NHS
Devon
Clinical Commissioning Group

Clinical Policy Engagement & Consultation Panel

MINUTES

Thursday 14 October 2021, 14.00-15.30

Via Microsoft Teams

Present:

Charlotte Burrows*	Governing Body Lay Member for patient & public involvement
Rebecca Owen	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 Nicola Bonas, Associate Director of Communications and Engagement and 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 17 June 2021

The panel considered the minutes from the meeting held on 17 June 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. **17/06/2021: 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.** **14/10/2021: Chris Roome advised that he had heard nothing further in respect of this and would consider this action completed from the perspective of the panel. Carol McCormack-Hole queried whether it would be helpful to link with the DCC engagement forum. Chris Roome agreed to flag this with Nicola Bonas and Jon Taylor.**
21/02	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 **This had been discussed as part of the conversations by the Commissioning Committee where it was agreed that people would not be mandated to travel for treatment. Action complete.**
21/03	Annual Report to be submitted the CCG for information and assurance **The Annual Report had been received by the Clinical Policy Committee and the Commissioning Committee. Action complete.**
21/04	Revise the panel Terms of Reference for the next meeting **There are plans for the Terms of Reference to be reviewed in light of the changes in membership and reporting arrangements with the transition to the Integrated Care System. This is planned to occur in conjunction with the revisions to the Clinical Policy Committee process and documentation.**
21/05	Highlight the need for appropriate guidance for external visitors for the attendance of meetings to the return to the office working group **This has been fed by via the Return to Office Working Group. Action complete.**

4. Discussion and recommendation on the Clinical Policy Committee decisions from 15 September 2021

Fidaxomicin for the treatment of *Clostridioides difficile* infection

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

The committee had reviewed the existing CCG policy for the use of Fidaxomicin for the treatment of *Clostridioides difficile* infection following an application from local microbiologists across Devon supporting its use. Reconsideration was requested in light of new guidelines and additional evidence since the CCG policy was published in October 2014. Recently published National Institute for Health and Care Excellence (NICE) guideline NG199 recommends fidaxomicin as a treatment option.

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's current policy for Fidaxomicin for the treatment of *Clostridioides difficile* infection, which had been in place since October 2014, had been reviewed in light of an application from local consultant microbiologists to reconsider its use in Devon. This had been in response to newly published NICE guidelines which now recommend it as a treatment option.

   Following consideration, the Clinical Policy Committee has now recommended an updated policy accepting the use of Fidaxomicin in Devon for the treatment of *Clostridioides difficile* infection.

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

   It was acknowledged that the availability of fidaxomicin as a treatment option in Devon would have a positive impact for patients. This provides another treatment option in addition to vancomycin or metronidazole and may be more effective at preventing relapses.

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 although it is more effective at preventing relapses, fidaxomicin is significantly more expensive than the alternative treatments of vancomycin or metronidazole. The recommended policy states that, to obtain the best value for money, vancomycin should be used in preference in certain clinical scenarios.

   An analysis by the Clinical Effectiveness team using local figures for current prescribing levels and predictions of future use estimated by NICE suggests an increased expenditure on fidaxomicin of £97,200 per year.

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 *Clostridioides difficile* infection and its treatment options.

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

   nhs.uk gives information on *Clostridium difficile*, including symptoms of infection, who is most at risk, how to look after yourself at home, how to stop it spreading and when to seek medical advice.

   In respect of treatment, it is stated that if the infection is mild, you should be able to recover at home. Your GP will advise if you need hospital treatment. If you're in hospital, you might be moved to a room of your own during treatment to reduce the risk of the infection spreading to others.

   It is noted that treatment for *Clostridium difficile* can include stopping the antibiotics thought to be causing the infection, if possible; taking a 10 to 14 day course of antibiotics that are known to kill the bacteria; or rarely, serious infections may require surgery to remove a damaged section of the bowel. *Clostridium difficile* infections usually respond well to treatment, with most people making a full recovery in a week or 2. But the symptoms come back in around 1 in 5 cases and treatment may need to be repeated.

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

Governance update to the Commissioning Policy for Assessment and Removal of Benign Skin and Subcutaneous Lesions

An overview of the Clinical Policy Committee recommendation and the context within which it had arisen was noted by the panel.

It was noted that there is no proposed clinical change to CCG's existing policy; the update proposed is for governance purposes only. This is to clarify that any digital images sent with referrals will not be reviewed by the CCG in the process of determining whether the referral meets the policy criteria.

Providing clarity of this within the CCG's policy and guidance was advised following legal advice.

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?

   The proposed governance update to the existing policy had arisen from a query from the GP Referral Facilitator (GPRF) team in respect of the correct course of action when digital images are attached with referrals. The team has seen an increase in these and wished to clarify their remit in respect of the images and the potential position this places them in.

   Legal advice on this point clarified that the GPRFs should not incorporate the digital images into their decision making when assessing whether the referral meets the policy criteria. The responsibility for diagnostic assessment lies with the referring GP and it is not the remit of the GPRF to make any diagnostic assessment of the patient separately to the referring GP on the basis of any digital images or give a "second option". It was therefore advised that this should be made clear in the CCG's policy and guidelines and to referring GPs. Supporting communications will also seek to clarify that images may be useful for specialists to consider when a referral has been passed through to them and attaching them is therefore no discourages, however they will not be considered *at the point of the referral being assessed.*

   The Clinical Policy Committee has subsequently recommended the addition of the following words to the policy:

   "Clinicians referring patients for assessment or removal of a benign skin or subcutaneous lesion should note that any digital images sent with referrals will not be reviewed by the CCG in the process of determining whether the referral meets the policy criteria."

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. The proposed update is for governance purposes to provide clarity on the use of images at the point of assessing a referral against the 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 update is for governance purposes only.

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

   The proposed update to the existing policy is for governance purposes only to provide clarity on the use of images at the point of assessing a referral against the policy. No particular public concern was noted.

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

   Not applicable; the proposed update to the existing policy is for governance purposes only to provide clarity on the use of images at the point of assessing a referral against the policy. There is no clinical change for patients.

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

Ulipristal acetate 5mg tablets (Esmya®) for intermittent treatment of uterine fibroids

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

An update to the CCG's previous policy for Ulipristal acetate 5mg tablets (Esmya®) for intermittent treatment of uterine fibroids was proposed in line with its revised license indication.

The licence of Esmya® had been temporarily suspended while a safety review was carried out and the CCG's policy was suspended in line with this. Following full consideration by the European Medicines Agency (EMA) it was considered that the benefits of ulipristal acetate 5mg in controlling fibroids may outweigh this risk in women who have no other treatment options. As a result it was recommended that the medicine remains available to treat premenopausal women who could not have surgery (or for whom surgery had not worked).

The Medicines and Healthcare products Regulatory Agency (MHRA) reinstated the licence in February 2021; however it now has a restricted indication for intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women who have not reached menopause when uterine fibroid embolisation and/or surgical treatment options are not suitable or have failed.

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's policy has previously been suspended pending the outcome of the EMA's safety review of Esmya®. The MHRA reinstated the licence in February 2021 with a restricted indication for the intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women who have not reached menopause when uterine fibroid embolisation and/or surgical treatment options are not suitable or have failed.

   Following consideration, the Clinical Policy Committee has now recommended an updated policy in line with the revised indication.

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

   It was acknowledged that the policy supports the EMA's assessment that the benefits of ulipristal acetate 5mg in controlling fibroids may outweigh this risk in

women who have no other treatment options, in line with its revised license indication. This will provide a potential treatment for a group of patients for whom no other treatment options are available.

There was discussion of whether there were be public understanding of the potential risks associated with this treatment. Local gynaecologists are aware of the context of this treatment and that the benefits and risks of treatment must be discussed with patients before prescribing. This is also supported by advice in the Devon Formulary on the discussions with patients prior to prescribing and the monitoring that should occur for patients treated with Esmya®. This includes monitoring of liver function tests / drug safety monitoring.

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 with the revised indication, the number of women now eligible for treatment with ulipristal acetate is much lower as it is limited to women who have not reached menopause and for whom uterine fibroid embolisation and/or surgical treatment options are not suitable of have failed. However it will provide a potential treatment for a group of patients for whom no other treatment options are available.

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 fibroids and 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 the various treatments for fibroids.

   In respect of Ulipristal acetate (Esmya®) it is stated that this is a medicine that can be used to treat fibroids. However, it should only be prescribed for occasional use if you have moderate to severe symptoms, you're an adult who has not reached the menopause and surgery and non-surgical procedures are not suitable or have not worked. This is because there is a risk of serious liver damage and liver failure.

   If your doctor thinks ulipristal acetate may be suitable for you, they should discuss the risks and benefits with you so you can make an informed decision.

   If you decide to try ulipristal acetate, your liver function will be closely monitored using liver function tests before, during and after treatment.

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

5. Any Other Business

The panel noted that this was Charlotte's last meeting. She was thanked for her insights and contribution to the group over a number of years and wished well for her new role with the Academic Health Science Network (AHSN).

6. Next meeting date

It was noted that the meeting scheduled for Thursday 9 December 2021 has now been cancelled. The next meeting will now be held on Thursday 10 February 2022.

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: 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.** **14/10/2021: Chris Roome advised that he had heard nothing further in respect of this and would consider this action completed from the perspective of the panel. Carol McCormack-Hole queried whether it would be helpful to link with the DCC engagement forum. Chris Roome agreed to flag this with Nicola Bonas and Jon Taylor.**	Nicola Bonas/ Chris Roome
21/04	17/06/2021	Revise the panel Terms of Reference for the next meeting **14/10/2021: There are plans for the Terms of Reference to be reviewed in light of the changes in membership and reporting arrangements with the transition to the Integrated Care System. This is planned to occur in conjunction with the revisions to the Clinical Policy Committee process and documentation.**	Rebecca Heayn