Lead(s)
20/01	04/06/2020	Annual report to be reported to the CCG for information and assurance.	Rebecca Heayn