NHS
Devon
Clinical Commissioning Group

Clinical Policy Engagement & Consultation Panel

MINUTES

Thursday 17 June 2021, 11.00-12.30

Via Microsoft Teams

Present:

Nicola Bonas	Associate Director of Communications and Engagement
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
Mark Taylor*	Lay Public Member, Clinical Policy Committee

* Denotes voting members

1. Welcome and Introductions

The group were welcomed.

Apologies were noted from Jon Taylor, Strategy Manager.

2. Declaration of Interests

No updates to the register or specific interests pertinent to the items for discussion on the meeting agenda were declared.

3. Minutes from the meeting 22 April 2021

The panel considered the minutes from the meeting held on 22 April 2021 and agreed them to be an accurate record.

The action log was updated as follows:

Action no.	Description and update
21/01	To support implementation of the updated policy for FreeStyle Libre, explore opportunities to communicate with Learning Disabilities groups to raise awareness of the availability of the technology for this cohort of patients. **Nicola Bonas and Chris Roome had met to discuss this and initial Clinical Policy Patient Support Information for learning disabilities groups had been drafted. Subsequent communications discussions have suggested that something more accessible may be needed; this is being prepared with Living Options Devon. As the CCG will not be able to directly identify the affected cohort, it is intended they will be identified and communicated with directly via their practice.**

4. Discussion and recommendation on the Clinical Policy Committee decisions from 19 May 2021

Removal of kidney stones

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

Development of a policy for the removal of kidney stones had been prompted by the second wave of the evidence-based interventions (EBI) programme guidance to CCGs published by the Academy of Medical Royal Colleges in November 2020.

Kidney stones are a common urological condition. Small kidney stones may pass spontaneously and be managed without intervention. However where this is not appropriate, removal is possible using shockwave lithotripsy or surgically using ureteroscopy or percutaneous nephrolithotomy.

The EBI recommendations outline when shockwave lithotripsy, ureteroscopy and percutaneous nephrolithotomy should be considered in adults. The guidelines intend to promote the use of shockwave lithotripsy over the two surgical interventions, where clinically appropriate, as it is less invasive and associated with fewer major adverse effects.

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 the development of a CCG policy for the removal of kidney stones had been prompted by the Academy of Medical Royal Colleges evidence-based interventions (EBI) guidance to CCGs, published in November 2020. This includes recommendations on shockwave lithotripsy, ureteroscopy and percutaneous nephrolithotomy for kidney stones.

   The Clinical Policy Committee had subsequently recommended a policy which acknowledges the EBI recommendations and is in line with the NICE clinical guideline for renal and ureteric stones.

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

   It was acknowledged that local specialists have indicated that they are already working in line with the NICE clinical guideline so it is not expected that there will be any significant change for patients.

The proposed policy will support existing practice in using shockwave lithotripsy in place of surgical procedures where clinically relevant.

However it was noted that it is not viable to have multiple lithotripters across Devon. Shockwave lithotripsy is only available at University Hospitals Plymouth as a host for the peninsula. Some patients in other areas may wish to avoid travel and to stay locally for treatment, which means instead opting for more invasive options.

It was acknowledged that the CCG has patient transport arrangements in place to assist patients on a practical level where travel to other centres for treatment is difficult or not possible for them. It was also felt that there that is an expectation that patients may at times have to be prepared to travel for treatment; it is not reasonable to expect all treatments to be available on their doorstep. However it is important to understand at an individual level the reasons why someone might not wish to travel.

There was discussion of the balance of patient choice and the expectation for patients to need to travel for some treatments, particularly where the national guidance promotes less invasive, non-surgical options, and whether it would be reasonable to mandate patients to travel in order to receive treatment. It was considered that this would likely require more detailed consultation and discussion, as well as assessment of the level of clinical support for such an approach. This would be fed in to commissioning and LTP discussions.

Action: Chris Roome and Nicola Bonas to feed this discussion back to the Director of Commissioning and into LTP discussions respectively

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 acknowledged that local specialists have indicated that they are already working in line with the NICE clinical guideline for renal and ureteric stones so no significant impact on local activity is anticipated.

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

   The panel were aware that kidney stones are a common urological condition; however they were not aware of any particular public concern in respect of shockwave lithotripsy or surgical treatment options for the removal of kidney stones.

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

   nhs.uk gives information on treating and preventing kidney stones, noting that most are small enough to be passed naturally, and that it may be possible to treat the symptoms at home with medication.

   Larger stones may need to be broken up or removed with surgery. It is noted that the three main types of surgery for removing kidney stones are shockwave lithotripsy, ureteroscopy and percutaneous nephrolithotomy.

   Shockwave lithotripsy involves using ultrasound shock waves to break the stone into smaller pieces so it can be passed naturally. It can be uncomfortable, so it usually carried out after giving painkilling medication. Both ureteroscopy and percutaneous nephrolithotomy are carried out under general anaesthetic and involve a thin telescope instrument being passed through into the kidney, via the ureter or the back, respectively.

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

Fusion surgery for mechanical axial low back pain

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

This is another area in which policy development had been prompted by the Academy of Medical Royal Colleges evidence-based interventions (EBI) guidance to CCGs, published in November 2020.

Spinal fusion is when two individual spinal vertebrae become joined together by bone formed as a result of surgery. This may involve the use of a bone graft and/or surgical implants. The aim is to stop motion at that joint in order to stabilise the joint.

The EBI recommendations state that spinal fusion is not recommended for patients with non-specific, mechanical back pain. This is in line with the NICE guideline for low back pain and sciatica.

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 the development of a CCG policy for fusion surgery for non-specific, mechanical back pain had been prompted by the Academy of Medical Royal Colleges evidence-based interventions (EBI) guidance to CCGs, published in November 2020.

   The Clinical Policy Committee had subsequently recommended a policy which acknowledges the EBI guidance and is in line with the NICE clinical guideline for low back pain and sciatica.

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

   It was acknowledged that the policy represents no clinical change to the current position for patients. Local specialists have stated that spinal fusion surgery is not used in Devon when there is no clear mechanical cause of a patient's back pain. It is also noted that the EBI data did not identify any such activity being carried out in Devon last year.

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 the policy is not expected to have an impact on surgical activity. Local specialists have stated that spinal fusion surgery is not used when there is no clear mechanical cause of a patient's back pain and EBI data did not identify any activity in Devon last year.

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

   The panel noted that back pain is very common, and that it often improves with conservative management and physiotherapy interventions. It was discussed that there is a back pain pathway in Devon; where other measures have not worked patients may be referred for specialist assessment in order to identify a cause of

their back pain. Spinal fusion is only indicated where a cause is identified for which surgery is a suitable treatment option.

It was queried what the exceptionality criteria for treatment might be under this policy. It was discussed that this would likely be if a clinician could not find a specific reason for the pain but wished to operate anyway. In these circumstances they would need to make a clinical case for doing so to the panel and each application would be considered on a case-by-case basis; it is difficult to clarify the specific circumstances in which this might occur. The main thrust of the guidance is about ensuring clinical appropriateness of treatment and only carrying out spinal fusion surgery when there is a known reason for doing so.

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

   nhs.uk notes that back pain is very common and usually improves within a few weeks or months. In most cases the pain is not caused by anything serious and will usually get better over time. There are tips given on how to relieve back pain and when to get help and advice.

   It is stated that a GP, specialist or physiotherapist may recommend extra treatments if they do not think the pain will improve with self-help measures alone, including group exercise classes, manual therapy treatments and psychological support.

   Spinal fusion surgery may be recommended if there is significant damage to the bones in the back (vertebrae) to fuse 2 vertebrae together to strengthen them. This can also help to reduce any related nerve pain as it stops the damaged vertebrae squeezing the nerves that pass through the spine. However 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 (prolapsed) disc, and other treatments have not helped.

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

Arthroscopic surgery for meniscal tears

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

This is another area in which policy development had been prompted by the Academy of Medical Royal Colleges evidence-based interventions (EBI) guidance to CCGs, published in November 2020.

Arthroscopy of the knee is a surgical technique where a camera and instruments are inserted into the knee through small incisions, usually under general anaesthesia. Following a detailed systematic assessment of the important structures within the knee joint a surgical procedure is performed which can involve repair or resection of meniscal tissue.

The EBI guidance recommends that use of arthroscopic surgery to treat degenerate meniscal tears should follow published guidelines from the British Association for Surgery of the Knee (BASK).

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 the development of a CCG policy for arthroscopic surgery for meniscal tears had been prompted by the Academy of Medical Royal Colleges evidence-based interventions (EBI) guidance to CCGs, published in November 2020.

   The Clinical Policy Committee had subsequently recommended a policy which acknowledges the EBI guidance and the relevant BASK guidelines relating to arthroscopic surgery.

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

   It was acknowledged that the policy represents no significant change for patients. There is a clinical referral guideline (CRG) currently in place in Devon for knee pain in adults. This contains referral details that are in line with the BASK guidelines, although as they are referral guidelines they do not detail when surgical interventions are appropriate.

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 the policy is not expected to significantly increase or reduce surgical activity. However Devon Referral Support Services (DRSS) report that a definitive policy position will allow the referral process to be managed in a more robust way than is possible by reliance on a clinical referral guideline (CRG) alone.

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 particular public concern in respect of meniscal tears or their treatment.

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

   nhs.uk gives information on cartilage damage, which is noted to be a relatively common type of injury often involving the knees, although joints such as the hips, ankles and elbows can also be affected.

   It can become damaged as a result of a sudden injury, such as a sports injury, or gradual wear and tear (osteoarthritis). Minor cartilage injuries may get better on their own within a few weeks, but more severe cartilage damage may eventually require surgery.

   Surgery is usually performed using arthroscopy – a type of keyhole surgery where instruments are inserted into the joint through small cuts (incisions) – although sometimes larger incisions need to be made. It is normally carried out under general anaesthetic.

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

Lisdexamfetamine for attention deficit hyperactivity disorder (ADHD) in adults

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

The CCG is in the process of commissioning a Devon-wide service to treat adults with attention deficit hyperactivity disorder (ADHD). ADHD is a condition that affects people's behaviour. It can make them seem restless or hyperactive, have trouble remembering things and focusing on tasks, and they may often act on impulse without stopping to think. It is usually diagnosed in childhood, but some people are not diagnosed until they are adults.

Lisdexamfetamine is a medication that, after oral administration, is rapidly absorbed from the gastrointestinal tract and broken down to dexamfetamine, which is responsible for the drug's activity. The CCG has an existing commissioning policy for lisdexamfetamine, but this is limited to children and adolescents. The Clinical Policy Committee has now considered its use in adults in Devon.

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 the CCG is in the process of commissioning a Devon-wide service to treat adults with ADHD. There are currently two treatments for ADHD in adults included in the Devon Formulary, methylphenidate, and atomoxetine. However, due to the absence of a commissioned service at the time, the existing commissioning policy for lisdexamfetamine is limited to children and adolescents.

   After consideration, the Clinical Policy Committee has now recommended a policy accepting the use of lisdexamfetamine in Devon in adults who have failed to gain an adequate response to, or tolerate, methylphenidate. This is in the same place in therapy as it is for children and adolescents.

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

   It was acknowledged that the proposed policy recommends lisdexamfetamine in Devon for the treatment of ADHD in adults in the same place in therapy as it is for children and adolescents. This provides consistency for patients whether they start treatment as adults or continue treatment from childhood.

4. Have the wider consequences on society been considered?

   It was acknowledged that, as a behavioural disorder with a relatively high documented prevalence this was a societal issue too. It was also felt that ADHD is partially socially defined.

5. Has the opportunity cost been considered?

   It was noted that estimating the cost impact and determining the size of the population they are commissioning for is one of the challenges for commissioners. In commissioning adult services from specialist providers, the CCG has taken into account average prescribing costs for existing adult patients currently prescribed lisdexamfetamine, atomoxetine and methylphenidate in Devon, and will have considered an increase in costs based on new adult diagnoses. It is understood that the business case estimates £450-500 per patient per year.

   A proportion of adults prescribed these medicines are likely to have continued treatment from childhood, while some may have started treatment as adults. The proportion of patients started in adulthood is not known. It was noted that, in the UK, prevalence of ADHD in adults is estimated at 3% to 4%, which equates to approx.

30,000-40,000 individuals in Devon. However as lisdexamfetamine is recommended as a second line treatment following failure of methylphenidate, it may be reasonable to expect the proportion of prescribing of each medicine to remain consistent.

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

   The panel were aware that ADHD is a well known condition. It was discussed that it is a behavioural disorder which is on a spectrum and that it is partially socially defined, with differing views on its diagnosis and treatment.

   There was consideration of the place of medication in treatment, and it was noted that in children and adolescents therapy is recommended as a first line treatment, while in adults medication is recommended first line. There was discussion of what plans there were to publicise the availability of this treatment. It was suggested that, although this would be an appropriate treatment option, there was a risk that raising its profile could potentially stimulate additional demand and the CCG may wish to be mindful of this in its communications.

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

   nhs.uk states that ADHD is a condition that affects people's behaviour. People with ADHD can seem restless, may have trouble concentrating and may act on impulse. Symptoms of ADHD tend to be noticed at an early age and may become more noticeable when a child's circumstances change, such as when they start school. Most cases are diagnosed when children are 6 to 12 years old.

   ADHD can be treated using medicine or therapy, but a combination of both is often best. There are 5 types of medicine licensed for the treatment of ADHD: methylphenidate, lisdexamfetamine, dexamfetamine, atomoxetine and guanfacine.

   In relation to lisdexamfetamine, it is stated that this is a medicine that stimulates certain parts of the brain. It improves concentration, helps focus attention and reduces impulsive behaviour. It may be offered to teenagers and children over the age of 5 with ADHD if at least 6 weeks of treatment with methylphenidate has not helped. Adults may be offered lisdexamfetamine as the first-choice medicine instead of methylphenidate. Lisdexamfetamine comes in capsule form, taken once a day.

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

Lixisenatide for the treatment of type 2 diabetes

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

The CCG has had a policy in place since 2015 accepting the use of lixisenatide in Devon. However since then, two other injectable glucagon-like peptide-1 (GLP-1) receptor agonists (semaglutide and dulaglutide) have been accepted for routine commissioning in Devon, and the developments in the treatment of type 2 diabetes has seen a shift from a focus on glycaemic control to cardiovascular outcomes.

During a recent consultation process, local endocrinology specialists and GPs requested that the Devon Formulary guidance for GLP-1 agonists was reviewed to simplify and rationalise the number of treatment options included. Subsequent consultation with specialists reinforced the suggestion that consideration should be given to removing lixisenatide from the formulary as it is rarely used.

The Clinical Policy Committee has considered its previous policy position accordingly and now recommends withdrawal of the existing commissioning policy for lixisenatide.

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 the existing CCG policy for lixisenatide for type 2 diabetes had been reconsidered in response to the request from specialists to simplify and rationalise the number of GLP-1 treatment options in Devon.

   After consideration, the Clinical Policy Committee has recommended that the existing commissioning policy for lixisenatide for type 2 diabetes should now be withdrawn. The Devon Formulary is required to include all medicines for which the Clinical Policy Committee has made a policy recommendation. Withdrawal of the policy for lixisenatide will enable review of this treatment area to simplify local options, avoid confusion and provide up-to-date advice.

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

   It was acknowledged that although it is proposed to withdraw this policy, local specialists have indicated that they do not currently routinely recommend lixisenatide. Prescribing data shows that over the last 12 months it has only been prescribed to 37 patients in Devon.

   There are a number of other treatment options available for patients; these have also demonstrated cardiovascular benefit where lixisenatide has not.

   It was also noted that individual patients who are stable on treatment with lixisenatide would not be made to switch to another treatment option as a result of withdrawal of this policy.

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 the withdrawal of this policy is not expected to have a significant impact on prescribing budgets as in practice specialists have not routinely recommended its use and the number of patients who have been initiated on to treatment with lixisenatide is very low.

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

   The panel were aware that type 2 diabetes is a well-known condition; however they were not aware of any particular public concern in respect of the treatment options, of which there are several.

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

   nhs.uk gives general information on type 2 diabetes, including medicines. It is stated there are many types of medicine for type 2 diabetes and it can take time to find a medicine and dose that is right for the patient.

   Lixisenatide and GLP-1 receptor agonists are not specifically described, however it is noted that patients will usually be offered a medicine called metformin first. If blood sugar levels are not lower after taking metformin, they may need another medicine, and over time, they may need a combination of medicines.

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

5. Annual Report 2020-21

The panel received an Annual Report setting out its activity, governance and operational arrangements in 2020-21.

The panel meetings in 2020-2021 were disrupted by a significant amount of the Clinical Effectiveness Team and NHS colleagues' work being reprioritised to address urgent matters arising in response to the first and second waves of the COVID-19 pandemic. Two meetings of the Clinical Policy Committee were cancelled during the year. This resulted in four panel meetings being held over the past year, considering and making recommendations to the CCG's executive groups on eight clinical policy recommendations. These meetings supported the resumption of regular business by the Clinical Policy Committee as soon as it was feasible to do. The panel were satisfied that the public interest issues had been fully considered and that further engagement or consultation would not yield additional insights.

It was highlighted that the panel had embraced the challenges of meeting virtually, adopting altered ways of working in order to support the continuation of meetings during the pandemic. All meetings in 2020-2021 were held virtually, either via Microsoft Teams or telephone/teleconference arrangements.

Rebecca Heayn was thanked for producing and presenting the annual report. This would now be submitted to the CCG for information and assurance.

Action: Rebecca Heayn to submit the Annual Report to the CCG for information and assurance

It was queried what the future for the panel was in light of the development of the new Integrated Care System (ICS) and the impact of this on existing NHS structures. It was discussed that the detail of this is not yet clear but there will be a period of working in shadow form. The ICS is a natural progression of working together, but statutory bodies will exist so there are some practical implications of what this means. Further discussions are taking place with regard to the future structures in place locally and evolving arrangements; however the Clinical Policy Committee and the Clinical Policy Engagement and Consultation Panel will continue until future changes and accompanying arrangements are known.

It was suggested that the Terms of Reference should be reviewed to reflect the respective advisory roles of Nicola Bonas and Jon Taylor more accurately. Currently these are both listed under 'communications and engagement'.

Action: Rebecca Heayn to revise the Terms of Reference for the next meeting

The plans for future meeting arrangements were discussed and the likelihood of a return to face to face meetings in future. It was explained that at present CCG discussions were underway with regard to a return to offices and the expectation was for hybrid working arrangements in future, with a mix of home and office working depending on teams' and individuals' needs and priorities. It was also anticipated that many meetings will continue to predominantly be held virtually.

Specific discussions regarding future panel meetings will be held once government guidance and CCG intentions are clearer. Where there is resumption of face to face meetings it was acknowledged that there should be appropriate guidance for external

visitors attending these meetings. This will be fed back to the return to the office working group.

Action: Rebecca Heayn to highlight the need for appropriate guidance for external visitors for the attendance of meetings to the return to the office working group

6. Any Other Business

No other business was raised.

7. Next meeting date

It was noted that the meeting scheduled for Thursday 12 August 2021 has now been cancelled. The next meeting will now be held on Thursday 14 October 2021.

ACTION LOG

Action no.	Meeting date	Action description	Lead(s)
21/01	22/04/2021	To support implementation of the updated policy for FreeStyle Libre, explore opportunities to communicate with Learning Disabilities groups to raise awareness of the availability of the technology for this cohort of patients. **17/06/2021 update: Initial support information for learning disabilities groups had been drafted. Subsequent discussions have suggested that something more accessible may be needed; this is being prepared with Living Options Devon.**	Nicola Bonas/ Chris Roome
21/02	17/06/2021	To feedback on discussions relating to whether it would be reasonable to mandate patients to travel in order to receive treatment to the Director of Commissioning and into LTP discussions	Nicola Bonas/ Chris Roome
21/03	17/06/2021	Annual Report to be submitted the CCG for information and assurance	Rebecca Heayn
21/04	17/06/2021	Revise the panel Terms of Reference for the next meeting	Rebecca Heayn
21/05	17/06/2021	Highlight the need for appropriate guidance for external visitors for the attendance of meetings to the return to the office working group	Rebecca Heayn