NHS
Devon
Clinical Commissioning Group

Clinical Policy Engagement & Consultation Panel

MINUTES

Thursday 22 April 2021, 14.00-15.00

Via Microsoft Teams

Present:

Nicola Bonas	Head of Communications
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 and Charlotte Burrows, Governing Body Lay Member for patient & public involvement.

The panel expressed their congratulations to Charlotte on the safe arrival of her baby in February and sent their best wishes.

2. Declaration of Interests

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

3. Minutes from the meeting 26 November 2020

The panel considered the minutes from the meeting held on 26 November 2020 and agreed them to be an accurate record.

It was noted that there were no outstanding actions or matters arising.

4. Discussion and recommendation on the Clinical Policy Committee decisions from 24 March 2021

Oral semaglutide (Rybelsus®) 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 use of semaglutide, a glucagon-like peptide-1 (GLP-1) receptor agonist, has already been accepted in Devon as an injectable treatment option for patients with type 2 diabetes. Semaglutide is also available as an oral formulation and an application had been received from local consultants to consider its routine use for patients in Devon.

The National Institute for Health and Care Excellence (NICE) guideline on the management of type 2 diabetes in adults (NG28) makes recommendations on the use of GLP-1 receptor agonists, in combination with metformin and a sulfonylurea, in patients for whom therapy with metformin and 2 other oral drugs is not effective, not tolerated, or contraindicated.

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 from local specialists for the use of oral semaglutide to be supported in Devon as a treatment option for type 2 diabetes.

   After consideration, the Clinical Policy Committee has recommended that its routine commissioning is supported in Devon for patients with type 2 diabetes who are suitable for treatment with a GLP-1, as described in NICE guideline NG28, but for whom injectable therapy is not suitable.

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

   It was acknowledged that the availability of oral semaglutide in Devon represents an additional treatment option for patients with type 2 diabetes who would otherwise not be able to receive drugs of this class. This would potentially support management of their glucose control and may alleviate anxieties with injectable treatment options.

   However the Clinical Policy Committee had discussed some limitations with the oral formulation. Although an oral treatment might be considered more convenient, it is poorly absorbed into the body. The manufacturer has added an enhancer, but absorption remains variable; in some patients, in whom it is absorbed, it works well but others may have little response at all. There is also no study to demonstrate cardiovascular benefit. For these reasons its use is not supported as a first-line treatment option, but it is supported as an option in patients for whom injectable therapy is not suitable.

   It was queried what the potential impact of poor absorption might be and whether patients may deteriorate. It was discussed that treatment takes a while to establish benefit and this may be difficult to quantify; however it could result in a few months of no increase in control of the management of their diabetes. It was considered that this would be within the remit of clinical responsibility; the effectiveness of the oral formulation in individual patients would be managed by their clinician.

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 routine commissioning of oral semaglutide for patients for whom injectable therapy is not suitable is not expected to have a significant budget impact. The cost of oral semaglutide is similar to the cost of injectable treatment options; any extra cost incurred would be as a result of additional patients being treated with a GLP-1.

   It was discussed whether the CCG is an innovator in terms of adopting oral semaglutide. It is not known whether other CCGs have yet approved the routine use of oral semaglutide; however it was confirmed that this is a licenced treatment and that injectable semaglutide is already in broad use.

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.

   Semaglutide 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.

FreeStyle Libre device for interstitial glucose monitoring in diabetes for people living with a learning disability

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 for the FreeStyle Libre device since 2018, specifying the circumstances in which its use is accepted in Devon for interstitial glucose monitoring in diabetes.

FreeStyle Libre is a glucose monitoring device marketed as an alternative to finger-prick glucose testing for people aged 4 or over who are self-managing their type 1 or 2 diabetes with multiple daily injections or use insulin pumps.

In March 2019 the Clinical Policy Committee made a recommendation to update the CCG policy to include criteria relating to additional patient groups identified by NHS England, including patients on haemodialysis, patients with diabetes associated with cystic fibrosis and pregnant women with type 1 diabetes.

The Clinical Policy Committee has recently recommended a further update to the policy after consideration of NHS England's update to their criteria for reimbursement in November 2020 to include patients with insulin treated diabetes who are living with a learning disability. The inclusion of this patient group into the CCG's commissioning policy was requested by local specialists.

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

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

   It was noted that local specialists had requested the inclusion of patients with insulin treated diabetes who are living with a learning disability in the CCG's FreeStyle Libre policy following NHS England's update to their criteria for reimbursement in November 2020.

   After consideration, the Clinical Policy Committee has recommended an update to the existing policy to include patients on insulin who are living with a learning disability, as recorded on their GP Learning disability register.

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

   It was acknowledged that specialists had identified that the inclusion of this additional cohort to the policy would be beneficial for a small group of patients. There was discussion around the general approach to those with learning disabilities who are known to suffer from worse outcomes across healthcare generally. The inclusion of this cohort to the policy may benefit individuals with learning disabilities, reduce their need for finger-prick testing and improve their health outcomes.

   Accepting the use of the FreeStyle Libre in this patient group is also consistent with the NHS long term plan to improve the health and wellbeing of people with learning disabilities.

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 there are currently 155 patients in Devon who are recorded on their GP Learning Disability register and are prescribed insulin.

   The routine commissioning of the FreeStyle Libre to this many patients would cost approx. £141,000 per year. This cost may be offset slightly as patients using the FreeStyle Libre would be expected to reduce the number of self-monitored blood glucose testing strips used. Depending on the number of testing strips reduced the offset budget impact is between £97,000 to £141,000 per annum.

   It was queried whether there has been much uptake of the FreeStyle Libre from this cohort via applications for exceptionality under the current policy. It was discussed that this was not readily known, although this could be checked with the Individual Funding Request (IFR) Panel. However it was noted that the existing policy already includes "Patients with type 1 diabetes who are incapable of self-management of their diabetes due to their physical or mental health needs, and therefore require third party assistance to carry out glucose monitoring". Some patients with learning disabilities may therefore have already been eligible under the existing criteria.

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

   The panel noted that there was public knowledge of the FreeStyle Libre device as a result of this having now been available for a number of years and promoted by the manufacturer.

   The panel members had seen television advertisements promoting its use and queried whether the CCG has seen an increase in applications as a result. It was clarified that applications to the CCG would not be needed if patients meet the

criteria set out in the policy. An increase in usage has been seen; however as Devon was an early adopter of the FreeStyle Libre the impact of the extension of the policy to the additional cohorts has been relatively small.

There was discussion as to whether any communication support is necessary in relaying the message about the availability of this device to patients with diabetes and a learning disability. It was felt that this would be helpful to support implementation of the updated policy. However it was noted that there are ongoing discussions via the Devon Formulary Interface Group with regard to implementation and how this would be delivered across the interface between primary and secondary care. As the Formulary Team is currently supporting work between primary and secondary care it was agreed that it would be best to await the outcome of this before taking further communications forward.

Action: Nicola Bonas to follow up with Chris Roome after the Devon Formulary Interface Group meeting next week.

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

   nhs.uk gives information on flash monitoring (FreeStyle Libre) as a system for measuring sugar (glucose) levels continuously throughout the day. It is stated that the Freestyle Libre is available on the NHS. Patients must meet certain criteria to get it on prescription, such as testing their blood glucose more than 8 times a day, having disabling hypos or being pregnant and having type 1 diabetes.

Considering all these factors together the panel recommended that no further engagement or formal consultation was required at this point. However as part of the updated policy implementation, it was recommended that the CCG communications team engages with Learning Disabilities groups to raise awareness of the availability of this technology.

Blepharoplasty (upper and lower lid) including brow lift

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

Blepharoplasty is surgery to remove excess skin or fat from the eyelids, the aim of which is to improve hooded or drooping eyelids or eye bags.

Blepharoplasty and brow lift are not routinely commissioned in Devon for cosmetic purposes, as referenced in the existing CCG policy for Cosmetic Treatments. However blepharoplasty is a procedure which may be undertaken for certain medical non-cosmetic reasons, for example where it interferes with vision. There has been a longstanding policy for blepharoplasty, which was put in place by the former commissioning organisations in Devon in 2011, which clarifies the circumstances under which it is routinely commissioned for patients in Devon.

The Clinical Policy Committee has recommended a refreshed policy to bring it into the same format as the other CCG clinical policies and ensure consistency. As part of the policy refresh, local ophthalmology specialists were asked for their specialist input to confirm that the criteria remain clinically appropriate.

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 there has been a longstanding policy for blepharoplasty, which was put in place by the former commissioning organisations in Devon in 2011. This policy had been refreshed to bring it into the same format as the other CCG clinical policies and ensure consistency. The criteria have also been reviewed with specialist input to ensure this remain clinically appropriate.

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

   It was acknowledged that it is already established that blepharoplasty is not routinely commissioned for cosmetic purposes, as referenced in the existing CCG policy for Cosmetic Treatments. However this policy covers the circumstances in which blepharoplasty may be undertaken for medical reasons, i.e. where it interferes with vision.

   The panel noted that this relates to a fairly small number of procedures each year and the policy is in line with current clinical practice. There is not expected to be any impact for individual patients.

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 only amendment to the existing policy is a small technical correction to the wording to reflect that correction of ectropion/entropion always refers to the margins of the eyelid. No other changes have been made and no change in overall blepharoplasty activity is anticipated from the refresh of this policy.

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 the blepharoplasty.

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

   nhs.uk gives information on eyelid surgery (blepharoplasty), which it states is cosmetic surgery to remove excess skin or fat from the eyelids. It advises people, before they go ahead, to be sure about their reasons for wanting eyelid surgery. It notes to bear in mind the cost, the risks, and the fact the results cannot be guaranteed. It also advises that it is a good idea to discuss plans with a GP first. There might be a medical condition affecting the eyelids or a reason why the operation is not appropriate.

   In respect of eyelid problems, nhs.uk notes that most of these are harmless. It is stated that types of eyelid problems include a lump on the eyelid, swollen eyelid, itchy, flaky or stickly eyelid, and drooping or hooded eyelid. A table of symptoms of drooping eyelids is given, which lists a number of possible causes including ectropion, entropion, dermatochalasis, and ptosis.

   Ectropion is noted in most cases to be associated with ageing. It can occur as the tissues and muscles of the eyelids become weaker as you get older. Treatment for ectropion depends on its severity and the underlying cause. Mild cases may not need any treatment. In more severe cases, an operation to correct the problem will probably be recommended.

Surgery for ectropion is a relatively minor procedure that takes up to 45 minutes and is usually carried out under local anaesthetic. It is normally performed on an outpatient basis.

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

Radiofrequency denervation

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 for radiofrequency denervation since August 2020. This policy was developed after clinical engagement as part of the spinal workstream within the peninsular clinical services strategy.

The Academy of Medical Royal Colleges published guidance to CCGs in November 2020 as a second wave of the evidence-based interventions (EBI) programme. The existing CCG policy has been reviewed in light of this guidance, which recommends that lumbar radiofrequency denervation should only be offered in accordance with National Institute for Health and Care Excellence (NICE) guideline NG59 on Low back pain and sciatica in over 16s.

The Clinical Policy Committee noted that the EBI guidance and the existing CCG policy are both based on NICE guideline NG59. No changes to the policy were therefore proposed, just the addition of wording to reflect that this has been reviewed with regard to the EBI wave two guidance.

There are no anticipated impacts for patients in Devon or on overall activity as a result of this update. The CCG policy is already in line with NICE guideline NG59, and hence the EBI recommendations.

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

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 radiofrequency denervation had been reviewed with regard to the Academy of Medical Royal Colleges Evidence Based Interventions (EBI) Guidance for CCGs.

   As both are based on NICE guideline NG59 on Low back pain and sciatica in over 16s, no changes to the policy have been recommended, just the addition of wording to reflect that this has been reviewed with regard to the EBI guidance.

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

   It was acknowledged that there is no change to clinical practice as a result of the proposed update to this policy and therefore no anticipated impacts for patients. This is already in line with the NICE guideline on Low back pain and sciatica.

   There was discussion of the markers for success of treatment, and it was explained that patients would have a nerve block injection prior to the procedure to test their response. If they see an improvement, they are likely to have the same degree of pain relief in response to radiofrequency denervation. It was noted that back pain can be problematic and may reoccur in the same or a different nerve; immediate success of treatment is easy to measure but the length of pain relief is trickier and would be for clinician assessment with individual patients.

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 there is no anticipated impact on overall activity as a result of this update to the policy.

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 the radiofrequency denervation, although it was noted that back pain is a common condition.

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

   nhs.uk states that back pain is very common and usually improves within a few weeks or months. There is general information on ways that people can relieve back pain, when to get help and advice, causes of back pain and on treatments for back pain from a specialist. 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.

   A procedure called 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 your spine. The procedure involves inserting 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.

   As with all procedures, radiofrequency denervation carries a risk of complications, including bleeding, bruising, infection and accidental nerve damage. Risks should be discussed with the surgeon before agreeing to treatment.

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

Chronic rhinosinusitis

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.

Chronic rhinosinusitis is defined as inflammation (swelling) of the nasal sinuses that lasts longer than 12 weeks.

The EBI recommendations cover first line treatment for chronic rhinosinusitis, referral for specialist assessment and consideration for surgery. Although the CCG does not currently have a commissioning policy for the management and referral of surgical intervention for chronic rhinosinusitis, there is an active clinical referral guideline (CRG), the content of which is in line with the EBI recommendations.

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 chronic rhinosinusitis 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 the treatment of chronic rhinosinusitis.

   The Clinical Policy Committee had subsequently recommended a policy which builds on and reinforces the active clinical referral guideline (CRG) that was published by the CCG in July 2019 and is in line with the EBI recommendations.

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

   It was acknowledged that the policy represents no change to the clinical criteria for individual patients. It is consistent with the clinical referral guideline (CRG) already in place and will support referrals to be managed in a more robust way. This is anticipated to help ensure the referral of patients at the appropriate point in the pathway and support consistency for patients across Devon.

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).

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 sinusitis, although it was noted that it is a common condition.

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

   nhs.uk gives information sinusitis, stating that it is a swelling of the sinuses, usually caused by an infection. It is common and usually clears up on its own within 2 to 3 weeks. Advice is given on how to check if you have sinusitis, how you can treat it yourself, how a pharmacist can help and treatment from a GP.

   It is stated that a GP may refer you to an ear, nose and throat (ENT) specialist if, for example, you still have sinusitis after 3 months of treatment, keep getting sinusitis or only have symptoms on 1 side of your face. They may also recommend surgery in some cases. Surgery to treat chronic sinusitis is called functional endoscopic sinus surgery (FESS) and is carried out under general anaesthetic. The surgeon can widen your sinuses by either removing some of the blocked tissue or inflating a tiny balloon in the blocked sinuses, then removing it. You should be able to have FESS within 18 weeks of your GP appointment.

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

Removal of adenoids for the treatment of glue ear

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

This is a further area in which the Academy of Medical Royal Colleges evidence-based interventions (EBI) guidance to CCGs has prompted review of an existing policy.

The CCG has had a policy in place for myringotomy/grommets and adjuvant adenoidectomy for the management of otitis media in children under 12 years since 2016. The recent EBI guidance recommends that adjuvant adenoidectomy should not be routinely performed in children undergoing grommet insertion for the treatment of otitis media with effusion. Adjuvant adenoidectomy for the treatment of glue ear should only be offered when set clinical criteria are met.

Although the existing CCG policy criteria are wider, engagement with local specialists has indicated that clinical practice is already in line with the EBI recommendations for adjuvant adenoidectomy.

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

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

   It was noted that review of the existing CCG policy for myringotomy/grommets and adjuvant adenoidectomy for the management of otitis media in children under 12 years had been prompted by the Academy of Medical Royal Colleges evidence-based interventions (EBI) guidance to CCGs, which includes recommendations on adjuvant adenoidectomy.

   The Clinical Policy Committee had subsequently recommended an updated policy which is in line with the EBI recommendations.

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

   It was acknowledged that, although the existing CCG policy criteria are wider, local clinical practice is already in line with the EBI recommendations for adjuvant adenoidectomy and therefore no change is anticipated for patients.

   Local specialists indicated that performing adjunctive adenoidectomy in the first instance, in the absence of adenoid symptoms, is an unnecessary procedure for two-thirds of patients and it is therefore not routinely performed.

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 updated policy is not expected to significantly increase or reduce surgical activity; local clinical practice is already in line with EBI recommendations.

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 adenoidectomy and/or myringtomy/grommets.

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

   nhs.uk gives information on adenoidectomy (an operation to remove the adenoids), and states when adenoids need to be removed. A child's adenoids can sometimes become swollen or enlarged. This can happen after a bacterial or viral infection, or after a substance triggers an allergic reaction. In most cases, swollen adenoids only cause mild discomfort and treatment is not needed. However, for some children, it can cause severe discomfort and interfere with their daily life.

   Adenoids may need to be removed if your child has breathing problems, difficulty sleeping, recurrent or persistent problems with the ears, such as middle ear infections (otitis media) or glue ear (where the middle ear becomes filled with fluid), recurrent or persistent sinusitis. Adults do not often need an adenoidectomy. Their adenoids have usually shrunk so they are not likely to cause problems.

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

5. Any Other Business

It was noted that the group's Annual Report for 2020-21 would be prepared for consideration at the next meeting.

6. Next meeting date

The next meeting will be held on Thursday 17 June 2021 and is expected that this will be a further virtual meeting at this time.

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.	Nicola Bonas/ Chris Roome