

Clinical Policy Committee

MINUTES

Wednesday 24th March 2021

Via Microsoft Teams

Present:

Dr Nick D'Arcy	Chair	NHS Devon CCG
Dr Glen Allaway	Voting Member	NHS Devon CCG
Dr Kay Brennan	Voting Member	NHS Devon CCG
Dr Andrew Craig	Voting Member	NHS Devon CCG
Paul Foster	Clinical Director of Pharmacy and Prescribing	T&SD NHS FT
Dr Lucy Harris	Voting Member	NHS Devon CCG
Barbara Jones	Head of Contracting	NHS Devon CCG
Dr Simon Jones	Voting Member	NHS Devon CCG
Dr Paul Melling	Voting Member	NHS Devon CCG
Mac Merrett	Lay Public Member	
Chris Roome	Head of Clinical Effectiveness	NHS Devon CCG
Mark Taylor	Lay Public Member	
Lorraine Webber	Associate Director of Commissioning (Community Services)	NHS Devon CCG

Guests:

Patrick English	Consultant Endocrinologist	UHP NHS Trust
Matt Howard	Clinical Evidence Manager	NHS Devon CCG
Helen Lockett	Consultant Endocrinologist	RD&E NHS FT
Naomi Scott	Healthcare Evidence Reviewer	NHS Devon CCG
Neil Walker	Consultant Endocrinologist	RD&E NHS FT

In attendance:

Fiona Dyroff	Clinical Effectiveness Governance Support Officer	NHS Devon CCG
Rebecca Heayn	Clinical Effectiveness Governance Manager	NHS Devon CCG

Observer:

Amy Rice	Clinical Effectiveness Pharmacist	NHS Devon CCG
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1. Welcome and announcements

Meeting etiquette

Nick D'Arcy explained the meeting etiquette.

Apologies

Richard Croker	Deputy Director for Medicines Optimisation	NHS Devon CCG
Dr Tawfique Daneshmend	Consultant Gastroenterologist & Hepatologist	RD&E NHS FT
Dr Andrew Harrison	Voting Member	NHS Devon CCG
Dr Claire Hooper	Voting Member	NHS Devon CCG
Dr Peter Rowe	Consultant Nephrologist and Honorary Associate Professor	UHP NHS Trust

Confirmation of voting members and Declarations of interest

The seven voting members present were identified.

Dr Andrew Harrison had delegated voting to Chris Roome.

Declarations of interest

Declarations of Interest were collected and reported. The Declarations made did not result in anyone being excluded from the meeting or from the discussion of any item. All Declarations of Interest are reported in the minutes.

DRUG/ TECHNOLOGY TO BE CONSIDERED	PHARMACEUTICAL COMPANY/ MANUFACTURER/ SERVICE PROVIDER
Oral semaglutide (Rybelsus®) for the treatment of type 2 diabetes Alternative treatments: Other GLP-1 mimetics Dulaglutide (Trulicity®) Exenatide (Byetta®, Bydureon®) Liraglutide (Victoza®) Lixisenatide (Lyxumia®) Semaglutide (Ozempic®) Other antidiabetic medication Metformin, Sulfonylureas, DPP4 inhibitors, SGLT2 inhibitors, Insulins	Novo Nordisk Limited Eli Lilly and Company Ltd AstraZeneca UK Ltd Novo Nordisk Limited Sanofi Novo Nordisk Limited Various manufacturers
FreeStyle Libre device for interstitial glucose monitoring in diabetes Alternative treatments: Blood glucose monitoring devices Continuous glucose monitors	Abbott Laboratories Ltd Various manufacturers Various manufacturers including Dexcom Inc and Medtronic Ltd

DRUG/ TECHNOLOGY TO BE CONSIDERED	PHARMACEUTICAL COMPANY/ MANUFACTURER/ SERVICE PROVIDER
Blepharoplasty (upper and lower lid) including brow lift	Would benefit from private provision of blepharoplasty including brow lift
Radiofrequency denervation	Would benefit from private provision of radiofrequency denervation for patients with chronic low back pain
Surgical intervention for chronic rhinosinusitis	Would benefit from private provision of surgical intervention for chronic rhinosinusitis
Removal of adenoids for the treatment of glue ear	Would benefit from private provision of adenoid removal for the treatment of glue ear

NAME OF ATTENDEE	ROLE	DECLARATION
Patrick English	Consultant Endocrinologist	Worked with Eli Lilly on development of PARM tool and was paid for my services in making a video and running a session on its use for primary care. Eli Lilly have sponsored my fee to attend Diabetes UK this year. I have previously received fees from Sanofi, Novo Nordisk and Astra Zeneca for speaking at educational events and previously been sponsored to attend meetings by all 3 though last sponsorship for meeting attendance prior to DUK was from Napp to attend EASD in 2019. I have received no fees from Astra Zeneca in the last 3 years. I have received a fee from Roche for chairing a symposium in the last 3 years.
Neil Walker	Consultant Endocrinologist	Previous support from Novo Nordisk to attend Diabetes Conference. Abbott Laboratories Ltd- received charity Libre donation from Abbott on behalf of our department during Covid-19 pandemic to allow remote monitoring for certain patient groups Dexcom Inc- attended paid Dexcom symposium Nov 2020.

Notification of Any Other Business

Members were asked if there were any items of AOB for consideration.

2. Minutes of the meeting held on 11 November 2020 and matters/actions arising

The minutes of the meeting held on 11th November 2020 were approved.

Summary of actions		
	Action	Lead
20/11	<p>Rivaroxaban for the prevention of recurrent deep vein thrombosis (DVT) and pulmonary embolism (PE) – Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.</p> <p>11/11/20 This is due to go to the North and East Devon FIG meeting on 19th November. The policy is expected to be published by the end of November 2020.</p> <p>24/03/21 This policy was published on 20th November 2020.</p> <p>Action complete.</p>	
20/12	<p>Rosuvastatin for the prevention of cardiovascular disease – CRG for familial hypercholesterolaemia to be forwarded to Aabha Sharma.</p> <p>24/03/21 An update has been received from Claire Hooper explaining that this piece of work has currently been stood down due to restoration priorities and that currently the date for it to restart is not known. For that reason, the guideline has not been sent to Dr Sharma. Dr Sharma will be consulted when work is restarted on guideline.</p> <p>Action closed.</p>	
20/13	<p>Rosuvastatin for the prevention of cardiovascular disease – Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.</p> <p>24/03/21 This policy was published on 1st February 2021.</p> <p>Action complete.</p>	

3. Oral semaglutide (Rybelsus®) for the treatment of type 2 diabetes

Oral semaglutide is the first oral Glucagon-like-peptide (GLP)-1 receptor agonist to be licensed. It is indicated for the treatment of adults with insufficiently controlled type 2 diabetes to improve glycaemic control as an adjunct to diet and exercise.

An application for oral semaglutide, as an alternative to current formulary GLP-1 receptor agonist, has been received from Dr Neil Walker from the RD&E. Naomi Scott, Healthcare Evidence Reviewer, NHS Devon CCG presented a paper. Dr Neil Walker, Dr Patrick English Consultant Physician, UHP and Dr Helen Lockett, Consultant NDDH were present for the discussion of this item.

The absolute bioavailability of semaglutide dosed orally is highly variable, on average it is expected to be 1%. Modelling estimates that 2-4% of patients will have no exposure at all. The maintenance dose is 14mg, which should be taken once a day on an empty stomach. This

dose was questioned by the licencing authority as a dose finding study comparing 2.5, 5, 10, 20 and 40mg oral semaglutide to 1mg subcut semaglutide showed 40mg had a markedly stronger effect on HbA1c. No clear argument for the selection of 14 mg as the maximal dose was provided. There is no trial evidence directly comparing the licenced dose of oral semaglutide to subcut semaglutide.

The primary efficacy study compared oral semaglutide to 1.8mg subcut liraglutide over a 52 week trial. Numerically there were more dropouts in the oral semaglutide arm, and a larger proportion of patients required additional glucose lowering medication.

The primary outcome was the change in HbA1c over 26 weeks, which was tested for non-inferiority using a margin of 0.4%. This is larger than the minimal clinically important difference for HbA1c recommended by the EMA of 0.3%. The estimated treatment difference between oral semaglutide and liraglutide of -0.1% met the criteria for non-inferiority based on this margin but as the 95% confidence intervals in the comparison includes 0.3%, it is not clear that non-inferiority would be established if the EMA recommended margin of 0.3% was used.

A network meta-analysis was identified which compared oral semaglutide to subcut GLP-1 receptor agonists. This analysis found oral semaglutide was associated with a statistically significantly larger HbA1c reduction after 26 weeks than all comparators except 1.5mg dulaglutide weekly, 1.8mg liraglutide weekly and weekly subcut semaglutide where no significant difference was found.

The study of cardiovascular safety found oral semaglutide to be non-inferior, but not superior, to placebo for a composite endpoint of cardiovascular death, non-fatal MI or non-fatal stroke. It is noted that cardiovascular outcome trials of subcut GLP-1 receptor agonists have demonstrated superiority over placebo for this outcome.

A published cost-effectiveness analysis found oral semaglutide to be dominant compared to liraglutide, that is it accrued more QALYs for less cost. However, this model was based on the CORE diabetes model which is driven by HbA1c reduction. It is noted that NICE are proposing updates to the clinical guideline for diabetes which will include a shift towards focusing on cardiovascular, renal and other relevant clinical characteristics rather than just consideration of glycaemic reduction. If this is the case the evidence of cardiovascular benefit of oral semaglutide is currently lacking. The manufacturers are currently undertaking an additional trial of cardiovascular outcomes, although this is not expected to be complete until 2024.

The annual acquisition cost of oral semaglutide is similar to the cost of subcut regimens of semaglutide, exenatide, and low dose liraglutide, more expensive than lixisenatide, and considerably less than high dose liraglutide. Local prescribing trends reflect suggestions from local specialists that new patients are being initiated mostly on subcut semaglutide. Therefore, the routine commissioning of oral semaglutide would not be expected to have a significant budget impact.

There is concern that the variable bioavailability of oral semaglutide may result in a proportion of patients gaining no benefit from the treatment. Due to the dosing escalation schedule, there is the potential that it will take up to 6 months to determine if a patient is gaining adequate efficacy from this treatment.

The committee considered issues pertinent to the routine commissioning of oral semaglutide for the treatment of type two diabetes. There was discussion about:

- Place in therapy – The applicant suggested that oral semaglutide would be best placed as a treatment option for patients who would be eligible for treatment with a GLP-1 receptor agonist, but who are not able to administer subcutaneous injections. It was suggested that sub-cutaneous preparations continue to be the first line treatment and that oral treatment be provided as a second line alternative for those who cannot self-administer injections.
- Costs - Specialists present suggested that costs may be reduced if fewer GP visits are required compared to subcutaneous administration.
- Cardiovascular outcomes – Further trial data is awaited. Oral semaglutide has been shown to not increase the incidence of cardiovascular events but it has not been shown to reduce the incidence of them. It was noted that other GLP-1 receptor agonists are available which have proven cardiovascular superiority over placebo.
- Bioavailability – for patients who cannot self-administer injections, oral preparations can be seen as an easier option, however oral semaglutide can be difficult to take as it must be taken on an empty stomach at least 30 minutes before eating, drinking or taking other oral medicines, and bioavailability of the oral preparation is variable.
- Dose titration is required.
- Weight loss – it was suggested that weight loss in patients taking semaglutide is statistically significant however no head to head trial of oral/sub-cutaneous semaglutide has been undertaken. A meta-analysis did not find a difference between the oral and sub-cutaneous preparation.
- Range of GLP-1 receptor agonists – There was discussion around the number of GLP-1 receptor agonists in the Devon formulary. It was noted that it is the role of the Devon Formulary Interface Group to decide the place in therapy for each drug commissioned by the CCG. A wider review of GLP1s will be undertaken, including giving consideration to how many it is appropriate to include in the local formulary.

The committee voted unanimously in favour of the routine commissioning of oral semaglutide for the treatment of type 2 diabetes in the place in therapy proposed, that is for patients eligible under NICE criteria for a GLP-1 receptor agonist but in whom injectable therapy is not suitable.

ACTION: Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.

4. Review: policy for FreeStyle Libre device for interstitial glucose monitoring in diabetes for people living with a learning disability

Devon CCG's FreeStyle Libre commissioning policy was originally developed following discussions at the clinical policy committee in 2018. The policy was reviewed in March 2019 following the publication of the NHS England criteria for reimbursement, and consequently commissioning of the libre in additional patient groups, including patients on haemodialysis, patients with diabetes associated with cystic fibrosis and pregnant women with type 1 diabetes was recommended.

In November 2020 NHS England added "People with Type 1 diabetes or insulin treated Type 2 diabetes who are living with a learning disability as recorded on their GP Learning Disability register" to the criteria for reimbursement. An application for the inclusion of this patient group has been received from Dr Neil Walker consultant from the RD&E. Naomi Scott, Healthcare Evidence Reviewer, NHS Devon CCG presented a paper. Dr Neil Walker, Dr Patrick English,

Consultant Physician, UHP and Dr Helen Lockett, Consultant NDDH were present for the discussion of this item.

NHS England have not detailed reasoning for their inclusion of this patient group. A literature search did not identify any trials of the use of FreeStyle Libre in patients with learning disabilities.

The committee considered issues pertinent to the policy for the FreeStyle Libre device for interstitial glucose monitoring in diabetes for people living with a learning disability:

- Patients with learning disabilities experience higher mortality rates and other inequalities. The NHS long term plan has stated an aim to address this.
- Patients with learning disabilities have fewer opportunities and less autonomy. They may not be able to attend Day Care Centres as carers and staff may not have the skills to do finger prick tests or pick up on other signs that there may be a problem. The use of the alarm on the Libre device provides options to patients with learning disabilities and their carers.
- The impact of Freestyle Libre in this patient group has not been studied. It was noted that it can be difficult to get informed consent from patients with learning disabilities.
- Issues relating to the diagnosis of Learning Disability and accurate inclusion of such patients on GP Learning Disabilities registers were noted.
- There is a cost pressure associated with Freestyle Libre. It is not expected to be cost saving in this patient group.

The committee voted unanimously in favour of the amendment to the CCGs policy for Freestyle Libre device for interstitial glucose monitoring in diabetes for people living with learning disability to include the new additional wording:

“OR Patients on insulin who are living with a learning disability, as recorded on their GP Learning disability register.”

ACTION: Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.

5. Review: policy for blepharoplasty (upper and lower lid) including brow lift

Rebecca Heayn, Clinical Effectiveness Governance Manager, NHS Devon CCG, presented a paper.

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. Many people acquire excess skin in the upper eyelids as part of the process of ageing and this may be considered normal. The skin loses its elasticity and muscles slacken with age. At the same time there is slackening of the muscle beneath the skin allowing the fat, which cushions the eyes in their sockets, to protrude forward to give the appearance of bagginess.

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. It is proposed to refresh this policy to bring it into the same format as the other CCG clinical policies and ensure consistency.

Local ophthalmology specialists were made aware of the intention to refresh this policy and were asked for their specialist input to confirm that the criteria set out within the policy remain clinically appropriate.

The only amendment proposed because of this was 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.

The committee considered issues pertinent to the refreshed policy for blepharoplasty (upper and lower lid) including brow lift. The discussion noted that:

- it would be useful if referral guidelines were produced,
- previously patients had been asked to provide evidence of visual impairment, however this is not the case now as not all opticians provide this service and there is a cost to patients. It was suggested that funding options through the CCG be considered. This may or may not result in savings overall.

The committee voted unanimously in favour of accepting the revised policy for blepharoplasty (upper and lower lid) including brow lift.

ACTION: Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.

6. Review: policy for radiofrequency denervation

Rebecca Heayn, Clinical Effectiveness Governance Manager, NHS Devon CCG, presented a paper.

Following the implementation of the first wave of the evidence-based interventions (EBI) programme, the Academy of Medical Royal Colleges published guidance to CCGs in November 2020 to introduce the interventions included in wave two. The guidance sets out clinical criteria for 31 interventions outlining, as with wave one, when they should be commissioned or offered.

The EBI guidance recommends that lumbar radiofrequency denervation should only be offered in accordance with NICE guideline NG59 on Low back pain and sciatica in over 16s.

The CCG currently has a policy in place for radiofrequency denervation for patients with chronic low back pain, which states that radiofrequency denervation is routinely commissioned in Devon when the criteria specified in NICE guideline NG59 are met.

The CCG policy was published in August 2020 following the recommendation of the Clinical Policy Committee and approval by the CCG, and after clinical engagement as part of the spinal workstream within the peninsular clinical services strategy.

Both the EBI recommendations and the existing CCG policy for radiofrequency denervation are based on NICE guideline NG59. It is therefore proposed to update the policy to reflect that this has been reviewed with regard to the EBI wave two guidance; however as both are consistent with the NICE guideline no other changes are proposed.

The committee discussed issues pertinent to the updated policy for radiofrequency denervation. Including:

- whether it should be specified that treatment will only be repeated if previous treatment has been successful,
- some people have multi-level disease.

The committee voted unanimously in favour of accepting the revised policy for radiofrequency denervation.

ACTION: Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.

7. Policy for chronic rhinosinusitis

The CCG does not currently have a commissioning policy for the management and referral of surgical intervention for chronic rhinosinusitis. However, an active clinical referral guideline (CRG) was published in July 2019. The content of this CRG is in line with the recommendations from the Evidence Based Interventions (EBI) programme.

It was considered that the wording of the EBI recommendations lacked clarity in some aspects and in other areas added information not usually included in a commissioning policy. Therefore, some adaptations were made, including clarifying clinical criteria. Naomi Scott, Healthcare Evidence Reviewer, NHS Devon CCG presented a paper.

Local specialists have indicated that if the recommendations from EBI were to be implemented in Devon it would not influence local activity. However, it is expected to aid DRSS in robustly managing referral into secondary care.

The CPC are asked to recommend whether the proposed policy, should be adopted into local commissioning policy.

The committee discussed issues pertinent to the policy for Chronic Rhinosinusitis:

- Under the current policy some patients are being referred to secondary care only to be returned to primary care for treatment in the first instance. Having a policy position will aid DRSS in managing the initial referral.
- There was discussion about how a commissioning policy could aid robust and equitable referral.

The committee voted unanimously in favour of accepting the EBI recommendations for Chronic Rhinosinusitis.

ACTION: Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.

8. Review: policy removal of adenoids for the treatment of glue ear

Naomi Scott, Healthcare Evidence Reviewer, NHS Devon CCG presented a paper.

Devon CCG currently commissions adjunctive adenoidectomy when children are undergoing myringotomy and grommet insertion for the treatment of glue ear. This policy was developed in 2016 in collaboration with local specialists when Right Care identified that the CCG had an exceptionally high rate of grommet insertion.

At the time it was proposed that in line with NICE guidance, adjunctive adenoidectomy would only be commissioned when patients have persistent and/or frequent upper respiratory tract symptoms. Local specialists raised objections to this restriction and a subsequent evidence review by the Clinical Effectiveness team identified clinical trial data showing that adjunctive adenoidectomy reduced the likelihood of requiring repeated grommet insertion and had a small, but meaningful, improvement in hearing. As the CCG was aiming to reduce the rate of grommet insertion this was deemed to be a positive outcome and the policy diverged from NICE in this instance.

In wave 2 of the Evidence Based Interventions (EBI) programme it is recommended that adjunctive adenoidectomy should only be offered when set clinical criteria are met.

As local specialists had previously indicated that the improvement in hearing was meaningful and the EBI references were not found to offer additional information than had been reviewed in 2016 the Clinical Effectiveness team contacted specialists to confirm whether they would be in favour of maintaining the current policy position.

Specialists indicated that, in clinical practice, adjunctive adenoidectomy is rarely undertaken in the first instance as they deem it to be an unnecessary procedure for three quarters of patients. As they agreed with the EBI criteria, it is proposed that these criteria are adopted.

The CPC are asked to recommend if the EBI recommendations for the removal of adenoids should be adopted into local commissioning policy or whether the current local position should be maintained.

The Committee considered issues pertinent to the review of the CCG's policy for removal of adenoids for the treatment of glue ear.

- It was noted that specialists agree with the EBI criteria.
- The CCG's policy was developed when there was pressure to reduce the rate of grommet insertion and it was considered that this would aid with that aim.

The committee voted unanimously in favour of the proposed update of the CCG's policy for the removal of adenoids to include the EBI criteria.

ACTION: Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.

9. Update from NICE Planning Advisory Group (NPAG)

The committee received reports of the NPAG meetings which had taken place on Tuesday 8th December 2020 and Tuesday 9th February 2021.

NPAG meeting Tuesday 8th December 2020

The meeting had considered thirteen NICE Technology Appraisals, four of which are CCG commissioned and nine are NHS England commissioned.

The meeting had noted one COVID-19 rapid guideline.

Also considered were two Antimicrobial Prescribing Guidelines, three Clinical Guidelines, four Medical Technology Guidelines, two pieces of Interventional Procedures Guidance and one piece of Diagnostic Guidance.

NPAG meeting Tuesday 9th February 2021

The meeting considered eight NICE Technology Appraisals, two of which are CCG commissioned and six are NHS England commissioned.

The meeting had noted two COVID-19 rapid guidelines.

Also considered were five Clinical Guidelines, one piece of Diagnostic guidance and six pieces of Interventional Procedures Guidance.

10. Update from Clinical Policy Engagement and Consultation Panel

The committee received an update from the Clinical Policy Engagement and Consultation Panel meeting which took place via Microsoft teams on Thursday 26th November 2020.

The Clinical Policy and Engagement Consultation Panel had considered one item.

- Rosuvastatin for the primary and secondary prevention of cardiovascular disease.

The panel saw no reason for further engagement or consultation actions on this item.

11. Any other business

Membership

Andrew Harrison was unable to attend this meeting of the committee. It was noted that Andrew had resigned from the group. The committee thanked Andrew for the significant contribution he had made to the Clinical Policy Committee and predecessor groups and wished him well for the future.

The committee also noted the imminent retirement of Peter Rowe who also had been unable to attend today's meeting and was similarly thanked for his contribution to the group.

Summary of actions		
	Action	Lead
21/01	Oral semaglutide (Rybelsus®) for the treatment of type 2 diabetes - Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.	Rebecca Heayn
21/02	Review: policy for FreeStyle Libre device for interstitial glucose monitoring in diabetes for people living with a learning disability - Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.	Rebecca Heayn
21/03	Review: policy for blepharoplasty (upper and lower lid) including brow lift - Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.	Rebecca Heayn
21/04	Review: policy for radiofrequency denervation - Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.	Rebecca Heayn
21/05	Policy for chronic rhinosinusitis - Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.	Rebecca Heayn
21/06	Review: policy removal of adenoids for the treatment of glue ear - Policy recommendation and QEIA to be prepared and subsequently progressed to final CCG approval and communication.	Rebecca Heayn