Northern, Eastern and Western Devon
Clinical Commissioning Group

South Devon and Torbay
Clinical Commissioning Group

Clinical Policy Engagement & Consultation Panel Meeting

Minutes

Wednesday 10 October 2018, 14.00-15.30

CFO Room, County Hall, Exeter and via teleconference

Present:

Ray Chalmers	Head of Communications & Strategic Engagement	South Devon & Torbay CCG
Rebecca Heayn	Clinical Effectiveness Governance Manager	NEW Devon CCG
Mac Merrett*	Lay Public Member, Clinical Policy Committee	
Chris Peach*	Non-Executive Director (Patient & Public Involvement)	South Devon & Torbay CCG
Chris Roome	Head of Clinical Effectiveness	NEW Devon CCG
Mark Taylor*	Lay Public Member, Clinical Policy Committee	
Jennie Willmott*	Lay Member, Patient & Public Engagement	NEW Devon CCG

* Denotes voting members

1. Welcome and Introductions

Attendees were welcomed to the meeting.

Apologies were noted from Jenny McNeill, Associate Director of Planning Development, NEW Devon CCG and Jon Taylor, Strategy Manager, NEW Devon CCG.

2. Declaration of Interests

No changes to the Register of Interest were advised and no specific interests pertinent to the items for discussion on the meeting agenda were declared.

3. Minutes from the meeting 14 August 2018

The panel considered the minutes from the meeting held on 14 August 2018 and agreed them to be an accurate record.

The action log was updated as follows:

Action no.	Description and update
18/07	Annual Report to be finalised and submitted to the CCGs for acceptance and assurance. **Ray Chalmers advised that the Engagement Committee had accepted and noted the Annual Report at their meeting on 2 October 2018.** **Action complete.**

18/08	The panel will be kept updated on the progress of the proposed merger of the CCGs in Devon so that the implications for the group membership and TOR can be considered accordingly. **The outcome of the recent poll of GP practices on the proposed merger of the CCGs was noted. The majority of GP practices in NEW Devon who voted supported the proposed merger; however South Devon and Torbay GP practices who voted did not. This had been noted at the last Governing Body meeting, with further discussions ongoing to understand the negative response and discuss the next steps. A further update is anticipated early next year.**

4. Discussion and recommendation on the Clinical Policy Committee decisions from 26 September 2018

Assisted conception

It was noted that some amendments had been recommended to the CCGs' Assisted conception policy relating to the sections on total failure of fertilisation and the eligibility criteria for assessment and treatment in respect of "previous children". These had arisen from Individual Funding Request (IFR) applications which had highlighted the need for clarity in these areas.

Specialists from the local fertility centres were present at the Clinical Policy Committee meeting and the value in early engagement with them to discuss and refine practicable policy amendments to present to the committee in this complex clinical area had been acknowledged.

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

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

   It was noted that the proposed amendments to the policy resulted from Individual Funding Request (IFR) applications which had highlighted ambiguity in the current policy wording in some areas. Changes in the wording relating to fertilisation failure, and related sub-sections, are to remove ambiguity and ensure consistency in the CCGs' policy approach for two attempts to produce pregnancy. Changes relating to the eligibility criteria for assessment and treatment seek to address the ambiguity and hence the questions that have arisen in interpretation of the existing policy.

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

   It was considered that the policy amendments relate to small numbers of patients. The amendments would provide greater clarity of the policy positions in these areas, removing existing ambiguity and questions of interpretation.

   In particular, it was noted that consistent interpretation of eligibility criteria relating to previous children had been challenging within the context of contemporary social and family structures. The proposed amendments move away from considerations of residency in respect of previous children, and the potential inequity that could result from this.

4. Have the wider consequences on society been considered?

   It was felt that there were no wider consequences of the proposed policy; this is an area with no broader impact beyond the individuals involved.

5. Has the opportunity cost been considered?

   It was advised that the policy amendments relate to small numbers of patients, and the changes are not expected to increase the number of patients referred for investigation or treatment.

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

   It was acknowledged that this is a complex and emotive area, but the changes proposed were for the purposes of clarity.

   There was discussion of the proposed clarification within the policy that the eligibility criterion relating to previous sterilisation also applies to cases where sterilisation has been reversed. Although it was felt that this may be contentious for some, it was considered that it provided clarification within the policy of the position that has been applied in practice. It was discussed that in general the avoidance of any grey areas within policies was welcomed.

   There was also consideration of the merits of cross-referencing between policies, i.e. between this policy and the CCGs' proposed reversal of sterilisation policy. The benefits of ensuring patients are well informed was acknowledged, as were the risks of stating the position of one policy within another. On balance it was felt that the issue of patients who have been sterilised (including where this has been reversed) not being eligible for assessment and treatment for infertility should inform the considerations at the point at which sterilisation occurs. As such, this could be included in the letter to specialists which is proposed to accompany communication of the policy for the Reversal of male and female sterilisation.

7. What information on the treatment and condition is available to patients via NHS Choices?

   NHS Choices gives information on the treatment of infertility, including assisted conception. This states that fertility treatment funded by the NHS varies across the UK, and the eligibility criteria can also vary. Individuals are therefore referred to their local CCG for information on their eligibility for treatment.

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

Fluticasone furoate, umeclidinium and vilanterol (Trelegy® Ellipta®) combination dry powder inhaler for Chronic Obstructive Pulmonary Disease (COPD)

An overview of the Clinical Policy Committee recommendation and the background to this treatment was noted by the panel. The use of Trelegy® Ellipta® combination dry powder inhaler for patients with moderate to severe chronic obstructive pulmonary disease (COPD) had been considered by the Clinical Policy Committee following an application from a local respiratory specialist. Trelegy® Ellipta® is a triple therapy dry powder inhaler containing fluticasone furoate (an inhaled corticosteroid [ICS]), umeclidinium (a long-acting muscarinic receptor antagonist [LAMA]) and vilanterol (and long-acting beta-2 agonist [LABA]).

The local specialist applicant joined the Clinical Policy Committee meeting for discussion of this item.

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

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

   It was noted that the request received was for Trelegy® Ellipta® combination dry powder inhaler to be accepted as another treatment option for patients with chronic obstructive pulmonary disease (COPD). After consideration, the Clinical Policy Committee has recommended the routine commissioning of Trelegy® Ellipta® in Devon as a maintenance treatment for patients with moderate to severe COPD.

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

   It was advised that two of the three inhaler components are already accepted treatments on the local formularies. There is currently one other triple therapy treatment option, Trimbow®, which is delivered via a metered dose ("press and breathe") inhaler. It was considered that a triple therapy delivered via a dry powder ("breathe in hard") inhaler would be a useful and

welcome additional treatment option. This may benefit patients unable to use a metered dose inhaler and/or those who might otherwise require multiple devices to deliver the triple therapy treatments (and who would need to master the differing techniques that may be associated with the different devices).

4. Have the wider consequences on society been considered?

   It was felt that there were no wider consequences of the proposed policy; this is an area with no broader impact beyond the individuals involved (and their carers).

5. Has the opportunity cost been considered?

   It was discussed that there was expected to be some economic advantage from the acceptance of Trelegy® Ellipta® as an additional treatment option. It is the same cost as the other triple-therapy combination inhaler treatment, and available at a lower cost than the combination of any two current locally recommended ICS/LABA and LAMA dry powder inhalers.

   However it was noted that the switching of patients who are stable on triple therapy using multiple devices is not licensed, so bulk switching of patients is unlikely.

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

   It was acknowledged that COPD is a well-known respiratory condition. However the panel were not aware of any specific public concern regarding the condition or the treatment option.

   It was considered that the application for this as an additional treatment option was part of the natural progress in treatments. It was discussed that an update to the National Institute for Health and Care Excellence (NICE) guideline on COPD is anticipated shortly, but that the concept of using triple therapy for the maintenance treatment of COPD was an accepted one.

7. What information on the treatment and condition is available to patients via NHS Choices?

   NHS choices gives information on treatments for COPD, which it notes includes inhalers and medications to help make breathing easier. It advises that there are several different types of inhaler for COPD and lists the main ones (short-acting bronchodilator inhalers, long-acting bronchodilator inhalers and steroid inhalers). It is noted that steroid inhalers are normally prescribed as part of a combination inhaler that also includes one of the long-acting medications.

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

Cosmetic treatments policy

A cosmetic treatments policy has been recommended by the Clinical Policy Committee to replace relevant parts of the existing low priority treatments policy. The existing policy has been in place for some time, having been agreed by the previous commissioning organisations, and comprises mostly cosmetic treatments alongside procedural Individual Funding Request (IFR) Panel notes.

Cosmetic treatments are considered a low priority for use of healthcare funds and are not routinely commissioned in Devon. However revisions have been made to update the policy and provide greater clarity. It contains a list of common cosmetic procedures, however this is not exhaustive and the policy applies to all treatment which is being carried out for cosmetic reasons.

Consultation on the proposed policy has taken place with local trusts, IFR panel and GP Referral Facilitator colleagues.

The panel considered the public interest themes in relation to the proposed 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 CCGs' low priority treatments policy has been reviewed and updated. As this comprises mostly cosmetic treatments, it is proposed to replace it with a cosmetic treatments policy, with other non-cosmetic procedures covered by specific policies.

   Cosmetic treatments are considered a low priority for use of healthcare funds and are not routinely commissioned in Devon. However revisions have been made to update the policy and provide greater clarity.

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

   It was commented that the CCGs' Individual Funding Request (IFR) Panel had received a significant number (353) applications for cosmetic treatment in the past 12 months.

   However it was acknowledged that there is no change to the CCGs' position in respect of the funding of cosmetic treatments; these are not routinely commissioned in Devon. Revisions have been made with the aim of making the policy clearer and more user-friendly. This includes a clear definition of cosmetic treatment and a list of commonly encountered cosmetic procedures, although this is not exhaustive.

4. Have the wider consequences on society been considered?

   It was felt that there were no wider consequences of the proposed policy; this is an area with no broader impact beyond the individuals involved.

5. Has the opportunity cost been considered?

   It was advised that it is not expected that the proposed policy will have a financial impact as there is no change to the CCGs' commissioning position in respect of cosmetic treatments.

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

   It was noted that the Clinical Policy Committee had discussed a number of conditions where the cosmetic nature or otherwise is unclear and that there may be some lack of clarity in what constitutes "cosmetic". This has been acknowledged at a national level. Although there will always be exceptions, the policy seeks to provide clarity of the CCGs' general position in respect of cosmetic treatments. The policy exceptionality statement allows for application to the CCGs Individual Funding Request (IFR) Panel for the consideration of treatment of an individual patient who does not meet the criteria set out in the general policy position.

7. What information on the treatment and condition is available to patients via NHS Choices?

   The information available via NHS Choices makes it clear that cosmetic surgery is not routinely provided on the NHS. It states that occasionally it may be provided on the NHS for psychological or other health reasons, but generally most people who wish to have cosmetic surgery will need to pay for this privately. Reconstructive or plastic surgery can be available on the NHS, but that this is distinct from cosmetic surgery. It is surgery to restore a person's normal appearance after illness, accident or a birth defect. It includes procedures such as rebuilding breasts after a mastectomy.

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

Reversal of male and female sterilisation policy

It was advised that a specific policy for the reversal of male and female sterilisation had been proposed as a result of the work to update and replace the CCGs' existing low priority treatments policy.

Reversal of sterilisation is considered a low priority for use of healthcare funds and is not routinely commissioned in Devon.

Consultation on the proposed policy has taken place with local trusts, IFR panel and GP Referral Facilitator colleagues.

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

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

   It was noted that the need for a separate policy clarifying the CCGs' position in respect of the reversal of male and female sterilisation has arisen from the revision and updating of the existing low priority treatments policy. It is proposed that the low priority treatments policy is replaced by a policy for cosmetic treatments, with other non-cosmetic procedures such as the reversal of sterilisation covered by specific policies.

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

   It was acknowledged that there is no change to the CCGs' position in respect of the funding of the reversal of sterilisation. Sterilisation is available on the NHS and people seeking it should be fully advised and counselled that the procedure is intended to be permanent. The reversal of sterilisation is not routinely funded.

   It was felt that this position is widely known and accepted. The CCGs' Individual Funding Request (IFR) Panel have received two applications for the reversal of sterilisation in the past 12 months, both relating to the reversal of vasectomy.

4. Have the wider consequences on society been considered?

   It was felt that there were no wider consequences of the proposed policy; this is an area with no broader impact beyond the individuals involved.

5. Has the opportunity cost been considered?

   It was advised that it is not expected that the proposed policy will have a financial impact as there is no change to the CCGs' commissioning position in respect of the reversal of male and female sterilisation.

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

   It was felt that the NHS position not to routinely fund the reversal of sterilisation was widely known and accepted.

   It was noted that there had been some discussion at the Clinical Policy Committee meeting with regard ensuring that patients who undergo sterilisation procedure are fully informed, in accordance with the Royal College of Obstetricians and Gynaecologists guidelines. The consent process should include specific considerations where the patient is under thirty, if they are childless, if there is conflict (or potential risk of coercion) between partners or if it is undertaken at the time of an abortion. The committee had proposed that this is reinforced in a letter to specialists when the policy is published. After discussion of the proposed changes to the Assisted Conception policy earlier in the meeting, the panel recommended that considerations relating to eligibility for assessment and treatment of infertility should also be included within this letter.

   ACTION: The letter to specialists to accompany publication of the policy to make reference to the fact that patients who opt for sterilisation would be rendering themselves ineligible for future Assisted Conception as the Assisted Conception policy specifically excludes those who have had sterilisation reversed.

   It was acknowledged that the policy exceptionality statement allows for application to the CCGs Individual Funding Request (IFR) Panel for the consideration of treatment of an individual patient who does not meet the criteria set out in the general policy position. However it was queried whether the exceptionality wording should be altered in this instance as no specific "criteria" are detailed within the policy; the policy statement is simply that the reversal of male and female sterilisation is not routinely commissioned in Devon.

It was agreed that consideration would be given to alternative wording to aid clarity. This would be circulated to the panel after the meeting for agreement.

ACTION: Consideration of alternative wording for the policy exceptionality statement to remove reference to "criteria" and aid clarity.

7. What information on the treatment and condition is available to patients via NHS Choices?

   The information available via NHS choices makes it clear that sterilisation reversal is not usually available on the NHS.

Considering all these factors together the panel recommended that no further engagement or formal consultation was required at this point. However the panel suggested that the letter to specialists to accompany publication of the policy should make reference to the fact that patients who opt for sterilisation would be rendering themselves ineligible for future Assisted Conception as the Assisted Conception policy specifically excludes those who have had sterilisation reversed.

Insulin Degludec (Tresiba®) for use in patients with type 1 diabetes

An overview of the Clinical Policy Committee recommendation and the background to this treatment was noted by the panel. The use of insulin degludec in patients with type 1 diabetes was reconsidered following an application from a local consultant paediatrician. Although its use had been requested in children and adolescents, the committee had considered its use in adults too, acknowledging that type 1 diabetes is a lifelong condition.

Insulin degludec is an ultra-long acting basal insulin given by injection once-daily, preferably at the same time, and has a duration of action of up to 42 hours.

The existing CCGs' policy position is that insulin degludec is not routinely commissioned for type 1 diabetes. This decision was reached due to limitations in the applicability of the evidence base to the intended patient groups and questions in respect of whether it represented good value for the local health economy. It was noted that, since this decision, the price of insulin degludec has reduced and there is new evidence more closely applicable to the groups in which local clinicians wish to use it.

Two local specialists were present for the Clinical Policy Committee meeting and it was noted that this had added value to the discussions and in understanding anticipated use and the expected benefits to both children and adolescent and adult patients.

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

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

   It was noted that the request received was for insulin degludec to be reconsidered for use in patients with type 1 diabetes. After reconsideration, the Clinical Policy Committee has now recommended the routine commissioning of insulin degludec for children and adolescents who have a history of diabetic ketoacidosis and/or hyperglycaemia (high blood glucose levels) with capillary blood ketones exceeding 1.5 mmol/L, and adults who experience frequent or severe hypoglycaemia (low blood sugar).

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

   It was considered that the availability of this treatment had the potential to reduce rates of hypoglycaemia and hyperglycaemia in the above groups of patients, which would be positive for patients and their parents or carers.

   It was acknowledged that severe and nocturnal hypoglycaemia can have a significant impact on patients. They may require help from another person and the risk of experiencing a nocturnal hypo in particular may make patients anxious.

   It was discussed that there may be poor adherence to treatment regimens, particularly in teenage years. Poor adherence can result in hyperglycaemia with ketosis in children and

adolescents. The ultra-long action of insulin degludec compared to other insulin analogues can reduce the risk of patients experiencing this and also have a positive impact for their parents/carers who may be anxious about poor diabetes control.

4. Have the wider consequences on society been considered?

   It was felt that there were no wider consequences of the proposed policy; this is an area with no broader impact beyond the individuals involved (and their parents or carers).

5. Has the opportunity cost been considered?

   It was discussed that although there are uncertainties in the overall anticipated budget impact, there is a potential cost impact from the use of insulin degludec as it is more expensive that other currently available long-acting insulins. However it was noted that its use in the groups set out in the proposed policy was considered to represent good value for money for the local health economy.

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

   It was acknowledged that type 1 diabetes is a long term condition which commonly presents in children and adolescents but can persist and start in adulthood. The panel were not aware of any specific public concern regarding this condition or the treatment option.

7. What information on the treatment and condition is available to patients via NHS Choices?

   NHS choices gives information on the use of insulin in type 1 diabetes, stating that there are different types taken at different times. It notes that long-acting, basal insulin is take once or twice a day, and fast-acting, bolus insulin is take with food or drink. However specific insulin analogues are not listed.

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

Insulin degludec (Tresiba®) for use in patients with type 2 diabetes

An overview of the Clinical Policy Committee recommendation and the background to this treatment was noted by the panel. Insulin degludec is an ultra-long acting basal with a duration of action of up to 42 hours. In patients with type 2 diabetes it can be administered alone, in combination with oral anti-diabetic agents and/or in combination with bolus insulin.

The CCGs' have an existing policy position in place under which insulin degludec is not routinely commissioned for type 2 diabetes. The use of insulin degludec in patients with type 2 diabetes was reconsidered following an application from a local consultant. The local specialist applicant was present for the Clinical Policy Committee meeting to outline the proposed use and the expected benefits.

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

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

   It was noted that the request received was for insulin degludec to be reconsidered for use in patients with type 2 diabetes. After reconsideration, the Clinical Policy Committee has re-confirmed its existing policy position; insulin degludec is not recommended for use in type 2 diabetes. Given the higher costs of insulin degludec and the limited benefit that would accrue to patients it was considered that it does not provide good value for the local health economy.

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

   It was discussed that insulin is dosed on a body weight basis and the applicant had requested reconsideration of the use of insulin degludec for patients with type 2 diabetes who are injecting more than 5 times a day to achieve the required dose. It was estimated that around 120-140 patients in Devon might be eligible for treatment.

It was acknowledged that the Clinical Policy Committee had considered that there may be a benefit for some patients from fewer injections to achieve their required insulin dose; however on the balance of the benefit and healthcare need, it was considered that it was not good value for money for the local health care system.

Current treatment options for patients include insulin glargine and insulin determir, which are available in a number of different presentations on the local formularies.

4. Have the wider consequences on society been considered?

   It was felt that there were no wider consequences of the proposed policy; this is an area with no broader impact beyond the individuals involved.

5. Has the opportunity cost been considered?

   It was advised that insulin degludec is more expensive that other insulins, including long acting analogues, and is not considered to represent good value for general use in patients with type 2 diabetes.

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

   It was acknowledged that type 2 diabetes is a long term condition which can occur in all age groups, but usually appears in middle aged or older people. The panel were not aware of any specific public concern regarding this condition or the treatment option.

7. What information on the treatment and condition is available to patients via NHS Choices?

   NHS choices gives information on understanding medication for type 2 diabetes. This noted that insulin is not often used for type 2 diabetes in the early years; it is only needed when other medicines no longer work. Specific insulin analogues are not listed.

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

5. Any Other Business

Mac Merrett reiterated that the engagement with specialists and their attendance at the Clinical Policy Committee meeting had been particularly helpful. It was felt that this had clearly benefited the discussions, which at the last meeting were across a range of complex areas, and it helped give the committee an understanding of the anticipated use of treatments and the expected benefits to patients.

6. Future meeting dates

The meeting which was scheduled for Wednesday 12 December 2018 has now been cancelled as the November meeting of the Clinical Policy Committee has been stood down.

The next meeting will therefore now be held on **Wednesday 13 February 2019** from 2.00pm in the CFO Room, County Hall, Exeter or via teleconference.

ACTION LOG

Action no.	Meeting date	Action description	Lead(s)
18/08	14/08/2018	The panel will be kept updated on the progress of the proposed merger of the CCGs in Devon so that the implications for the group membership and TOR can be considered accordingly. **10/10/2018 update: The outcome of the recent poll of GP practices on the proposed merger of the CCGs was noted. The majority of GP practices in NEW Devon who voted supported the proposed merger; however South Devon and Torbay GP practices who voted did not. This had been noted at the last Governing Body meeting, with further discussions ongoing to understand the negative response and discuss the next steps. A further update is anticipated early next year.**	Rebecca Heayn
18/09	10/10/2018	The letter to specialists to accompany publication of the policy to make reference to the fact that patients who opt for sterilisation would be rendering themselves ineligible for future Assisted Conception as the Assisted Conception policy specifically excludes those who have had sterilisation reversed.	Chris Roome
18/10	10/10/2018	Consideration of alternative wording for the Reversal of male and female sterilisation policy exceptionality statement to remove reference to “criteria” and aid clarity.	Chris Roome